# Endotracheal Tube Cuff Valve

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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 create 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 was to modify the existing tube-cuff-valve system to allow regulation of the pressure in the cuff, in order to be safely utilized in pediatric cases. A prototype was constructed that consists of a relief valve system designed to release excess air and stabilize the pressure in the cuff at safe levels. However, the prototype is not fully functional because a valve that releases and stabilizes at exactly the right pressure has not been found. A set of tests have been performed to demonstrate that the only missing portion of the design is a valve with the correct release pressure. Continued work on this project could involve the design and production of a valve made specifically for use with this system.

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## Problem Statement

Our client, Dr. Lester Proctor, has charged us with the task of designing an endotracheal tube cuff valve that would systematically and predictably release excess pressure when an operator attempted to inflate the cuff past 25 centimeters $H_2O$ pressure. 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 this system that make it unsafe for use in pediatrics. The smaller diameter endotracheal tube used in pediatric cases traditionally does not have a cuff at the distal end. Accordingly, Dr. Proctor would like us to design a system so in future procedures the child will benefit from all the advantages of a cuffed tube, without the possibility of harm from 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 distal 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 because it reduces the likelihood of the tube becoming 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, and also prevents pollution of the air in the operating room 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).

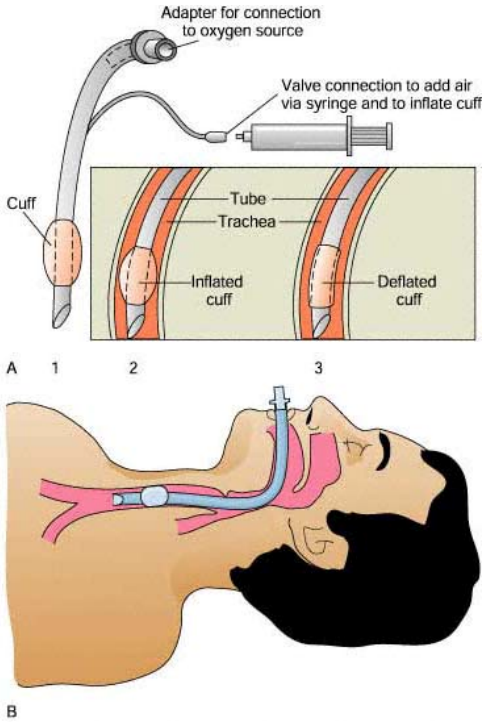


Figure 1: ***Endotracheal Tube Placement***
**[Source: http://connection.lww.com/]**

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) haves shown that cuff pressure is highly variable among patients. 27% of their sample

population had endotracheal tube cuffs inflated past 40 centimeters $H_2O$. Over inflation 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

The Hi-Lo® Tracheal Tube With Lanz® Pressure Regulating Valve is designed with a pressure-regulating system the endotracheal tube cuff, and is similar to the type of product desired by our client. This design is not suitable for children, however, because the crack pressure is too high for use in pediatric intubations.

Currently, one release valve for endotracheal tube cuff pressure has been designed and marketed by Microcuff GmbH, Weinheim, Germany. Three doctors in Switzerland have successfully tested the device for applications in pediatric cases ("Dullenkopf, *et al*., 2006"). The design consists of a cuff pressure pop-off valve that is attached between the syringe or monometer, used to inflate the cuff, and the pilot balloon that leads to the cuff. The valve is removable and reusable, and is meant to crack at 20 centimeters water pressure. If marketed, its estimated cost is 72 euros or about 90 dollars. The valve has been tested in simulated tracheas made of PVC piping. Test results have shown that the pop-off valve works effectively during rapid cuff inflation

and also in the presence of nitrous oxide, which can cause hyperinflation of the cuff. This design relates well to the needs of our client.

## Design Constraints

The design must follow several specific requirements, some of which have been detailed by the client. The new system must perform at the same level as the existing endotracheal tube system. Improvements should be made on the existing design, incorporating the changes set forth by our client and the industry. FDA approval for use in human pediatrics is required for the entire apparatus, in order to be able to successfully market the product. The requirement of the valve to open at 25 cm $H_2O$ +/- 0.25 cm $H_2O$ pressure is mandatory and must be very reliable, as this is the most important modification to the existing device. Failure cannot occur before or after 25 cm $H_2O$. The tube, cuff, and valve must be able to last for the duration of the patient intubation, and will be disposed of when they are no longer in use. In optimal conditions, the shelf life should be one year, with little outside exposure. Use in both Emergency Room and Operating Room settings will occur. Materials used should not increase visibility of the tube in MRI situations. The finished product should be clean, with a white finish for high visibility. Our goal is to produce a working prototype without adding more than five dollars to the current cost. Because our client already has the means to inflate the cuff, our modifications should focus on a means to bypass the valve. The failure of the cuff at 25 cm $H_2O$ must be able to be overridden to accommodate unforeseen and emergency situations. (A full product design specification is available **Appendix A**.)

