Endotracheal Tube Cuff Pressure Indicator

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Abstract

Endotracheal intubation is required for most invasive surgeries. The current tubes used in adults have a cuff attached at the end of the tube that when inflated, creates an air tight seal inside the trachea to prevent aspiration. However, this cuff system is not suitable for pediatric intubations since it can cause injury and scarring to the tissue of the trachea if over inflated. The goal of the new design is to modify the existing tube-cuff-valve system to indicate, for the purposes of regulation, pressure in the cuff so that it may be safely utilized in pediatric cases.

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Problem Statement

Our client, Dr. Lester Proctor, has charged us with the task of designing an endotracheal tube cuff system that would indicate the cuff pressure for purposes of regulation. Dr. Proctor is a practicing anesthesiologist and professor working in the University of Wisconsin hospitals. One of the duties he must perform is the intubation of patients undergoing invasive surgical procedures. Normally, he uses a cuffed endotracheal tube for the intubation, but for all the advantages the cuff provides there are several risks associated with it that make it unsafe for use with pediatrics. The smaller diameter endotracheal tube used in pediatric cases traditionally does not even have a cuff at its end. Accordingly, Dr. Proctor would like us to design an endotracheal tube that is also cuffed so in future procedures the child will benefit from all the advantages of a cuffed tube, without the possibility of harm due to excess cuff pressure.

Background Information

Every year the UW hospital system performs upwards of 20,000 operations. 25% of those procedures are on children over the age of five, and 75% of those children are intubated using an uncuffed endotracheal tube (Proctor, 2006). When an adult patient is intubated, a cuffed endotracheal tube is used. In this process, a plastic tube is inserted into the patient's trachea, past the larynx (Figure 1), where it will serve to provide oxygen and other various medical gasses to the anesthetized patient. A cuff at the posterior end of the endotracheal tube is then inflated with air. The cuff is a simple balloon that encircles the end of the endotracheal tube which, when inflated, pushes against the tracheal wall. This provides several advantages to the doctors and patients. First, it

anchors the endotracheal tube in the trachea. This is important in the progression of the surgery, so that the tube does not become accidentally dislodged. Second, the cuff creates an airtight seal between the respiratory machine and the lungs. The seal allows for more accurate delivery of oxygen at lower pressures, as well as prevents pollution of the air from medical gasses. Finally, the cuff prevents patient aspiration. Aspiration occurs when foreign matter, be it bacteria laden mucous or vomit, enters the lungs (Spray *et al.*, 1976). Normally, the foreign matter would be dispelled from the lungs via an involuntary reflex, usually coughing, but the anesthetized patient is unable to cough due to the various paralyzing agents used in surgery. Foreign matter that remains in the lungs for an extended period of time can ultimately cause infection and pneumonia. Adults receiving mechanical ventilation have an incidence of Ventilator Associated Pneumonia of up to 60% with an attributed death rate of 27% (Fagon *et al.*, 1993).

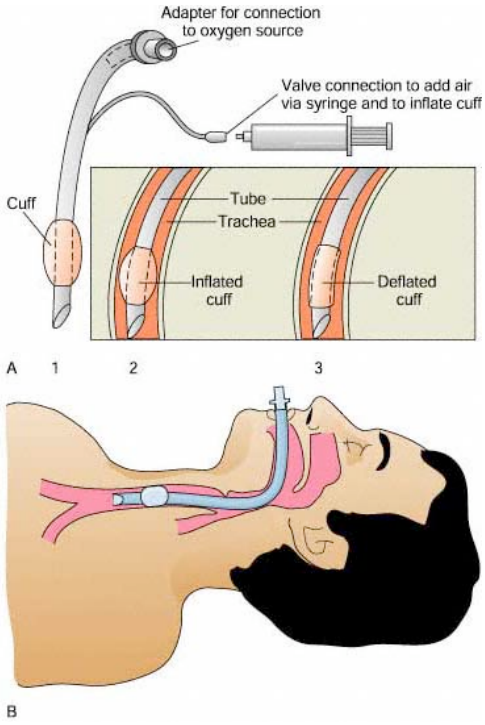

Figure 1: Endotracheal Tube Placement [Source: http://connection.lww.com/]

