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**
    a. *Standards and Specifications*: FDA approval for use in human pediatrics.
    b. *Customer*: Customer already has means to inflate cuff. Needs indicator of intracuff pressure.
    c. *Competition*: Lanz® brand endotracheal tubes (30 cm H_2O)