## Design Alternatives

In generating different design possibilities, it is important to consider design requirements. After some preliminary research and brainstorming, the design process was initiated. Ideas were evaluated according to the customer specifications and the top three designs were selected: a t-valve, a clip valve, and a two-valve system and clamp. From these three designs, a chosen design was pursued.

### Design 1: T-Valve

*Overview*

The T-Valve (Figure 2) is a simple design that adds another valve on the pilot balloon to allow for pressure release. The new valve will be added to the original existing valve system, separating the outtake and intake parts of the valve. The new added valve will be used as a safety valve, releasing excess pressure when pressure inside the valve, directly correlating with cuff pressure, exceeds 25 centimeters $H_2O$. The release valve will be a one-way outtake valve that is held shut by a spring, much like the current intake valve found on the endotracheal tube that is made to inflate only by means of inserting the syringe. When the pressure in the valve reaches 25 centimeters $H_2O$, the spring will no longer be able to hold the valve closed, releasing the pressure in the valve until it falls to the desired level.

Modifications such as a readable gauge, a manometer, can also be applied to this design.

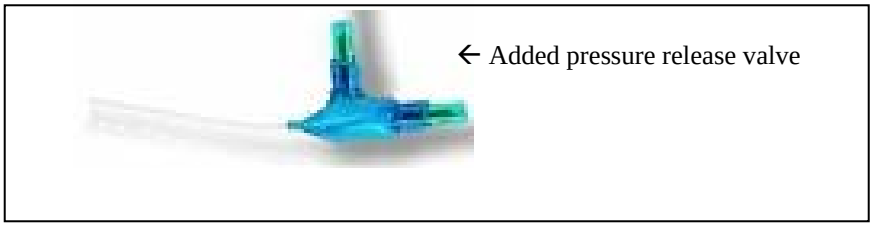


Figure 2. ***Schematic for T-valve system***
***[Source: http://greatcare.ec51.com/images/bank/1098801555.jpg].***

*Advantages and Disadvantages*

The most noticeable advantage of this device is its extremely simple design. With not much being changed, this design would retain most, if not all, of the advantages of the original device without adding too many new variables to be accounted for i.e. federal approvals, unforeseen problems or failures, etc. Furthermore, it'd be more familiar to the doctors who would operate this device compared to our other designs.

A safety advantage of this design is that it's constrained to one place, providing only one place on the design to look out for problems occurring. Another advantage is the ability to modify the design by adding a readable gauge, much like a tire gauge, or a balloon that regulates pressure.

A disadvantage of this design compared to our other designs is that a manual override of the system (needed when an unforeseen situation occurs) is not as straightforward. Also, if it sticks, preventing proper failure, overriding it would be tricky. Another disadvantage is the fabrication this device. With it being one whole piece, the whole device would have to be custom made from scratch.

**Design 2: Clip Valve**

*Overview*

The Clip Valve design (Figure 3) is a basic one-piece lever system. This design works exclusively with the pilot balloon. A clip (which could be fashioned out of plastic, metal, etc.) with two protrusions, one to close the release valve and one in contact with the pilot balloon, will be attached on the exterior of existing valve and be spring loaded to keep the valve shut when the pilot balloon is deflated and pressure is below 25cm $H_2O$. When pilot balloon (which inflates with the cuff balloon) reaches the pressure/size of 25cm $H_2O$, it will be able to push the end of the clip up far enough to cause the release valve, previously shut by the clip, to open, releasing pressure. When pressure drops enough for the lever to fall back in place, the release valve is closed allowing for continued inflation if desired.

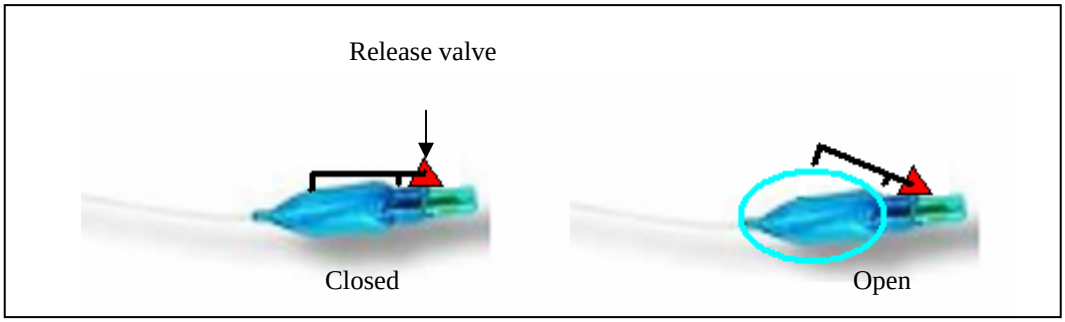


Figure 3. ***Schematic for clip valve system***
***[Source: http://greatcare.ec51.com/images/bank/1098801555.jpg].***

*Advantages and Disadvantages*

This device can be very easily overridden, both to keep the valve open or closed. To keep it open, just lift up clip up. To keep it closed, just hold it down. One could also keep it closed by holding it down with a rubber band or a clamp of some kind. The

ability for it to reset and re-fail repeatedly is also advantageous because it makes it self-maintained.