The cuff is inflated with air via a one-way valve attached to the cuff through a separate tube that runs the length of the endotracheal tube. A syringe is inserted into the valve and depressed until a suitable intracuff pressure is reached. *Sengupta et al.*, (2004) has shown that cuff pressure is highly variable among patients. 27% of their sample population had endotracheal tube cuffs inflated past 40 centimeters H_2O. Overinflation of

the cuff past the optimal range of 20 – 30 centimeters H_2O is associated with the risk of Ischemia in the trachea. Ischemia is a shortage of blood supply to an organ or tissue (Wikipedia, 2006), in this case due to pressure exerted on blood vessels in the tracheal wall. Extended shortages of blood supply can lead to necrosis in the area, scarring, and even closure of the trachea. Children are particularly susceptible to ischemia, which is why anesthesiologists use the uncuffed endotracheal tube.

Current Devices

Several patents with ideas for intracuff pressure-regulating systems exist as well, although none have been seriously marketed. Most of the patented ideas consist of designs that include either bulky, expensive, electronic components or non-disposable components. The goal of this semester's project is to produce a working prototype that is inexpensive, and easy to use. (A summary of current patents can be found in ***Appendix A***.)

Currently one product exists on the market with a pressure-regulating system designed for the endotracheal tube cuff. This is the Hi-Lo® Tracheal Tube With Lanz® Pressure Regulating Valve. It is not suitable for use in pediatrics, however.

Design Constraints

This semester's design must adhere to several requirements that have been specified by the client. Singularly most important among the design specification is that any modification cannot negatively impact the performance of the existing endotracheal tube. FDA approval for use in human pediatrics is required in order to successfully

market and produce the product. Indication of, or a way to maintain intracuff pressure at 25 cm H2O must be reliable to +/- 2 cm water pressure, and will be the most important modification to the existing device. The complete system (consisting of the tube, cuff and valve) must last for the duration of the patient's intubation and will be disposed of when it is no longer in use. The system must have a shelf life of one year, in optimal conditions with little outside exposure. Use in both Emergency Room and Operating Room settings will occur, so the materials of the product should not decrease MRI or CT compatibility. The finished product should be clean, with a white finish for high visibility. The semester goal is to produce a working prototype without adding more than 1 dollar to the current cost. Because the client already has a means by which to inflate the cuff, the design should focus on installation of an indicator of the intracuff pressure. Finally, the modification must be able to be bypassed in order to accommodate unforeseen situations. (A full product design specification is available in ***Appendix B***.)

Design Alternatives

Design 1: Electrical Design

Overview

The first design is an electrical approach at creating an endotracheal tube cuff pressure indicator. The fundamental basis of this design is a pre-existing electrical pressure transducer manufactured by Omega Engineering, Inc **(Figure 2)** use micro-machined silicon pressure sensors to produce highly accurate pressure

Figure 2: PX-138 Pressure Transducer [source: omega.com]

readings. The PX-138 is capable of measuring pressures in the range of 1 pounds per square inch, or 70.31 cm H2O +/- .3% which would cover the safe operating pressure range of the endotracheal tube cuff.

