Endotracheal Tube Pressure Monitor

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Abstract

The goal of this project is to design an external pressure monitor for inflation of the cuff on endotracheal tubes. This device would reduce the risk of over inflation of the cuff which can lead to tracheal damage. The chosen design incorporates a moving diaphragm that compresses an indication disk up a plastic cylinder with pressure markings. Testing was conducted to calibrate the device and to assure material integrity. Future work for this device includes researching the use of a bellows instead of using the rolling diaphragm and spring system, and pursuing a patent.

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Problem Statement

Dr. Lester Proctor, a professor of anesthesiology and pediatrics for the UW medical school, has expressed the need for a pressure indicator which would be used for endotracheal tubes. Over-inflation of the cuff on an endotracheal tube can cause tracheal damage, especially in children. Dr. Proctor is looking for a qualitative indicator which would be attached to the endotracheal tube and give a consistent reading of the pressure in the inflated cuff.

Design Motivation

Most patients who undergo invasive surgery are anesthetized and intubated with an endotracheal tube. This allows medical professionals to regulate the patient's breathing and administer anesthetic gases while in the operating room. Endotracheal tubes, or ET tubes, provide a direct, stable airway to a patient's lungs. Today, a wide variety of ET tubes are used in hospitals and by emergency response teams. Most adult-sized ET tubes, and many used in pediatrics, have a small, inflatable balloon called a cuff located at the distal end. The cuff creates a tight seal between the ET tube and trachea that secures the tube in place during intubation. A significant problem occurs if the pressure of the cuff is too great, causing lesions on the trachea, which can lead to severe complications during and well after the surgery. No convenient means of measuring the inflated cuff pressure exists. The client, Dr. Proctor, has given the task of designing a method to quickly, easily, and consistently monitor the inflated cuff pressure of an ET tube. If successful, this device can be used in all settings where a person is intubated, and would minimize the chance of human error in over-inflation of the tube that would cause damage to the trachea.

Background Information and Current Competition

Dr. Proctor, an anesthesiologist at UW-Hospital, performs multiple adult intubations daily with cuffed endotracheal tubes. Endotracheal intubation is required for most invasive surgeries. In this process, a plastic endotracheal tube is inserted into the patient's trachea, past the larynx (Figure 1), where it will provide oxygen and other 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.

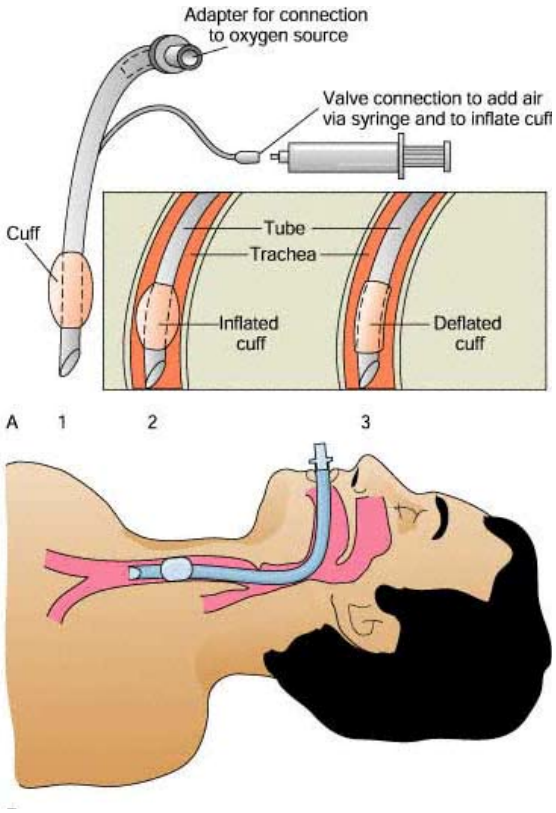

Figure 1 Intubated Patient [Source: http://connection.lww.com/]

Proper inflation of the cuff is vital for three reasons. First, it anchors the endotracheal tube in the trachea, reducing the likelihood of the tube becoming dislodged. Second, the cuff creates an airtight seal between the respiratory machine and the lungs, allowing for more accurate delivery of oxygen at lower pressures, and preventing pollution of the air in the operating room from medical gasses. Finally, the cuff prevents patient aspiration using the airtight seal against the inner tracheal walls. 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, like 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.