A primary disadvantages however, is that this clip device will be on the exterior of the valve. This means that the device is exposed to the surroundings and could easily get caught on something or be damaged. Moreover, this device could be damaged in two critical spots. One is at the spring and another is at the release valve itself. Damage to either of these spots could lead to malfunction.

**Design 3: Two-Valve System and Clamp**

*Overview*

While this system operates similar to current design, there are several modifications to consider. This design involves the attachment of a second pilot tube and pilot balloon to the existing pilot balloon (**Figure 4**). 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 centimeters water pressure, the pressure release valve will open to rid the cuff of extra pressure and the release valve will close again when the pressure is about 25 centimeters water pressure. Another modification required in this design is the manual override clamp.

Since Dr. Proctor requires the ability to countermand the pressure release for emergency purposes, the clamp would be used to force the outtake valve to be 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.

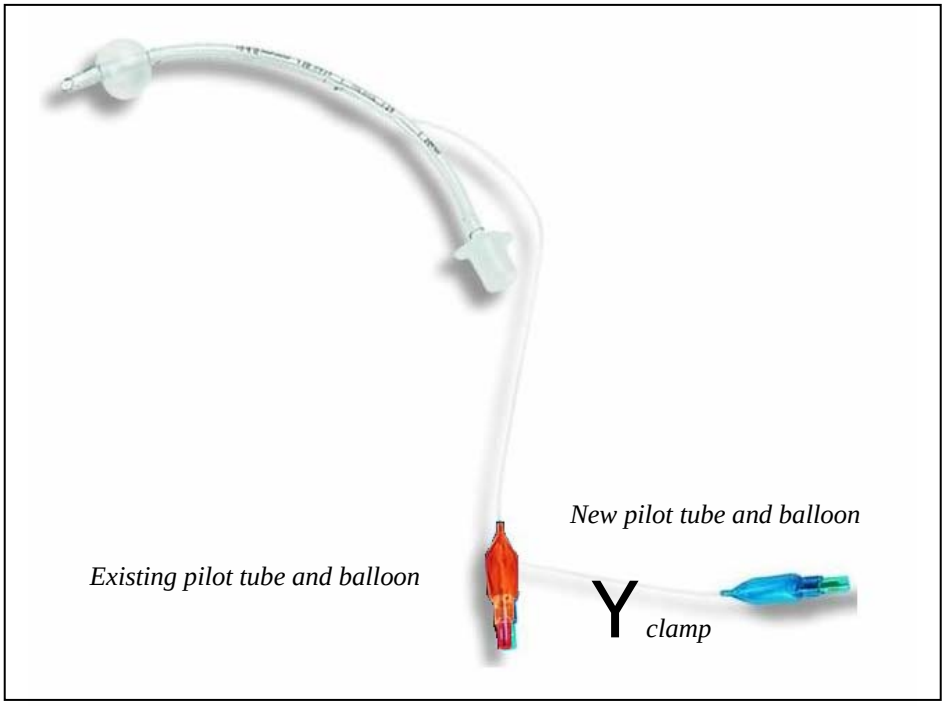


Figure 4. ***Schematic for two-valve system with clamp capabilities [Source: http://greatcare.ec51.com/images/bank/1098801555.jpg].***

*Advantages and Disadvantages*

One main advantage of this design is its ability to consistently fail by having the ability to override the device. Also, this design has the ability to fail, reset, and re-fail numerous times. The additional pilot tube and balloon should be relatively easy to manufacture because they are already in production for the current design.

There are a few minor drawbacks including possible clamp failure. The size of the extension has the possibility of becoming in the way of a procedure. Also, the seamless manufacturing from one pilot tube to two pilot balloons may present some roadblocks. This prevents inexplicable valve error, which is seen in current endotracheal tubes.

## Design Matrix

In order to compare the designs, a design matrix (Table 1) was created to grade each on its merits in five categories that are relevant to the project: *Safety*, *Effectiveness*, *Simplicity*, *Ease of Use*, and *Price*. *Safety* takes into account the likelihood of failure, and is extremely important for an *in vivo* medical product, so it was weighted higher than the other categories with 10 being a perfect score. Similarly, *Effectiveness* was rated out of 10, as the product must perform its duties while a human life is on the line. *Simplicity* 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. Finally *Price* is important, as the product will be used for a short time before being disposed of.

| | **Safety (10)** | **Effectiveness (10)** | **Simplicity (5)** | **Ease of use (5)** | **Price (5)** | **Total (35)** |
|---|---|---|---|---|---|---|
| **T-Valve** | **9** | **6** | **5** | **4** | **5** | **29** |
| **Clip** | **7** | **6** | **2** | **5** | **1** | **21** |
| **Clamp** | **10** | **10** | **4** | **4** | **3** | **31** |

Table 1: ***Design Matrix***

Being the simplest design, the T-valve was given a perfect score for simplicity and projected price, but lost points in the other categories because it cannot be easily bypassed. The clip valve is the easiest mechanism to work with, but its multiple moving parts make it too complex, expensive and prone to failure. The clamp design is by far the safest and most effective of the designs, but it lost some points due to form factors and the possibility of mistaking the two valves. In the end, the clamp design garnered the most points, and was the design pursued for prototyping and production.