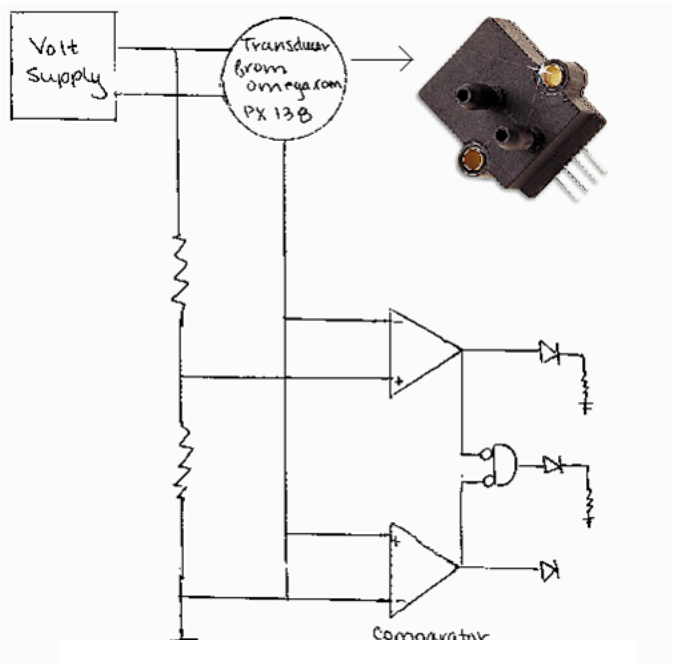

Figure 3: Electric Ciruit [Source: Tim Shedd]

Electrical transducers function by converting pressure into a fraction of the supplied voltage. The output voltage can than be applied to various functions; In this case, a simple circuit composed of a power source, the transducer, and a set of comparators **(Figure 3)**. The comparators interpret the output voltages from the transducer and power a set of LEDs in such a way that they would illuminate corresponding to three different intra-cuff pressure ranges, namely when the cuff is inflated to less than 20 cm of H2O pressure, between 20 and 30 cm H2O, and greater than 30 cm H2O. In addition, the LEDs would be color coordinated: yellow would represent under-inflation; green, ideal pressure; and red, over-inflation.

The transducer, circuit, and LEDs would be attached to the endotracheal tube near the pilot balloon. At this location they could be easily be read by the physician at the time of inflation.

Advantages and Disadvantages

A great benefit to this design is its accuracy. As previously mentioned, the transducer can produce precise measurements within our relatively low working pressure range. The device is also very user friendly. Since it utilizes three different colored LEDs to display the pressure to the administrator, it is difficult to misread the pressure within the cuff. This minimizes the chance of user error.

However, there are some problems associated with this design, the most prominent being price. The cost per unit for an electrical pressure indicator would be well above the target allowance established by the client. The pre-manufactured transducer alone costs $85.00. Even at an estimated bulk discount of $10 per transducer, the electric design would still be overwhelmingly more expensive than the allotted price increase of $.1-$1 over the price of the base endotracheal tube. Another disadvantage of this design is the electrical approach itself. The problem is that any form of electronic device has the potential to interfere with other medical equipment in the operating room.

Design 2: Mechanical Design

Overview

Whereas the first design relied almost entirely on electrical means of reading and displaying the pressure, the second utilizes a mechanical approach. It is essentially a small-scale pressure gauge, utilizing the same concepts as those used in measuring the pressure inside automobile tires.

Similar to the electrical device, the gauge would be connected to the cuff air supply tube near the pilot balloon so that it could measure the pressure within the cuff at the time of inflation. The air pressure in the system would act on a piston inside of the device **(Figure 4)**. The force of the air would push on one side of the piston, moving it as the pressure increased. On the other side of the sealed piston, there would be some form of calculated resistance to the force of the air pressure. The original design called for the use of a metal spring, however, due to the design specification of MRI compatibility, a non-metallic form of resistance will need to be used.