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. In general, the cuff inflates properly for adults, but physicians often over-inflate the cuff during pediatric intubation using endotracheal tubes with smaller diameters. In results from one study, high cuff pressure (> 40 cmH_2O) was observed in 90.6% patients from the PACU after anesthesia with nitrous oxide, 54.8% of patients from the ICU, and 45.4% of patients from the PACU after anesthesia without nitrous oxide (Braz *et al.*, 1999). Gauging pressure is also a problem. In another study, physicians detected over inflated ET tube cuffs with only 22% sensitivity (Hoffman *et al*., 2006). Over inflation of the cuff past the maximum pressure of 25 centimeters H2O is associated with several risks, including lesions, tracheal rupturing, and ischemia in the trachea walls. Ischemia is a shortage of blood supply to an organ or tissue, 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 often use the uncuffed endotracheal tube. Dr. Proctor desires a reliable pressure monitor to assure safe air pressure levels within the cuff so patients' tracheae are not damaged during intubation, and also so cuffed tubes can be used in the smaller trachea of children.

Multiple products to monitor pressure exist, but nothing suitable for our client's function. Currently, there is one endotracheal tube cuff pressure monitoring system on the market that stands out from the rest. This is the Hi-Lo® Tracheal Tube With Lanz® Pressure Regulating Valve. However, it is currently available for larger tube diameters and adult-use only.

Several patents with ideas for intracuff pressure-regulating systems exist (Appendix A), although none have been seriously marketed. Most of the patented ideas consist of designs that include too large, impractical, computerized, or non-disposable components. The goal of this semester's project is to design a working prototype that is small, consistent, and easy to use.

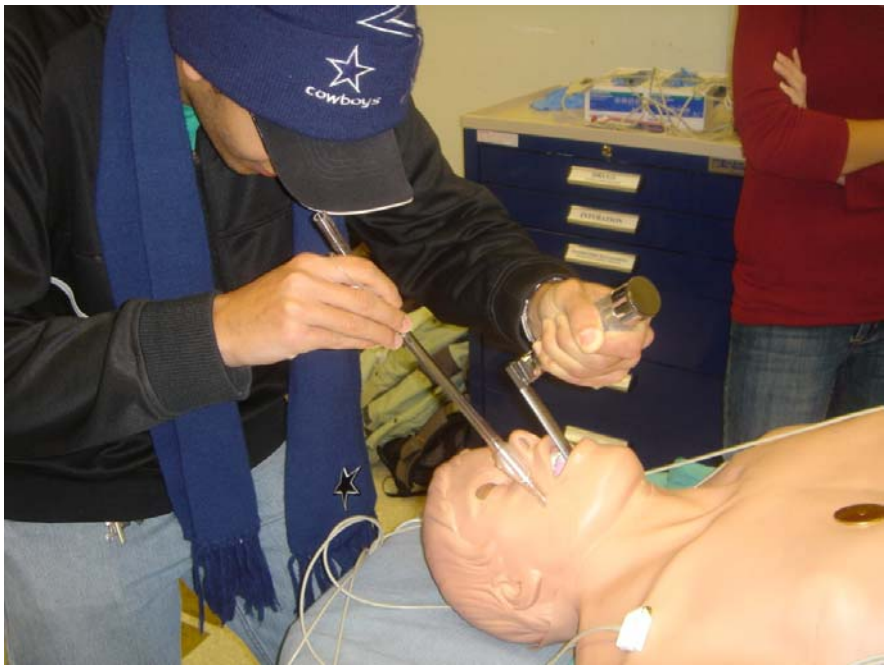

Figure 2
The intubation process: A laryngoscope is used to open the pathway to the trachea for the tube to be inserted.