## Final Design

The two-valve system with clamp final prototype can be viewed in Figure 5. We began work on the prototype with a standard cuffed endotracheal tube by Sheridan® provided to us by our client, Dr. Procter. We modified the standard endotracheal tube to our specifications by first cutting the line leading from the pilot balloon to the cuff and placing a PVC "Y" splitter obtained from Qosina Inc. (www.qosina.com) between the two sections. After securing and sealing the two sections of original tubing with superglue, a third length of PVC tubing, also procured from Qosina Inc., was secured to the empty port of the "Y" clamp. Finally, a clamp, for bypassing the relief valve, was slipped over the length of free tubing and a check valve with 0.5 psi cracking pressure and barb hose connectors from Smart Products, Inc. was placed on the terminal end of the tubing. Figure 6 shows the two-valve assembly close up. Notice that when clamped only the pressure relief valve will be bypassed. Also, the pressure relief valve empties out into the

Figure 5. ***Final design prototype***

Figure 6. ***Final design prototype***

Figure 7. ***Check Valve from Smart Products***

surrounding atmosphere to end the airflow circuit.

The Smart Products valve is a “poppet” type check valve with a cracking pressure of 0.5 psi, or 35.15 cm $H_2O$. The actual check valve is a cartridge housed in a medically friendly polypropylene body with barb line connectors (Figure 7). Poppet type check valves (Figure 8) contain a piston that seals the valve at zero pressure with the use of a pre-compressed spring. When the pressure behind the piston exceeds the force exerted upon it by the spring, the piston “pops” open and vents the medium until static equilibrium is once again achieved. The pressure at which the medium causes the valve to open is known as the crack pressure. The Smart Products reported crack pressure ratings of their check valves apply directly to fluid mediums rather than gas, a fact not disclosed on the products specifications listings. The implications of this discovery will be explored in the discussion section of this paper.

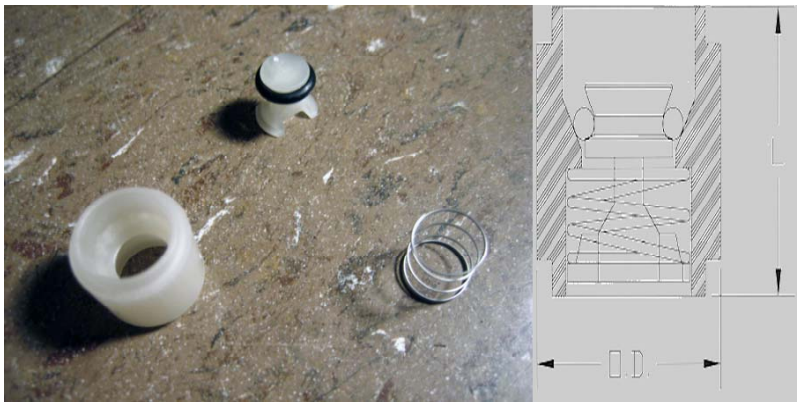


Figure 8. ***Poppet type check valve and compression diagram***

## Testing: Pressure Consistency

Throughout the construction of the prototype, our team worked with a variety of valves that we maintained from various manufacturers. Upon realizing that none of these valves cracked at exactly the predicted pressure of 25 cm $H_2O$, we decided to test the

accuracy of the valves in order to show that the only component missing from our prototype was a valve that opened at the appropriate pressure.

We used a simple test to demonstrate the consistency of the stabilization pressure of two different types of valves with separate marketed cracking pressures. We began by choosing the two types of valves to be tested: the first with a marketed cracking pressure of 24.13 cm $H_2O$ and the second with a marketed cracking pressure of 35.15 cm $H_2O$. Using a monometer, we inflated the cuff testing two separate methods of inflation. The first method consisted of inflating the cuff in a very controlled manner over a span of seven seconds, while the second involved a very rapid inflation of the cuff (<1 second). Using the monometer, we measured the pressure after stabilization. We repeated this procedure 40 times, testing each method on each valve 10 times. We recorded the stabilization pressure after each test and performed a statistical analysis of the data.

