Product Design Specifications for BME 300 group 18: Bioreactor

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Problem Statement: The aim of this project is to re-design and improve upon a previous version of a bioreactor that will be used for the culturing of human vocal fold fibroblasts. The previous design was able to vibrate two pairs of cell-seeded strips under tensile stress, but had design flaws that needed improvement, including keeping the bioreactor leak-proof, subjecting the cells to more stimuli, and allowing the equipment providing the stimuli to be controlled by a computer. Our goals are to finish the design and fabrication of this new model, to obtain at least one substitute for the cellular substrate, Tecoflex, and to test the bioreactor and cellular substrate for optimal design and operating conditions. The bioreactor will be made from 2 T-flasks, 2 moving magnet linear voice coil actuators, 2 rotary stepper motors, and 2 linear stepper motors. A total of 2 pairs of strips will be immersed in a buffer in each T-flask, and subjected to vibration, tensile stress, and angular changes between each pair of strips. This device needs to be easily replaced with disposable and/or sterilized parts, fit inside a standard incubator, and have a capacity to generate vibrations within the frequency range of 50-400 Hz.

Client requirements: (improvement of design)

- Even vibration across length of cell-seeded strip
- Vibration frequency of 50-400 Hz
- Contact between each pair of cell-seeded strips during vibration.
- Easily sterilized and/or disposable parts
- Obtain and test alternative(s) to Tecoflex substrate
- Cost limit $5,000

1. Design requirements

Since this device is an improvement upon a previous bioreactor (which most of the new design and some of the machining has already been accomplished), the focus for this project is to improve and finish building the current design, and to extensively test it along with one or more new cellular substrates. In addition to testing the bioreactor for design flaws, two support systems for the device must be designed and machined. A Tecoflex substrate needs to be replaced by a more optimal material, such as a crosslinked hydrogel. Furthermore, the parts of the device need to be disposable and/or easily sterilized. The vibration frequency should range from 50-400 Hz. Overall, the expenses should not exceed $5,000.

a. Performance requirements: This device is meant to culture and research the reactions of vocal fold fibroblasts (and potentially other cells) to various stimuli, such as frequency and duration of vibration, varying tensile stress, and changing angle between each pair of strips.

b. *Safety:* Cell culture procedures will need to be followed. The reusable portions of this

device will need to be disinfected periodically. The disposable parts of the bioreactor will need to be replaced frequently. Fluid from inside the T-flask cannot leak out onto the base of the bioreactor, which could potentially make contact with the electrical motors and cause a safety (and financial) risk.

c. *Accuracy and Reliability:* The system may need calibration when operating under computer-controlled conditions.

d. *Life in Service:* The T-flask and most of its interior parts are disposable components of the bioreactor that are disposed of after each use (at least several days at a time). The life-limiting factors of the bioreactor will probably be the motors.

e. *Shelf Life:* The T-flask, polystyrene pipettes, cellular substrate, and o-rings are disposed of after each use. The other components, including the aluminum parts and motors, should have a shelf life of at least several years.

f. *Operating Environment:*

- Temperature range: Incubator (37° C)
- Pressure: Negligible differences in pressure.
- Corrosion from fluids: The humidity in the incubator may compromise the capabilities of the motors and the quality of the metal components over time.

g. *Ergonomics:* The T-flask should be easy to remove and replace.

h. *Size:* The bioreactor must be able to fit inside a standard incubator, therefore it is limited to 18" x 18" in width and length.

i. *Weight:* The weight of the bioreactor will probably be several pounds, as well as the amplifier and function generator(s) required to operate the voice coil actuators.

j. *Materials:* Two T-150 cell culture flasks, 2 moving magnet linear voice coil actuators, 2 rotary stepper motors, 2 linear stepper motors, vibration bars and connectors, spring holders, cellular-seeded strips, moving forceps, left- and right-handed threaded rods, and base plates. If the system will be computer controlled, there will also be two power sources, 2 data cards, and 4 MicroLynx controllers. If not, 1-2 function generators and one amplifier will be used.

k. *Aesthetics, Appearance, and Finish:* Although the aluminum parts are easy to machine, lightweight, and are great conductors of heat, they are also aesthetically pleasing.

2. Production Characteristics

a. Quantity: Although we are only making one prototype, the client has shown interest in having several replicas in order to perform experiences with many variables. 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 a dozen

at most.
b. *Target Production Cost:* The cost of a similar (yet simpler) existing bioreactor was around $15,000, thus it is expected our bioreactor will have a comparable cost. Because the majority of the parts of the bioreactor were purchased over the summer, our costs for the semester are expected to be much less than $5,000.

3. Miscellaneous

a. Standards and Specifications: The bioreactor 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:* Because of the very limited demand for this product, there is no intent by any party to patent this design.