Client Requirements

Dr. Proctor has several design requirements for the project. What he considers most important is that the device consistently measures the intracuff pressure. He does not mandate that the device be precisely accurate (an error of +/- 2 cm H2O is reasonable), but that it consistently delivers the same respective qualitative marker for each trial. He also wants the device to be permanently attached to the ET tube. The doctor performing the intubation should only have to worry about the ET tube and not any other miscellaneous parts that he would have to attach. Also, many surgeries are performed on adults and children of all different sizes. This pressure monitor should be versatile enough to function on any type or size diameter of ET tube.

With those requirements in mind, the device must also be as small as possible (ideally less than an inch in length), disposable with the ET tube, and have a low manufacturing cost. Lastly, the device needs to be FDA approved for human use, not jeopardizing the safety of the patient whatsoever. For a more complete list of design requirements, see attached Product Design Specifications in Appendix B.

Ethics and Safety

As with any device that enters a patient's body, certain safety standards must be met, and this is a significant factor in the design selection process. The indicator doesn't physically enter inside the patient, merely being attached to the ET tube via the pilot tube, but sterility of the device for the patient and medical staff is required since it will be in direct human contact in operating rooms during use.

The only restriction is it must be composed of non-latex materials. Assuring accurate and consistent readings of intracuff pressure to protect the patient's trachea is vital. "Any pressure above 25 centimeters H20 runs the risk of damaging and scarring the trachea," (Proctor). Therefore the device must warn against the maximum allowable intracuff pressure of 25cm H20 and be effective and accurate at all levels below this.

Food and Drug Administration (FDA) approval is required for any device before it can be released to the market and used in hospitals. This device needs to meet class two requirements to ensure that it is safe for human use. Another concern is the device's compatibility with magnetic resonance imaging (MRI) and computed tomography (CT) machines. The client expressed that although compatibility isn't necessary, it would be required down the line, so material selection is essential. This eliminates the use of ferrous materials in the device. The monitor isn't located directly inside the patient, but its close proximity could cause interference

with these machines, leading to an incorrect diagnosis or other negative effects. The client expressed that the use of non-ferrous metals is not a problem, as there already is a stainless steel spring in the ET tube syringe injection port. The final safety concern involves the ability of the person inflating the cuff to attain a correct reading from the indicator and be able to override any control it may have on air pressure. The main goal of the project is to ensure patient safety, but some of the risk is at the discretion of the physician controlling air flow into the cuff.

Mechanical Spring Design

The Spring-Fall 2006 design teams created a mechanical spring pressure indicator (Figure 3) and constructed a successful prototype, but it was too large for our client. It consisted of a hollow cylinder with a small inlet where the ET tube pilot tube connects. "It is essentially a small-scale pressure gauge 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," (Endotracheal 11). As air from the cuff enters the cylinder, its force suppresses the piston against a spring with calculated resistance to the force of the air pressure. As the pressure increases, the piston increasingly recedes into the cylinder (the direction opposite incoming air supply), and the indicating stem would proportionately emerge from the top of the tube. The length qualitatively indicates to the medical staff administering the air, the corresponding intracuff pressure levels. The stem will be equipped with a color-coded pressure scale printed on its outside. An airtight cap is sealed in place. The monitor is connected

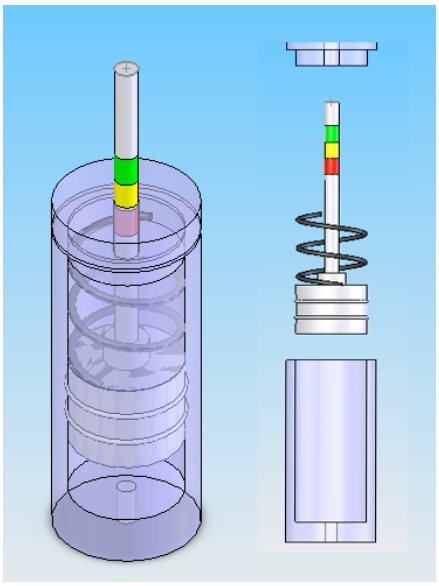

Figure 3 Mechanical Spring Design (Endotracheal 17)

to the syringe air input valve via a T-valve that splits air either way and interfaces directly with the pilot tube from the ET tube.