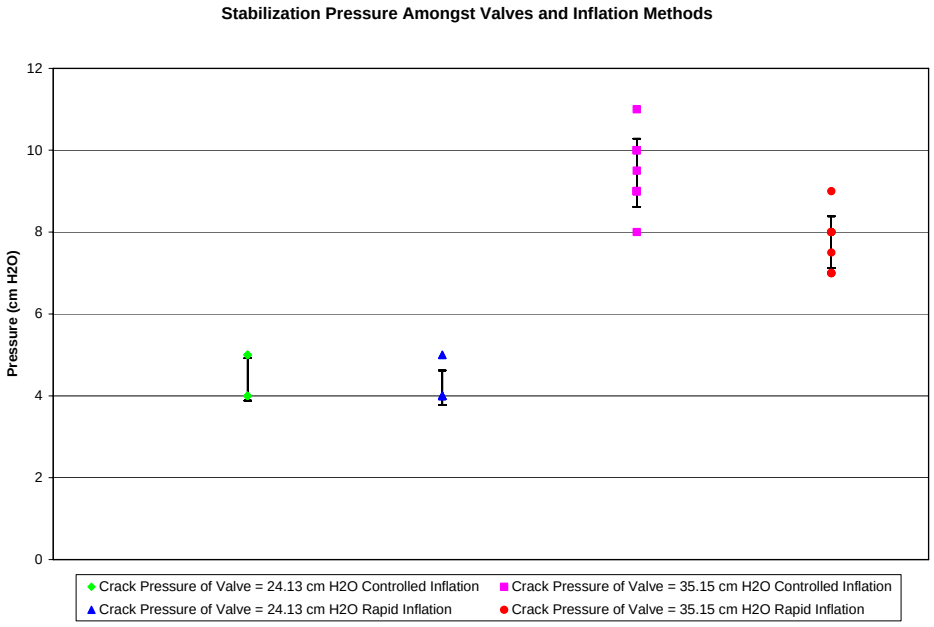


Figure 9. ***Graph summary of stabilization pressures***

Our data clearly shows that the valves stabilize reliably. However, the compilations of data show standard deviations greater than the stated tolerances for pressure within +/- 0.25 cm $H_2O$ of the safe intracuff pressure. The first set of data was compiled from tests performed on the prototype using the valve with a marketed crack pressure of 24.13 cm $H_2O$ during controlled inflation of the cuff. The average value for stabilization pressure was 4.4 +/- 0.52 cm $H_2O$ (Table 1, Appendix B). Table 1 (Appendix B) is a graphical representation of this data and clearly shows the consistency of the stabilization pressure. The second data set consists of test results using the same valve, but with rapid inflation of the cuff. The average value for stabilization pressure was 4.2 +/- 0.42 cm $H_2O$ (Table 2, Appendix B). Figure 2 (Appendix B) is a graphical representation of this data and depicts ideal consistency. Using controlled inflation of the cuff paired with the valve, marketed crack pressure of 35.15 centimeters of water, the third data set was collected. The average value for stabilization pressure for this data was 9.45 +/- 0.83 centimeters of water (Table 3, Appendix B). This data showed a slightly higher standard deviation, but overall the numbers were consistent as is shown in Figure 3 (Appendix B). The final data set came from using the same valve, but with a rapid inflation of the cuff. The average value for stabilization pressure for this data was 7.75 +/- 0.64. (Table 4, Appendix B) This data also had a slightly higher standard deviation, but was relatively consistent as presented in Figure 4 (Appendix B).

The use of the analog monometer produced relatively inaccurate test results because the monometer is not made for the type of tests that were conducted. With more accurate tools, the variance in the measured stabilization pressures would be reduced even further.

The standard deviations in each case, though not within the extreme safety factor range, are all less than one centimeter $H_2O$. This is an acceptable value, especially since the product is only in the early design stages. After analyzing test results, we are confident that using a valve made to our specifications future standard deviations will decrease and precision will increase significantly.

## Discussion

We tested steady-state pressure in each cuff after controlled and rapid inflation. We did so to see the reliability of our design to seal and hold a precise steady pressure, after its release from over inflation, under various conditions of inflation. Naturally, the extremes were tested.

As the results from our testing show (Appendix B), our design shows a consistent steady-state cuff pressure after release from over inflation. However, the pressure was far below our objective of 25 cm $H_2O$. With our first valve (marketed cracking pressure of 24.13 cm $H_2O$), we had mean steady-state pressure of 4.4 cm $H_2O$ during controlled inflation and 4.2 cm $H_2O$ during rapid inflation. With our second valve (marketed at 35.14 cm $H_2O$), we had steady-state pressures of 9.45 cm $H_2O$ and 7.75 cm $H_2O$ with controlled and rapid inflation respectively. While the steady-state pressures were far too low for compliance with our device, an important note is that, as shown by the results of our testing, the device works reliably in preventing over inflation and gives a steady pressure state after pressure release over various conditions.

For many of the valves we received from our manufacturers (SmartProducts, Inc. and Quosina Inc.), which were all marketed at about 25 cm $H_2O$ of cracking pressure,

almost all of them could not sustain a steady-state pressure of more than 4-5 cm $H_2O$. We believe the main reason for most of our valves failing is that their intended purpose was not to be used as release valves, rather check valves. Check valves are designed to keep flow going one way, preventing backwards flow, and also to prevent the system from draining when it is "off", meaning no pressure in the outflow direction. Thus, the marketed cracking pressures of each valve were not the calibrated release pressures we were looking for, making it hard to find the right valve. Ideally, what we needed was a release valve, which provides an auxiliary path, away from the main flow pathway, for a release in pressure. However, even though there are many release valve products on the market, almost all of them are made for large hydraulic or pneumatic equipment, making it extremely difficult to find a manufacturer that produces or is willing to produce such a small scale product.