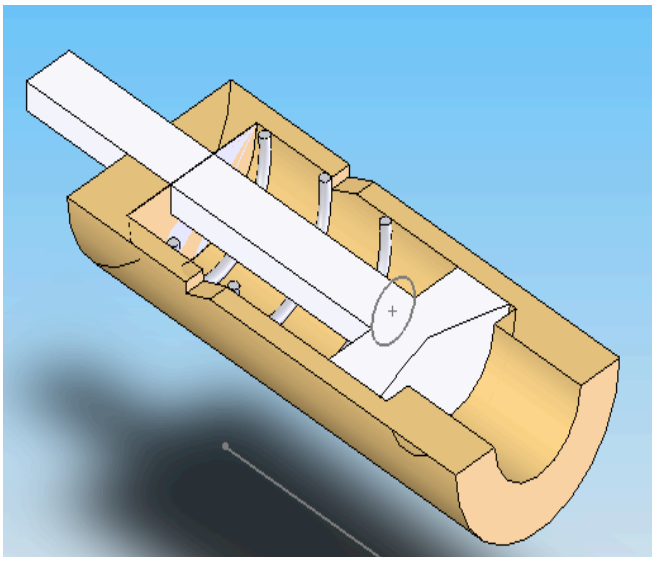

Figure 4: Inner Workings of Design

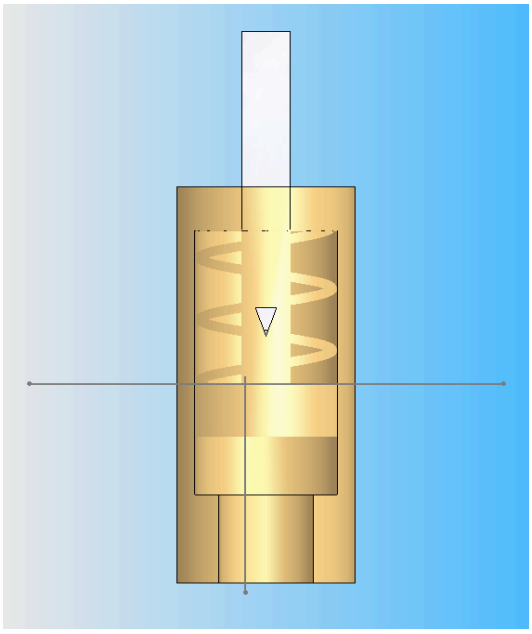

Figure 5: External view of device with indicating stem protruded

As the pressure increases and the piston increasingly recedes into the body of the device (moved in the direction away from the air supply), it will protrude an indicating stem. This indicating stem will extend to a length proportional to the intracuff pressure. **(Figure 5)**. The stem will be equipped with an easy-to-read pressure scale printed on its outside, which will be calibrated to reflect the respective

pressures inside the cuff, and subsequently give a reading of the intracuff pressure to the physician.

Advantages and Disadvantages

An advantage of this design is that it is economical. Whereas the electrical design is way out of the prescribed price range, this approach is estimated to be, at max, $5 over the suggested unit price. The savings in unit price would come at the price of the level of precision, but, the device can be calibrated to perform within the specified accuracy criteria. Because it's made mostly of plastic (which is relatively low-cost and requires less labor to fabricate with compared to other materials), in mass-produced, its unit price should fall within the ideal range. Another advantage to this design is that the device would be versatile. Since it reads pressures through a range of values rather than at specific predetermined intervals, physicians could choose exactly pressure to which they would like to inflate the cuff. This allows for physicians to use different pressures for different situations at their digression, permitting them to compensate for factors such as the size, gender and age of the patient.

This design does have its setbacks, however. It will be challenging to calibrate this device to the required accuracy, which means initial design testing could be grueling. Also, because it has to be MRI compatible, a traditional metallic spring will not suffice, so an alternative form of resistance will need to be implemented.

Design 3: Relief Valve

Overview

This design involves the attachment of a one-way pressure relief valve inline with the current one-way intake valve on the endotracheal tube (**Figure 6**). Because the pressure inside the cuff is equal to the pressure inside the pilot balloon, the new one-way release valve will respond to the pressure in the original balloon and new tube. Once the pressure exceeds 25 cm water pressure, the pressure release valve will open to rid the cuff of excess pressure and the release valve will close again once the pressure returns to slightly below 25 cm water pressure. Another modification required in this design is the manual override clamp.

