

Project Design Specification

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Team Members: Matt Smith, Micah Brown, Chris Wegener, Ashley Anderson

Function:

The function of our device is to deliver a set ratio of a helium/oxygen mix in order to image the airways and lungs of an anesthetized rat within an MRI machine. Currently, the scanning time is longer since the helium contrast agent can only be administered once every four breaths. By incorporating the oxygen into each breath, our client will be able to image every breath and therefore reduce the scan time by a factor of four.

Client Requirements:

- Must be compatible with MRI scanners. However, since the injection system will be outside the magnet bore, ferromagnetic materials are permissible as long as they are away from the magnetic field.*
- Oxygen/Helium must be at a ratio of 20%:80%*
- Tidal volume of breaths must be variable and controlled by computer*
- Must minimize the time the oxygen and helium are mixed to reduce the amount of helium depolarization.*

Design Requirements:

1. Physical and Operational Characteristics

- a. Performance Requirements- The device must be able to inject a set tidal volume of 20%:80% oxygen/helium mix into an anesthetized rat every breath.*
- b. Safety- The device's ferromagnetic components must be outside the magnetic field created by the MR scanner in order to reduce the danger of attraction and presence of artifacts in the scans. Also, the device may not cause any harm to the animals being tested.*
- c. Accuracy and Reliability- Device must be able to deliver set tidal amount and set oxygen/helium ratio every breath continuously for the entire scan time (average scan time is 3 minutes)*
- d. Shelf Life- The device must last up to 5 years, for the entire duration of the client's study.*
- e. Operating Environment- Must be operated outside the magnetic field of 1.5T produced by the MR scanner. Must be able to withstand daily cleaning with industrial strength disinfectants for sterilization purposes.*
- d. Ergonomics- The device should be easily transported, set-up, and torn down to reduce the total scan time on the animal.*
- f. Size and Shape- The device will be incorporated into a 1' cubic box. This will reduce the weight of the device, as well as make setting up the device very easy.*
- g. Weight- No more than 20 lbs. in order to make the device easily transported.*

- h. Materials- Ferromagnetic materials are allowed to be used in this design, as the device will be outside of the magnetic field. Aluminum and other light metals will be used to reduce the weight of the device.*
- i. f. Aesthetics – It doesn't have to look pretty, function is more important..*

2. Product Characteristics:

- a. Quantity – Only one device is needed.*
- b. Target Product Cost- The device should stay within the client budget of \$1,000.*

3. Miscellaneous:

- a. Standards and Specifications- The device should comply to the guidelines setup up by the FDA for medical instruments. Further information is available online at the FDA's website, but it's too extensive to specifically list. The device is subject to performance and safety standards without exemption, for its classification.*
- b. Patient-related concerns- The patient in this case is an anesthetized rat. The device must not harm the animal in any way.*
- c. Competition-No known devices exist for the injection of a helium contrast agent to be used for the imaging of a rat's airways and lungs.*