Another difficulty we came across was that the valves we tested were designed and manufactured for liquids and not gases, which is what our designed product manages. We had troubles with the valves leaking because of an inadequate seal made by the O-ring interface. While the design of the valve allows for reliable functionality when dealing with liquids, the seal is not adequate in preventing the much smaller gas molecules from leaking through. Professor Tim Shedd, of the University of Wisconsin-Madison, advised us that a design such as one with a rubber ball plunger and a sharp metallic interface that "bites" into the rubber, making a more airtight seal would be ideal. (See Figure 10) An interface such as this could greatly increase reliability and closure time of the seal effectively maintaining pressure in the endotracheal tube cuff.

The difference between cracking and closing pressures makes closure time of the valve, after the release of pressure, important. With the dynamic flow of air rushing through the valve once the valve cracks, the valve will not be able to seal immediately after it is below the cracking pressure. Unfortunately, this results in the steady-state pressure of the cuff to be lower than the cracking pressure. Consequently, this requires an initial cracking pressure above 25 cm $H_2O$ in order to achieve a functional steady-state pressure (after the pressure from over inflation has been released) of 25 cm $H_2O$. With a faster closure time, we can decrease the amount of pressure we need to set the cracking pressure at. While the valves that were tested all had low standard deviations from each other when they reached a steady pressure, it was hard to see the difference in cracking and closing pressures due to the leaky nature of the valves. Further testing of this aspect will need to be done once suitable valves are acquired.

Unlike the pressure-limiting valve newly produced by Microcuff GmbH (Microcuff, Ltd.), our design has a y-connection design splitting the pathway of the release valve from the rest of the endotracheal tube inflation system. As we discovered with such a design, there is an important aspect of tubing diameter and pathways that need to be managed. In our first prototype, we noticed that most of the air being inflated into the cuff had quickly escaped out the release valve before even entering the cuff. We realized that the tubing for our exit pathway had a much larger diameter than our cuff pathway. Furthermore, our connections in the "Y" connector seemed to promote a path of least resistance towards the release valve. In our later prototype, we rearranged the connections in the connector and created an exit tube that was close to the same diameter as the tubing leading to the cuff and had a much more desirable inflation while still

effectively releasing pressure. Our goal, ideally, is to have the exit pathway having an equal or slightly higher pathway of resistance in order for the cuff to full inflate before cracking pressure is released.

## Future Work

The design and prototype created this semester serves as a proof of concept, however there is considerable room for future work to be done on the design. The work accomplished this semester effectively shows that a one-way check valve can be used as a pressure relief device to create a safe pediatric endotracheal tube with cuff.

The next step in the design process would be to improve the current design by manufacturing our own custom valve in the machine shop. One idea of how to do this is shown in Figure 10.

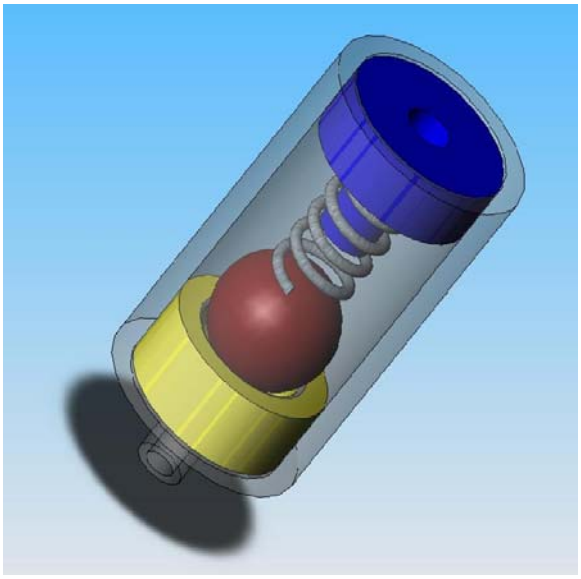

Figure 10. ***Alternative design possibility with an airtight seal using a ball mechanism [Created with SolidWorks].***

The valve would be constructed using a more compliant material to create an airtight seal. One option would be using a ball bearing opening, however unless manufactured on a precision machine, it would be very difficult to manufacture the ball

bearing to work properly and close while maintaining pressure. With compliance in mind, a natural rubber ball paired with a hard metallic surface would produce a conforming surface to close off the airflow.

Another aspect of the design to consider altering is the tube diameters. It would be ideal to increase the diameter of the tube that connects the pilot balloon and decrease the diameter of the tube attached to the check valve. This would ensure that the air follows one-way flow and begins in the cuff and exits through the check valve. While this design may sound simplistic, it would be a very trying experience.

Along with having a new prototype design new testing techniques must be developed. Professor Tim Shedd brought to the forefront that for ideal testing, we would require a very expensive actuator. While these can run up to three thousand dollars, it would be worth researching because it is so difficult to obtain good test result on such a small scale pressure and flow system. An inexpensive alternative that could work to produce better test results with sensitive pressure and flow monitors, would be utilizing LabView.