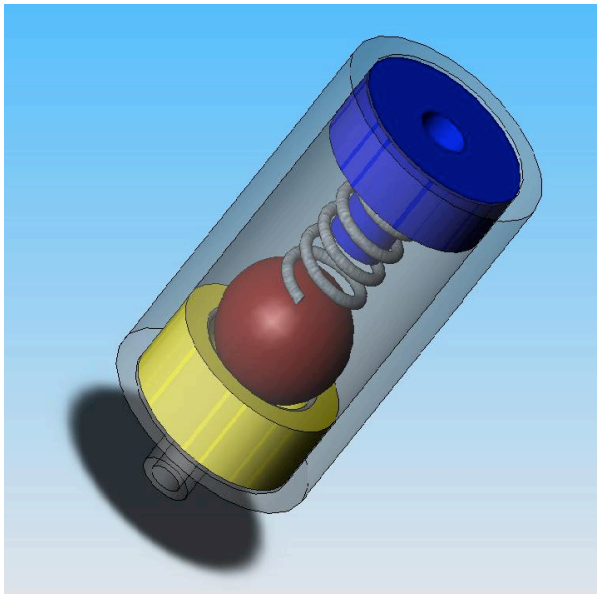

Figure 6: Schematic for pressure relief valve

Since Dr. Proctor requires the ability to countermand the pressure release for emergency purposes, the clamp would be used to bypass the relief valve, rendering it ineffective. The design would allow for the use of any medical clamp commonly found in emergency vehicles and hospitals. Slide clamps, plastic tube clamps, and roller clamps similar to those on IV's are being considered as possible override mechanisms.

Advantages and Disadvantages

One main advantage of this design is its ability to reliably release pressure. Also, this design has the ability to work in the background of the hospital facility. This implies

that the valve can function without user or physician intervention. The additional relief valve should be relatively inexpensive to manufacture because they are already in production for other medical applications.

There are a few drawbacks including MRI and CT compatibility. Aside from having to find a MRI compatible material for the spring, there is also a need for precision manufacturing. This is due to the fact that there is high precision and accuracy required in this pressure relief valve and a minute amount of pressure to work with. Finally, this design was pursued last semester and is not exactly what the client is looking for now.

Design Matrix

In order to compare the designs, a design matrix (Table 1) was created to grade each option on its merits in five critical categories: Safety, Client Preference, Ease of Use, Effectiveness, and Price. Safety, Client Preference and Price were deemed the most important and weight on a higher scale of ten. Safety takes into account the likelihood of failure, and is extremely important for an *in vivo* medical product. Similarly, Client Preference is crucial, as the product must fit the specifications laid out by our client Dr. Proctor, an experienced clinician with insight into how the product would be used in practice. Price is important because the product will be used for a short time before being disposed and should be affordable to ensure high usage. Finally, Effectiveness and Ease of Use of the design are important because the circumstances under which the product will be used may be hectic, and the less time that goes into figuring out how the product functions the more effective it may be while a human life is on the line.

	Safety (10)	Client Preference (10)	Ease of Use (5)	Effectiveness (5)	Price (10)	Total (40)
Electrical	9	1	5	4	1	20
Mechanical	8	10	4	4	10	36
Relief Valve	10	6	5	3	7	31

Table 1: Design Matrix

The electrical design is the easiest device for physicians to work with, but its circuitry makes it too expensive. This design also has the potential to cause numerous problems regarding interference with other medical devices and treatment possibilities. The mechanical design is by far the most like our clients proposed project, but adding a pressure relief system may prove difficult. Being the safest, the relief valve was given a perfect score for safety and a fairly high score for projected price, but lost points in the other categories because it cannot be easily manufactured when one takes into account MRI compatibility and the precision manufacturing/calibration required. The relief valve also lost some point in the Effectiveness category because it has no way of indicating the pressure, it can only regulate. In the end, the mechanical design garnered the most points, and will be the design pursued for prototyping and production.

Future Work

Our remaining work for the semester can be divided into three key goals: finalizing our design, manufacturing a prototype and testing the prototype. Once these goals are accomplished we can look to various companies or physicians for help manufacturing or marketing our design. As always, research, acquisition of new skills, and recording all of our findings/results will go along with all aforementioned work.

As of now, we have a general idea of how our prototype will look and how it should operate. We still need to specify the exact dimensions and how it will fit onto the existing endotracheal tube. We must also decide on what materials to use in the manufacturing of our prototype. We must consider materials that do not interfere with any medical imaging equipment, but also relatively inexpensive to fit into our target price range (under 25 cents). Above all, we must dimension our prototype in such a way and build it out of materials that give us a useable variance in the mechanical plunger. Once we establish a constant variance in the plunger height with respect to pressure we can scale the device so that it can be read as a pressure meter.