Advantages and Disadvantages

The client was favorable towards this prototype, but requires its size reduced to not pose a distraction during medical procedures. Also the materials used were heavy, difficult to fashion, and created excessive friction between the tube and the plunger. Testing and calibrating the device was also a challenge. Also the indicator peg may be susceptible to breaking, poses safety issues, and presents unnecessary length to the device. Finding a non-ferrous spring isn't difficult, but obtaining one that is non-metallic to comply with MRI standards presents a challenge in keeping with a decent range in elasticity values to deflect a noticeable amount and provide adequate resistance due to the minute cuff air pressures. The device is cost-effective because it is made mostly of plastic, so in mass-production its unit price should fall within the ideal range. The device is also versatile, indicating pressures through a qualitative range of values, allowing physicians to use different pressures for various situations at their discretion. This permits them to control the device to compensate for factors such as the size, gender, and age of the patient.

Revised Mechanical Spring Design

The concept is similar to the previous semester's design project but with a few notable changes. The spring is beneficial and would be a good design to pursue, but a different material would be used that is less friction producing and is easier to machine. The design would still utilize the T-valve, but the indicator would be more directly connected to it, rather than at the end of a long tube. This design will consist of a partially clear tube made of material similar to polypropylene in a syringe, and the indicating stem removed (Figure 4). Indicating ranges will be printed on the side, so the medical staff can monitor the pressure by directly viewing the plunger

moving the spring within the ranges. The spring will be positioned at the top of the cylinder to provide the resistance. Possible complications for colorblind individuals are taken care of if the ranges are segmented enough; a distinction will be able to be made.

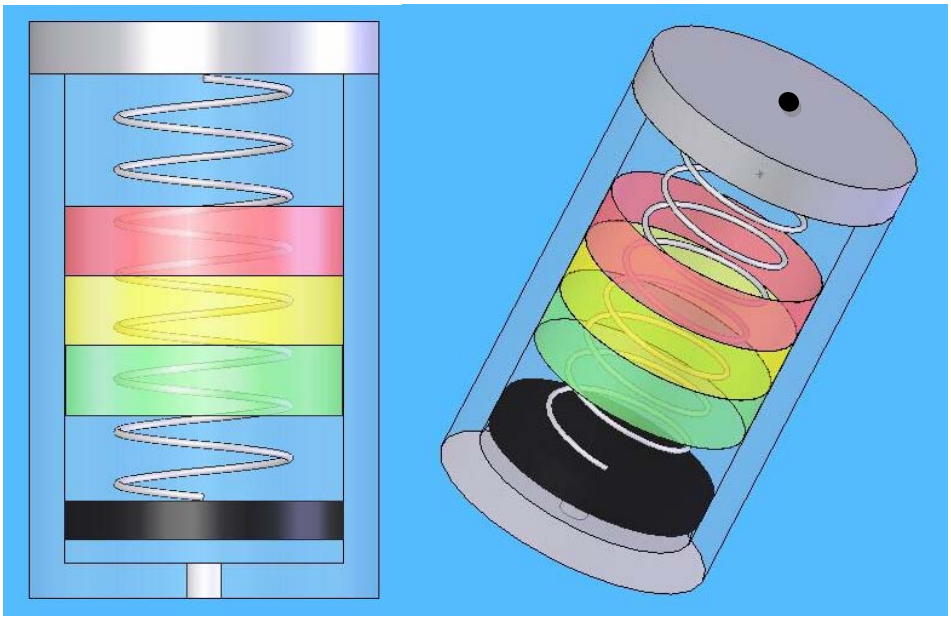

Figure 4 Revised Mechanical Spring Schematic

Advantages and Disadvantages

Keeping the indication ranges on the cylinder decreases size and increases practicality of the device. Having a clear cylinder will aid the medical staff in seeing what is happening in a possibly chaotic situation. It will be comfortable to work, but the concerns about the spring still apply. It will allow the medical staff to watch the indicator and have a free hand in contrast to feeling the pilot balloon on the current ET tube. The device is also MRI and CT compatible. The biggest challenge presented seems to be eliminating friction as the plunger slides, so a true pressure reading can be obtained.