The ultimate goal would be to have this mass produced by a manufacturer to our specifications. Aside from attempting to prototype this new design, finding a manufacturer would prove to be a challenge in itself. The ability to manufacture a mass quantity of endotracheal tubes and the check valves to our specifications would be ideal. The straightforward design would help make the custom request affordable for consumers and professionals. Associated with mass production, each valve would have to be specially calibrated before going out to medical professionals.

Looking ahead to manufacturing and marketing ideas, there are two possibilities for

affordability and use. One obvious possibility would be to make each endotracheal tube with the pressure relief valve separately and completely disposable and effectively make it one time use only. Another option would be to sell "naked endotracheal tubes" that include the clamp, the extra tubing, and the pilot balloon all attached to the cuffed endotracheal tube. These "naked tubes" would be disposable and used only once, but the check valve would be sold separately and calibrated for each use. Ideally this valve would have an additional mechanism to calibrate after each autoclave cleaning. Of course along with this second option comes much more research with a special focus on medical standards for repeat use devices.

## Conclusion

It is clear from the earlier discussion that the device created has great potential to function as a successful pediatric, cuffed endotracheal tube. While we encountered several problems, from valves to developing testing techniques, this is simply the process of engineering. With timelines and budget constraints weighing heavily on this project, we have gained valuable knowledge and improved both technical and interpersonal skills. Ideally we would like to refine, rebuild, and completely finish this design to the point where it can be proposed to a manufacturing company. We would love to gain rights to the intellectual property that we have created and are planning to disclose for a patent. Dr. Lester Proctor, our client, has been very cooperative throughout the semester in terms of providing equipment and constructive input to our ideas. If we were to have the opportunity to work on this project again, we would begin immediately building a new prototype from the ground up, finding custom manufactures, and pursuing a patent.

It is our belief, that while there have been some setbacks, pursuing this further and perfecting the accuracy and precision on endotracheal tubes would benefit millions of patients.

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*Special thanks to:*
*Professor Tim Shedd, Mechanical Engineering, University of Wisconsin-Madison*

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# Appendix A

**Product Design Specification**

**Client Requirements:**

- Cuff cannot fail before reaching 25 cm $H_2O$ pressure.
- Cuff must fail after 25 cm $H_2O$ pressure**.**
- Cuff failure can be bypassed to accommodate unforeseen situations.

**Design Requirements**

1. **Physical and Operational Characteristics**
    a. *Performance requirements*: Must perform at level consistent of existing endotracheal tubes (i.e. intubation for surgery, through recovery).
    b. *Safety*: Must be FDA approved for humans. No need to be autoclavable.
    c. *Accuracy and Reliability*: Must fail at 25 cm $H_2O$ +/- .25 cm $H_2O$
    d. *Life in Service*: Must last for duration of patient intubation, whether short term or long. Will be disposed of when no longer in use.
    e. *Shelf Life*: Should be able to be stored in optimal conditions for 1 year.
    f. *Operating Environment*: During use, the cuff valve will be used in both E.R. and O.R. settings. During storage, it will be held on a shelf with little outside exposure.
    g. *Materials*: Should not increase MRI visibility of endotracheal tube.
    h. *Aesthetics, Appearance, and Finish*: Should be clean, with white finish for high visibility.
2. **Production Characteristics**
    a. *Quantity*: Working prototype
    b. *Target Product Cost*: < $10
3. **Miscellaneous**
    a. *Standards and Specifications*: FDA approval for use in human pediatrics.
    b. *Customer*: Customer already has means to inflate cuff. Must have means to bypass valve.

*Competition*: Lanz® brand endotracheal tubes (30 cm $H_2O$)

## Appendix B: Test Results

**Marketed Crack Pressure of Valve = 24.13 cm H2O**

- CONTROLLED INFLATION

Table 1

| Trial | Measured crack Pressure (cm H2O) |
|---|---|
| 1 | 4 |
| 2 | 4 |
| 3 | 5 |
| 4 | 5 |
| 5 | 4 |
| 6 | 5 |
| 7 | 4 |
| 8 | 5 |
| 9 | 4 |
| 10 | 4 |
| Average | 4.4 +/- 0.516397779 |

- RAPID INFLATION

Table 2

| Trial | Measured crack Pressure (cm H2O) |
|---|---|
| 1 | 10 |
| 2 | 9 |
| 3 | 9 |
| 4 | 8 |
| 5 | 11 |
| 6 | 9 |
| 7 | 9.5 |
| 8 | 10 |
| 9 | 9 |
| 10 | 10 |
| Average | 9.45 +/- 0.831664997 |

**Marketed Crack Pressure of Valve = 35.15 cm H2O**

- CONTROLLED INFLATION

Table 3

| Trial | Measured crack Pressure (cm H2O) |
|---|---|
| 1 | 4 |
| 2 | 4 |
| 3 | 4 |
| 4 | 4 |
| 5 | 4 |
| 6 | 4 |
| 7 | 4 |
| 8 | 4 |
| 9 | 5 |
| 10 | 5 |
| Average | 4.2 +/- 0.421637021 |

