The Effects of Repeated Depression on Air-Filled Bulbs Used in Tongue Exercises for Swallowing Problems (Air-Filled Bulb)

Project Design Specifications
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Function:

Dysphagia, or difficulty swallowing, is a symptom that is experienced by up to 76% of stroke patients and 22% of people 55 years and older. Without treatment, pneumonia, malnutrition, dehydration and airway obstruction can result in patients having higher rates of morbidity and mortality. The Iowa Oral Performance Instrument (IOPI) is a device that has been used in exercises that progressively strengthen the tongue, but it has been reported to have a decreased responsiveness over time. We aspire to determine whether the IOPI bulb undergoes alterations after repeated use and if so, what the cause of these changes are. We will then seek to modify the design of the bulb in order to alleviate these problems.

Client Requirements:

- Alterations should prevent IPOI bulb from changing in elasticity during 8 weeks of use.
- Must be harmless to the tongue, palate, and other interior surfaces of the mouth.
- Must hold up to the standards and regulations of the Food and Drug Administration.

1. Physical and Operational Characteristics

A. **Performance requirements**: This product will need to deliver accurate and consistent results for the entire 8-week duration of the exercise regimen.
B. **Safety**: The product cannot be harmful to the mouth, tongue, or throat, as it will be placed between the palate and tongue during exercise.
C. **Accuracy and Reliability**: Consistent readings from the device are essential, so that the patient can continue exercising in accordance with the program. The bulb must be designed so that there is no pressure loss or material degradation over time.
D. **Life in Service**: The bulb must be usable 60 times a day, 3 days a week, for the 8-week length of the exercise regimen. This amounts to 1,440 uses at 37 °C.
E. **Shelf Life**: The product should be capable of being stored at standard room temperature and pressure for an extended time period. Without compression of the plastic or disruptions from the environment (i.e. extreme heat: >30 °C, extreme cold: <5 °C , or significant humidity >75%) the product's functionality is not expected to decline.
F. **Operating Environment**: The product design must be made to function in the oral cavity of a human patient. A typical oral cavity contains extensive amounts of human saliva, which must not interfere with proper function of the device. The normal temperature of the oral cavity is 37 °C.

G. **Ergonomics**: As a great majority of patients suffering from dysphagia are geriatric and a significant portion have suffered from a stroke or other medical condition, ergonomics is extremely important. The final product must be easy to control by a patient with below-normal motor functioning. The product must also have minimal set-up and be easy to operate. The device must not require excessive maintenance or re-application once it is inserted into the mouth, and it must have displays that are large enough to be clearly read by patients with considerably poor vision.
H. **Size**: The product must be small enough to fit inside the oral cavity of users. Current products on the market are approximately 20 mm, as this size reduces choking hazards while still being small enough to easily operate.
I. **Weight**: The product should be as lightweight as possible without impeding functionality or usability, as the user may be weak or easily fatigued. A heavy product may cause physical strain or discomfort to the user.
J. **Materials**: All of the materials used in this project must be compliant with the standards of the Food and Drug Administration, as this device is designed for use on human subjects. The materials must also be resilient enough to withstand eight weeks of use without changing properties in any way.
K. **Aesthetics, Appearance, and Finish**: The product should be simple to use. Print on the product should be readable to users with vision problems.

2. Production Characteristics

A. **Quantity**: One air-filled bulb will be used for a maximum of eight weeks of exercising.
B. **Target Product Cost**: Current air-filled bulbs are available from $3.50 to $4.00 each, so modified bulbs should be similar in price.

3. Miscellaneous

A. **Standards and Specifications**: The final product will require the approval of the Food and Drug Administration. If the current plastic (polyvinyl chloride, PVC) is used it is already approved for this application.
B. **Customer**: The intended customer is likely to be a stroke or geriatric patient, and will therefore desire a product that is relatively simple to use, comfortable, can effectively improve their ability to swallow, and is reasonably priced. All of these factors must be considered when altering the design of the current device.
C. **Patient-related Concerns**: In order to become available to patients for therapeutic use, our changes to the device must be in compliance with all restrictions enforced by the Food and Drug Administration. It must not be harmful to its user in any way. The final product must also be ergonomic to allow use by unqualified patients.
D. **Competition**: Once it is fully developed, our design could potentially become a competitor to the current bulbs used with the IOPI device. These bulbs are used to measure tongue strength and fatigability via tongue squeezing. They are sold in sealed packages and can be sterilized with cold gas as they are clean but not sterile upon delivery. They cost between $3.50 and $4.00 a piece and are recommended for single use only.