Inflatable Balloon Design

One design alternative involves somewhat of an external mirror image of the inflated cuff. A T-valve allows an additional, external air supply tube to feed into the cuff pressure monitor. The main body of the device is a small, clear cylinder. Enclosed inside it is a balloon similar to the cuff that is inflated from the pressure given by the air supply tube. Markings are placed on the cylinder indicating ranges of air pressure. As the balloon is inflated, it rises inside the cylinder, and the pressure range can be easily read. Expelling air from the system deflates the balloon back to its un-stretched length.

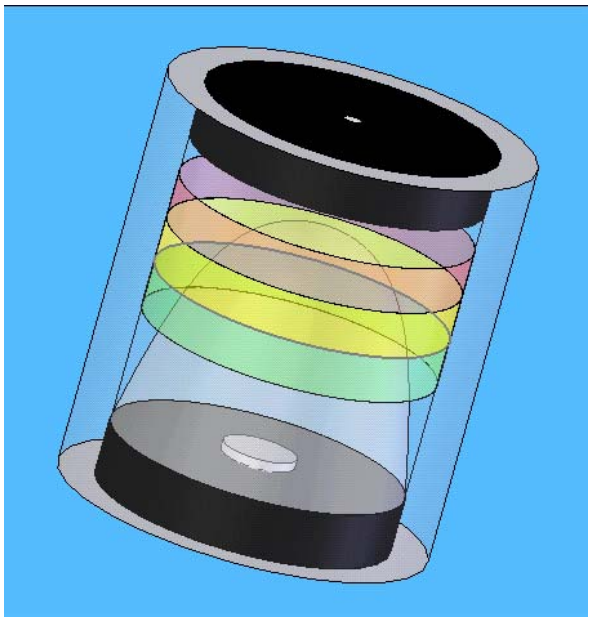

Figure 5 Design of Inflatable Balloon

Advantages and Disadvantages

This design offers a simple means of reading the air pressure, and is also compact, with no parts protruding from the cylinder. Also, air leaks do not need to be considered if the balloon is correctly attached to the air supply tube. However, manufacturing a small device like this could prove to be quite difficult. The small balloon also presents some problems. It must be made of a material that does not deform when inflated, so that similar air pressure will create

identical inflation in successive uses. Also, the cylinder's markings must be calibrated precisely according to the balloon inside.

Electronic Design

One design alternative we have considered is using an electrical approach to relay the endotracheal cuff pressure to the doctor. This would be done using a pressure transducer. A pressure transducer transforms the pressure measured into an analog electrical signal (Omega Engineering 2007). Inside the pressure transducer is a Wheatstone bridge containing strain gauges. At different forces, the strain gauges, attached to a silicone diaphragm, deform a certain amount, and that amount corresponds to a change in resistance. The Wheatstone bridge is present to minimize changes in resistance due to other natural elements, such as temperature. This change in resistance of the strain gauges will alter either the output voltage or current, depending on the type of pressure transducer. This voltage can be fed into a series of operational amplifiers used as comparators. The comparators will compare the input voltage to reference voltages that we define. Depending if the input voltage is greater or lesser than the reference voltage, a positive or negative output voltage will be the result. This voltage can be used to light up an assortment of light emitting diodes (LEDS) or perhaps lead to a readout on an liquid crystal display (LCD), which will indicate to the physician what the cuff pressure is. This device would be very similar to catheters that measure cardiac pressure and flow measurement (Webster 2004).