- RAPID INFLATION

Table 4

| Trial | Measured crack Pressure (cm H2O) |
|---|---|
| 1 | 8 |
| 2 | 8 |
| 3 | 9 |
| 4 | 8 |
| 5 | 7.5 |
| 6 | 8 |
| 7 | 7 |
| 8 | 7 |
| 9 | 7 |
| 10 | 8 |
| Average | 7.75 +/- 0.634647759 |

**Figure 1**

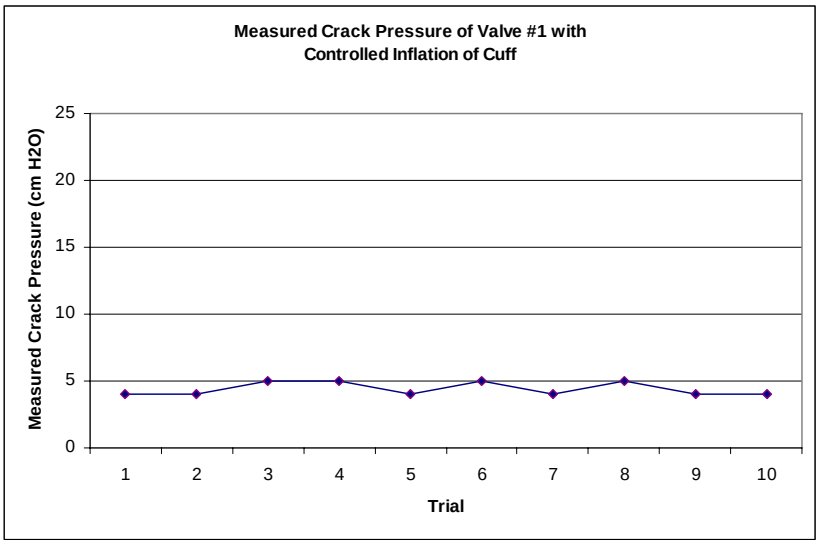
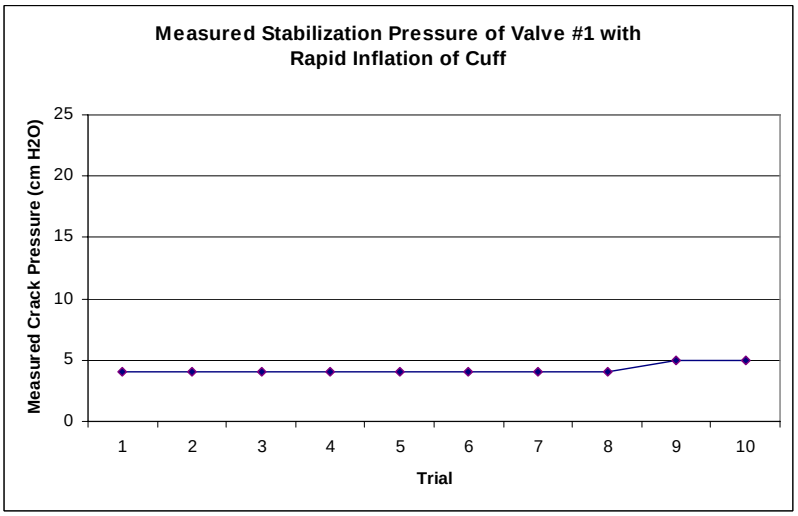
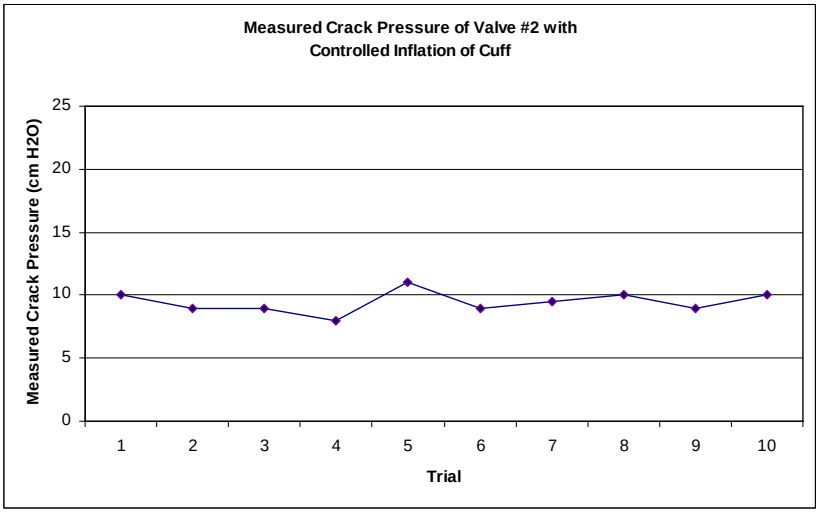



**Figure 2**



## Figure 3




## Figure 4