

Product Design Specifications

Function

Over 18 million adults in the U.S suffer from swallowing pathologies. Swallowing disorders result in aspiration pneumonia, which causes a great number of deaths in the elderly. Many elderly develop swallowing disorders as a result of sarcopenia, the atrophy of muscle that occurs with ageing. These disorders can be treated or prevented with proper exercise of head and neck musculature. A device has been developed to facilitate exercise of the tongue in a laboratory or clinical setting. Now this device is being adapted for use by patients in a non-clinical setting.

Client Requirements

In order to allow patients to easily perform exercises on their own, the Client has developed criteria for such a device. It must be:

- Portable
- Simple and easy to use
- Compact, self contained
- Safe
- Comfortable
- Cleanable/ can be sanitized
- Able to provide useful feedback
- Accurate
- Reliable
- Durable
- Aesthetically appealing, all around
- Comfortable in mouth
- Able to provide more detailed feedback when combined with complimentary output device
- Fairly cheap, around 100 USD to manufacture

Design Requirements

1. Physical and Operational Characteristics

- Performance requirements:* The device will be used by the patients three times a week for about 10 minutes each day. Each use will include 8-10 repetitions, three 3 times per day. The device should be able to sense pressures of up to 80-100 KPa, at the front and middle of the palate.
- Safety:* Because the device is put in the patients' mouth, it must be very durable so parts do not break off, causing choking. It must be biocompatible with the mouth as to not cause irritation. The electrical aspects must be insulated or at low enough current so no shocks are created. There are no real safety concerns with the feedback device.
- Accuracy and Reliability:* The device must fit into the mouth so that the pressure of the tongue is measured at the same spot, within 2-3 mm, every time. Enough

data must be collected to ensure that the exercise is conducted properly, with both the front and the middle of the tongue producing pressure. The force measured must be within 5% of the actual force.

- d. *Life in Service*: It must last 5 years.
- e. *Shelf Life*: The device will have a case for storage. It must be cleaned after every use. It should be stored at room temperature.
- f. *Operating Environment*: Because the device will be used in the mouth, it will be able to sustain 37° C, a pH of 6.8-7.8, digestive enzymes, tongue pressures and biting. It should be able to withstand stronger forces and a reasonable amount of abuse from handling between exercises, especially when carrying the device from one place to another.
- g. *Ergonomics*: Any part that is inside the mouth must not cause discomfort or gagging. The mouthpiece portion of the device must be portable; such that it can be taken and used in many settings such as the home, car, or park. The system must be easy to use for the elderly. This includes large displays, controls that are easy to manipulate, and a very simple interface (see 3c below).
- h. *Size and shape*: The device must be compact enough to be portable, easily carried by one person, including those people with minor disabilities. Parts of the device that go inside the mouth must accommodate the huge variety of different shapes of palate. If the device consists of two or more pieces, there must be considerations to keep the parts from being separated or lost.
- i. *Weight*: The mouthpiece should not weigh more than twice the plastic mouthguard. The feedback device should be around 1-2 pounds or less. Anyone without a major disability should be able to lift and use it.
- j. *Materials*: No materials that degrade with saliva or food can be used. It must be easily cleaned and not irritate the mouth.
- k. *Feedback*: The device must provide some form of feedback to notify the user when the target force is applied. The feedback must be simple, clear, and easy for the elderly layperson to understand. The feedback should also be usable by those with various disabilities (see 3b below). The target force value should be easily changed by the user as muscle strength increases.
- l. *Aesthetics, Appearance, and Finish*: Bright colors, motivational feedback. It must look safe, easy to use, and appealing to the target population. It must also look and be packaged like a therapeutic medical device, not like an untested gadget.

2. Production Characteristics

- a. *Quantity*: One prototype, in the future this device may be mass produced. Initial market may be around 1,000 units.
- b. *Target Product Cost*: Each unit should cost no more than \$100.

3. Miscellaneous

- a. *Standards and Specifications*: The device needs to meet all applicable safety standards.
- b. *Patient-related concerns*: Many of the potential users of this device suffer from other disabilities besides swallowing disorders. These disabilities range from minor to severe. Examples include muscular disorders, hearing disorders, poor sight, stroke-related disabilities, and general weakening and impairment resulting

from old age. Therefore, the device must be usable by those with one or several such impairments.

- c. *Operation*: The mouthpiece should be able to be formed by the end-user, without the assistance of a medical professional or technician.
- d. *Competition*: This device may be an improvement on a previous BME project.
- e. *Two Piece Design*: The device should be separated into two pieces, one mouthpiece and a feedback device. The mouthpiece should be able to be used on its own, as a passive device for practice without the motivational feedback.