Product Design Specification

Client Requirements:
- Intracuff pressure must reach 25 cm H2O pressure.
- Intracuff pressure must be known or released at 25 cm H2O pressure.
- Modification can be bypassed to accommodate unforeseen situations.

Design Requirements
1. Physical and Operational Characteristics
   a. Performance requirements: Must perform at level consistent with existing endotracheal tubes (i.e. intubation for surgery, through recovery).
   b. Safety: Must be FDA approved for humans.
   c. Accuracy and Reliability: Must maintain or indicate intracuff pressure of 25 cm H2O.
   d. Life in Service: Must last for duration of patient intubation, (short or long term). Disposable.
   e. Shelf Life: Storage in optimal conditions for one year.
   f. Operating Environment: The system will be used in both E.R. and O.R. settings. When not in use, it will be stored with little outside exposure.
   g. Size: Cannot add noticeable amount of size to existing tube system.
   h. Weight: Cannot add noticeable amount of weight to existing tube system.
   i. Materials: MRI and CT compatible.
   j. Aesthetics, Appearance, and Finish: Clean, with white finish for high visibility.

2. Production Characteristics
   a. Quantity: Working prototype
   b. Target Product Cost: < $1 over base ET tube.

3. Miscellaneous
   b. Customer: Customer already has means to inflate cuff. Needs indicator of intracuff pressure.
   c. Competition: Lanz® brand endotracheal tubes (30 cm H2O)