

# **The Product Design Specifications (3/12/08)**

## **Larynx Model**

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### **Function:**

The goal of this project is to develop a physical 3D laryngeal model, with moving laryngeal cartilage, bones, membranes and muscle, to demonstrate nerve/muscle action and interaction in the larynx for voice, airway, and swallowing. The model is to be used as a clinical tool for patient education for improved understanding of the laryngeal mechanism; and to plan treatment based on diagnosis of voice, airway, and/or swallowing disorder. The goal for the current semester is to develop a model that will demonstrate the function of the cricothyroid, thyroarytenoid, and interarytenoid muscles in vocal fold adduction, abduction, and elongation.

### **Client Requirements:**

- The model must be 3x scale or greater
- The model needs to be light enough and small enough for one person to easily move it.
- The model must contain the section of the larynx spanning from the hyoid bone to the first 2 tracheal rings and show soft tissues, major muscles, bone, and cartilage.
- The model must show movement of the larynx opening and closing, and the elongation of the vocal folds
- Each of the movements should take no less than 2 seconds

### **Design Requirements:**

#### **1. Physical and Operational Characteristics**

##### *a. Performance requirements:*

The model must demonstrate the function of the muscles and cartilage in the larynx during both normal function and partial paralysis. The muscles whose motion needs to be included are the thyroarytenoid, cricothyroid, and interarytenoid muscles. The motion should be automated, and should not require human force to drive it. It should allow the user to see the mechanism of the movement of the larynx, not just the motion, to allow for demonstration of the cause and result of laryngeal disorders.

- b. *Safety:*  
The model must not have any small, detachable parts that could become hazardous if a small child is left alone in vicinity of the product. Moving parts should be shielded so that fingers, hair, etc cannot be caught in them. Plastic edges must be rounded off as to eliminate the possibility of sharp points harming the user.
- c. *Accuracy and Reliability:*  
The model should recreate the same motion with high precision and accuracy. Accuracy needs to be ( )% to create a realistic representation of the function of the human larynx. Model should be created to scale, three times larger than the actual human larynx.
- d. *Life in Service:*  
The model will potentially be used daily for education of patients, for as long as is necessary each time. May travel throughout hospital or to another area for educational use.
- e. *Shelf Life:*  
The model should be kept clean, through periodic cleaning to minimize dust build up. Also it will need to have some sort of power source, to be determined as of right now.
- f. *Operating Environment:*  
Temperature range: must function at room temperature (20-30°C), and be able to withstand winter temperatures without damage (as low as -10°C). Humidity: must withstand normal indoor humidity (40% to 60%). Dirt or dust: must be undamaged by dirt or dust accumulation from periods of nonuse or handling with dirty hands, and must be easily cleanable. Corrosion from fluids/handling: must be able to withstand frequent handling and gentle rubbing without damage to its structure or finish. Noise: must be quiet, so that it doesn't interfere with a conversation. Operators: The device is to be designed for operation by medical and educational personnel. Durability: must be able to be dropped from 3 ft. onto carpet without breaking. Life span: must last ten years with only minor repair (i.e. motor repair and repainting).
- g. *Ergonomics:*  
The movement of the cartilages and vocal cords must not damage (i.e. cut or pinch) the operator's fingers.
- h. *Size:*  
The size of the larynx portion of the model should be 33 x 14 x 16cm, mounted on a box no larger than 25 x 25 x 16 cm (specific sizes of the individual cartilages will be added when the plastic model arrives).

The model must be transported without difficulty from room to room by one adult. It must be easily stored either as a countertop display or in a box for long term storage or shipping.

- i. *Weight:*  
The product must weigh less than 2.5 kg.
- j. *Materials:*  
Bone and cartilage: Polycarbonate, or a comparable thermoplastic. Muscle: made from silicone formed around a wire or natural rubber core. Membrane: a durable, colorable elastomer.
- k. *Aesthetics, Appearance, and Finish:*  
The final model should look like a genuine human larynx, with the soft tissues tinted red, the focal folds tinted white, and the trachea tinted blue-gray.

## **2. Production Characteristics**

- a. *Quantity*  
One prototype for use by our client. Further production of additional models will be determined by the client.
- b. *Target Product Cost:*  
The model should have a production cost of less than \$1000.00.

## **3. Miscellaneous**

- a. *Standards and Specifications:*  
The larynx model is to be produced solely for one client, not mass produced, and thus does not require FDA approval. The model will be handled by both the client and patient, and will need to be safe for direct contact with skin.
- b. *Customer:*  
The model should be large enough to demonstrate the function of the larynx, but small and light enough to be easily moved and held with one hand. The model should be relatively odorless and non-distracting for both client and patients. The preliminary model should be able to demonstrate larynx function with human application, in the future a remote control is preferred in order to operate the model.

c. *Patient –related concerns:*

The model will mainly be handled by the client, and potentially by patients as well. Thus, it should be cleaned regularly (once a day) to prevent the spreading of germs. The model should not contain any sharp or harmful elements since it will be handled directly by the client and patient.

d. *Competition:*

The client currently owns a hard larynx model with separate parts that does not effectively demonstrate the function of the larynx. There are hard models on the market that demonstrate epiglottis and cartilage movement but not to the extent desired by the client. Models demonstrating laryngeal vocal fold movement could not be found. Prices generally range from \$100 to \$500 for a single larynx model unit.