Product Design Specifications – May 4th, 2011

MRI-Compatible Bioreactor for Cancer Cells (MRI Bioreactor)


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## Function

The purpose of staging cancer is to describe the severity and extent of the malignancy. Stage is one of the most important factors that oncologists consider when determining treatment plans and prognoses for their patients. There is a potential to use information about the metabolic state of cancer cells to characterize their stage. One way to follow this metabolism noninvasively is to implement magnetic resonance imaging (MRI) to track hyperpolarized carbon-13 labeled pyruvate as the cells break it down. We aspire to create a bioreactor that will permit a cell scaffold containing malignant cells to be imaged by an MRI scanner. This system will be supplemented with equipment capable of flowing the necessary gases and substances through it for testing.

## Client Requirements

- Device needs to house tissue scaffolding and other components needed to sustain cell viability.
- Device must have sensors to monitor dissolved oxygen (DO), pH, temperature, and other conditions to maintain an optimal environment for the cells.
- Device must have the ability to inject substances into the cellular environment and ensure even dispersal.
- Device must be MRI compatible.

## Design Requirements

1. **Physical and Operational Characteristics**
   a. *Performance Requirements:* The product must be able to house, monitor, and deliver nutrients to a tissue scaffold and all the cells maintained within it.
   b. *Safety:* The product cannot cause any harm to the operators, MRI components, or data acquisition.
   c. *Accuracy and Reliability:* Any substances injected into the cellular environment must be dispersed evenly at an accurate rate (between 0.25 and 4.00 mL/min). Device must maintain a cellular environment of 37.0 ± 1.0 °C, 7.4 ± 0.1 pH, and 0-20% DO.

d. *Life in Service:* The device will be used throughout the time period required to determine if monitoring cell metabolism is a viable method for staging cancer. This is expected to be around two years.
e. *Shelf Life:* The device should be able to maintain a shelf life of approximately two years for storage between experiments.
f. *Operating Environment:* The expected environment for use is at standard room temperature (20 °C) and pressure (100 kPa), in an isolated MRI scanner.
g. *Ergonomics:* The device must be easily sterilized and operate without continuous user supervision. The operator should be able to inject substances in 2-5 seconds.
h. *Size:* Any components not entering the MRI scanner can be of any size, however, the portion that houses the cellular environment must be less than 10.8 cm in diameter.
i. *Weight:* Weight is negligible for any components outside of the MRI scanner. Components within the scanner should be no more than 2.0 kg.
j. *Materials:* The device should be made of materials that are MRI compatible, non-ferromagnetic, and either easily sterilized or disposable. The canister that houses the cellular environment cannot be cytotoxic.
k. *Aesthetics, Appearance, and Finish:* For this project the client emphasized functionality over appearance and therefore this category is not applicable to our design.

**2. Production Characteristics**

a. *Quantity:* One device is required.
b. *Target Product Cost:* The entire device should not exceed the cost of a commercially available bioreactor, which is typically around $3,000.

**3. Miscellaneous**

a. *Standards and Specifications:* There are no federal regulations that need to be met for this device; however, basic cell culture guidelines must be followed.
b. *Customer:* The final product is intended for use by our client; however, it has the potential to be integrated into other research protocols involving imaging of *in vitro* cell cultures.
c. *Patient-related Concerns:* The device is intended for use on *in vitro* cell cultures and not actual patients. However, it must be able to maintain cell viability throughout its use.
d. *Competition:* FiberCell® Systems currently makes a hollow fiber bioreactor system with a horizontal cartridge. No known testing for MRI compatibility has been performed. Additionally, the system lacks sensing components and all together costs around $3,000.