Project Design Specifications
March 3, 2006

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Function:

Develop a method and device for measuring and recording airway pressure during a Valsalva maneuver. A device must be compatible in an MR environment. The device may not interfere with current imaging protocol.

Motivation:

Our client Dr. Haughton is currently studying CSF flow during Valsalva maneuvers performed by children with Chiari I malformations. Current research suggests that CSF flow decreases during Valsalva maneuvers in these patients. The airway pressure device would help monitor the exhalation force exerted by each child. Knowing the pressure exerted by each patient in the study would be extremely beneficial for data analysis and accuracy.

Client Requirements:

- *Must be compatible with MR.*
- *Must be small, elegant and portable*
- *Must be compatible with all components associated with MR scanner*
- *Must not affect patient safety*
- *Must be accurate to +/- 10%*
- *Must be easy for technologist to use and allow for easy monitoring near the MR host computer*

Design Requirements:

1. **Physical and Operational Characteristics**
    a. *Performance Requirements - The device must be able to measure airway pressure in children while they perform a Valsalva maneuver within 10% accuracy. It also must be capable of measuring pressures of at least 60 mm Hg.*
    b. *Safety - The device must comply with the standards for medical devices established by the FDA. It must be MR safe and cause no harm or discomfort to the patient.*
    c. *Accuracy and Reliability - Results must be reproducible. Scans must be consistently free of artifact and maintain an acceptable SNR.*
    d. *Shelf Life - The device must last 10-20 years and be stable enough for use one per week.*
    e. *Operating Environment - Must be able to withstand magnetic field up to 3 T (MR coil). Must be able to withstand daily cleaning with industrial strength disinfectants for sterilization purposes.*
    d. *Ergonomics - Operation of the device should be easy to use, and not interfere with the standard MR procedures. It also must not interfere with ECG and respiratory monitoring systems. It should also not significantly lengthen the scan.*

e. *Size and Shape - Must fit within the MR scanner and standard head coil. It should be sufficiently small to allow easy storage.*
f. *Weight - Must be under 1-2 lbs so that a small child could maintain its position during use.*
g. *Materials - Must be non-magnetic and radiolucent.*
h. *Aesthetics – It should be smooth, elegant, and safe-looking.*

2. Product Characteristics:

a. *Quantity – Only one device needed, but sufficient documentation must exist for reproduction.*
b. *Target Product Cost - The device should stay within the client budget of $100-200.*

3. Miscellaneous:

a. *Standards and Specifications - The device should comply with the guidelines setup up by the FDA for medical instruments. Further information is available online at the FDA's website, but it too extensive to specifically list. The device is subject to performance and safety standards without exemption, for its classification.*
b. *Customer - The customer will primarily use the device in MR scanners; therefore, its use should be tailored for use in MR scanners. The prototype should be compatible for MR requirements.*
c. *Patient-related concerns - The patient must feel comfortable and the device must be child-friendly.*
d. *Competition - No known devices exist for measuring airway pressure during an MR scan in such a fashion.*