Our group is currently investigating the most feasible way to manufacture our prototype. We have looked at and compared injection molding, rapid prototyping, and machining. Currently it looks like machining the parts out of existing pieces of plastic is the most practical option. Injection molding is useful for the mass production of parts, but it is too time consuming to create the aluminum molds for making just one or two pieces. Rapid prototyping may be a feasible option since we already have the necessary drafting models, but finding open time on the machine may not be possible within the

remainder of the semester. Machining the pieces appears to be the easiest and cheapest route if our goal is to only make one or two prototypes.

To test our working prototype, we hope to use analytical software such as Labview to quantify our results. We will need to test the accuracy of pressure readings along with the release pressure of the safety mechanism. Most likely we will not achieve our desired results with our first prototype, so we will use our test data to make necessary adjustments and further design constraints.

Our current design for the prototype attaches on to a pre-manufactured endotracheal tube. Ultimately, we would like our design to be integrated with the tube in the manufacturing process so that it can arrive at the hospital prepackaged and ready to use. Long-term work will likely include determining if any companies that manufacture endotracheal tubes would be interested in integrating our design in their products.

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Appendix A

Current Patents

US Patent Number 5235973
A tracheal tube is equipped with two air lines to the inflatable cuff, one for monitoring cuff pressure and another of larger diameter for inflating the cuff. Intracuff pressure monitored via the smaller diameter line is continuously displayed. A cuff pressure control system allows independent adjustment of cuff pressure via the larger diameter line from high pressure during inspiration to low pressure during expiration. The switchover point is determined by a detecting pressure monitor in the mechanical ventilator inspiration line. The circuit also adjusts automatically to changes in the baseline expiration pressure. The output of a bidirectional mass flow sensor tracks airflow in the cuff inflation line and is integrated to indicate volume. Volume into the cuff is then compared to volume out of the cuff to detect cuff leakage.

US Patent Number 7018359
The patented component consists of a clear, plastic cylinder that locks onto the pilot balloon and is delimited with marks that correspond to the intracuff pressure. When attached to the pilot balloon a small piece juts out and opens the inflation valve. Air enters the cylinder and depresses a bellows that acts like a piston. The distal end of the bellows is open to the atmosphere so pressure differences between the cuff and atmosphere cause the piston head of the bellows to move proportionally to the intracuff pressure. Using the calibrated markings on the outside of the cylinder, a close pressure measurement can be taken.

US Patent Number 5487383
This idea uses a unique integration of two tubes of different diameters going into the endotracheal tube cuff. The larger diameter tube is used for rapid inflation of the cuff, while the smaller tube is used for monitoring and adjusting the pressure. The goal of this invention is to achieve a monitoring and control system that delivers constant cuff pressures high enough to prevent aspiration without causing any damage to the tracheal mucosa. With the two tube system, this devise is constantly inflating and deflating the cuff to monitor and control pressure. This feature can ensure a constant seal during the inspiration/ expiration of a mechanical ventilator. Pressure is displayed on a CRT or a LED bar graph. Pressure is controlled by the use of two solenoid release valves hooked up in series on the smaller deflation tube.

US Patent Number 4924862
This system has 2 parts: the release valve and the excess pressure flow monitor. The release valve is a 2-way valve and is adjustable. It has an inlet and outlet connected in series between the cuff and the source of inflation. Two relief valves are used: a low pressure valve in series with a high pressure valve. There is an exhalation drive line connected to the tube, and this controls the low pressure release valve. The flow detector is located in the cuff inflation line and produces some kind of electrical signal if excess airflow occurs. This device involves an attachment and a two-way release valve.

US Patent Number 4617015

This device is a bottlecap-shaped addition to the cuff air supply tube that is added in-line near the valve for the syringe. It visually indicates pressure to the anesthesiologist. As pressure increases, a diaphragm flexes, and that flexing indicates pressure levels. The price of this design is a relatively greater value compared to other more expensive methods of indicating pressure. The overall idea of this device is similar to that of a tire pressure gauge—as pressure increases, a stem or rod protrudes from the device indicating inflation of the cuff and ideally, an actual value for the amount of pressure inside the cuff.

Appendix B

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)