

Product Design Specifications for BME 201 group 35: Bioreactor

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Problem Statement: The aim of this project is to redesign and reproduce a pre-existing Bioreactor that is specific to the culturing of human vocal fold fibroblasts. The existing design models the vibration of a single vocal fold under tensile stress and provokes the elongation of fibroblasts and the subsequent formation of an extra-cellular matrix, characteristic of vocal fold fibroblasts. Our goal is to improve upon this model by simulating contact between two vibrating vocal folds and potentially finding a better substitute for Tecoflex, because its porosity is non-uniform and the pore size is too large. The bioreactor will be made from a T-flask with elastic vibrators immersed in a buffer, which will function as vocal folds. This device needs to be easily replaced with disposable parts, along with 2 pairs of artificial vocal folds and a capacity to generate (computer controlled) vibrations at a frequency (0-400Hz).

Client requirements: (improvement of design)

- Vibrator Bars on both sides of T-flask
- Vibration Frequency 0-400Hz
- Contact between each pair of cell-seeded strips during vibration (2 pairs in T-flask)
- Simultaneous concerted vibration of Vibration Bars
- Cartilaginous structures around cell-seeded strips
- Easily sterilized with disposable parts
- Find alternative to Tecoflex substrate
- Cost limit \$5,000

Design requirements: Since the device has already been designed, the focus for this project is to improve the current design and construct a better working model. The first improvement will be the construction of vibrator bars on both sides of the T-flask, which would better distribute the vibration evenly across the strips. Also, each pair of cell-seeded strips and the attached cartilaginous structures must come into contact with each other during vibration, to further mimic the action of the vocal folds. The Tecoflex substrate needs to be replaced by a better material to eliminate the porosity of the strips. Furthermore, the parts of the device should be disposable and easily sterilized. The vibration frequency should range from 0-400Hz. Overall, the expenses should not exceed \$5,000.

a. *Performance requirements:* The device is meant to culture and research the reactions of vocal fold fibroblasts to various stimuli, such as duration of vibration, tensile stress, angle of vibration and other experimentally-controlled environments.

b. *Safety:* This device does not need to be sterilized often because the T-flask is disposable and other components require periodic cleaning. The device must be sealed properly to prevent leakage of cell-culturing medium.

c. *Accuracy and Reliability:* The device will be operating in a medium that is denser than air therefore a different frequency of vibrations will be applied to the system. The current substrate Tecoflex poorly distributes vibrations because of its porosity. The angle between

the vibrating cell-seeded strips (matrices) should be adjustable prior to vibration but fixed during vibration.

d. *Life in Service:* The T-flask and its interior are disposable components of the Bioreactor that are disposed of after each use (several weeks per use). The life-limiting factor of this Bioreactor would be the vibration-generating motor.

e. *Shelf Life:* The Bioreactor itself has a long shelf life. The T-flask and its internal components are disposed after each use. Periodic cleaning and maintenance of the device is required to avoid contamination of the system and therefore prolong shelf life.

f. *Operating Environment:*

Temperature range: Incubator (37°C)

Pressure: Negligible differences in pressure (only ½ psi difference between atmosphere and inside the body).

Corrosion from fluids: Any corrosive fluids would be retained in the T-flask and therefore would not come into contact with the rest of the Bioreactor.

The device must effectively simulate the environment of human vocal folds by uniformly providing ample vibrations to the cell-seeded strips in the T-flask.

g. *Ergonomics:* In the endeavor to imitate the inner body environment around the vocal folds, gas flowrates, temperature, and pH should all be constant inside the system. These internal environmental factors would be monitored and controlled by a programmable logic controller (PLC). Most of the Bioreactor will be computer software controlled, however the periodic replacement and sterilization of the device will be conducted manually.

h. *Size:* For this project, the design will be focused mainly around the T75-culture flask, its contents contained within and the required electrical components to provide vibration to the system. Thus the actual size of the device will be somewhat slightly larger than the T-flask itself.

i. *Weight:* Actual weight of the bioreactor will depend on the amount of cell-seeded strips that could fit within the T-flask. A weight cannot be specified at the moment; however, the weight of the electrical and mechanical components of the device will be of little consequence to the function of the Bioreactor itself.

j. *Materials:* T-75 Culture Flask, Clear Polyester Lid, Elastomeric Boots, Actuator Base and Rods, Threaded Connectors and Rods, Lever, Low Mass Vibrational Bar, Labview Software, Analog Output Board, Two Stage Amplifier, Position Feedback Sensor, Servo Drive.

Actuators: Electromagnetic Voice Coil Actuator and Vibrational Actuator

k. *Aesthetics, Appearance, and Finish:*

Texture: The T-flask should be smooth on the inside and outside. No extra furnishings would be necessary. The focus of this design is function over aesthetics.

2. Production Characteristics

a. *Quantity:* Although we are making only one prototype, the client has shown interest in using several devices simultaneously in experiments. Because of the specific characteristics

of the device and the small number of institutions involved in this particular type of research, production of the bioreactor would be limited to several dozen at most.

b. *Target Product Cost*: The cost of a similar existing bioreactor was around \$15,000, thus it is expected our bioreactor would have a comparable cost. Because our bioreactor will probably not be complete with all the elements the previous bioreactor had (such as software), our device is expected to cost less than \$5,000.

3. Miscellaneous

a. *Standards and Specifications*: The product of this design will not be used for human contact and therefore doesn't need to adhere to any international or national standards.

b. *Customer*: Anyone operating this device will be using it for research purposes, particularly with vocal fold fibroblasts. Because of its nature, strong computer and cell-culturing knowledge is required to obtain meaningful results.

c. *Patient-related concerns*: Since this device is not used for human contact, patient-related concerns do not apply.

d. *Competition*: This device is to be improved from a previous design, which was also for research purposes only. There is no intent by any party to patent this design.