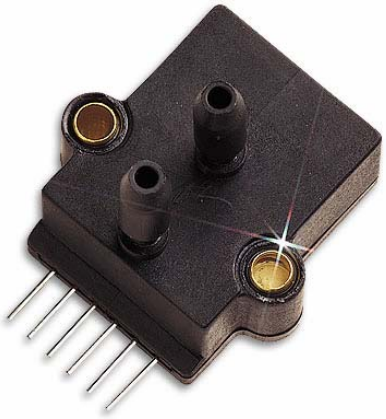

Figure 6 Omega PX137-001DV Low Cost Silicon Pressure Sensor with Millivolt Output

Advantages and Disadvantages

There are several advantages to this design. The main advantage is that this device will be very accurate. The entire setup relies on the accuracy of the pressure transducer and the error values associated with the circuit resistors connected to the operational amplifiers. Another advantage is that the device would be easily readable by anyone in the room. Unfortunately, the disadvantages of this design severely outweigh the advantages. Most of the design goes against the client's requirements. This device will be very expensive, as the pressure transducer alone costs upwards of $60.00. Due to this, the device will very likely not be disposable, and each endotracheal tube will not have its own monitor, which means the device will have to be constantly reconnected and disconnected from the endotracheal tube. And while smaller components could be used in the future, the prototype will be rather large and cumbersome for any doctor to use.

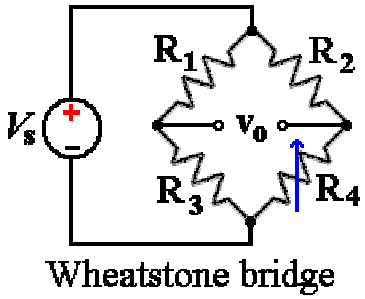

Figure 7 Wheatstone Bridge

Color Changing Plastic Design

The last design option would be to use a stretchable, color changing plastic to indicate the pressure in the ET tube's cuff. There has been new research done at the University of South Hampton and the Deutsches Kunststoff-Institut which utilizes polymer opal films and their photonic crystals to create a stretchable material which changes colors when distorted. When the material is stretched it changes the color by increasing the space between the components of the lattice structure of the polymer. This technology could be adapted into a design for a pressure indicator. The material could be used to fabricate a small balloon, similar to that of the pilot balloon. This balloon would be attached to the line leading from the syringe to the ET tube and

as air was injected into the cuff the balloon would also inflate. From the nature of the material, the color would gradually change as the balloon were inflated more and this color change could be used to indicate the pressure in the cuff. The plastic could also be used as a cover or balloon inside of a cylinder depending on design needs.

Advantages and Disadvantages

While this design would utilize the most recent technology, it does not necessarily fit the needs of this client. A major problem would be that this plastic is not currently available commercially, making it extremely difficult to obtain for use in this project. Also, there would be issues with the durability of the material and its ability to shrink back to its original shape and color if air were to be removed.

Design Matrix

Table 1 Design Matrix

Category	Weight of Category	Electronic	Mechanical Spring	Balloon	Revised Spring	Color Changing Plastic
Safety	5	5	3	5	5	4
Ease of Use	15	11	13	14	14	15
Client Preference	10	3	8	6	8	5
Effectiveness	15	13	13	13	13	14
Price	20	5	15	16	15	8
Size	20	6	15	16	17	15
Durability/Repeatability	10	10	10	7	10	1
Ease of Manufacturing	5	1	3	4	3	3
Total	100	54	80	81	85	65

To evaluate the five given designs, a design matrix, as seen in Table 1, was constructed. Eight categories, as shown above, were deemed important in comparing and ranking each design. Price and size were given the most weight, as the client expressed these as integral to the device. Safety was considered to be absolutely necessary across the board and was given a low weight

comparatively since all five designs require it. The Electronic device was ruled out because of high price and level of manufacture beyond the group's ability. The Color Changing Plastic device will not be pursued due to low scoring notably in the durability/repeatability and client preference categories and it is not yet available on the market. The Mechanical Spring design scored highly but the indicating peg was decidedly too unsafe. The Balloon and Revised Spring devices scored closely highly in most categories, so the assets of each were combined to create the final design.

Final Design

After much discussion and consideration the chosen final design incorporates a combination of the top features of the modified mechanical spring and balloon designs. The previous team's basic spring idea is efficient and cost-effective but must be a scaled down to a proper size and have improvements made on it. A rolling diaphragm incorporated into the spring design addresses some of the problems that the previous team encountered. It acts like a balloon and is attached directly to the valve and lead tube, which will prevent air leaks. This design also eliminates the indicating stem, with the pressure ranges displayed directly on the clear cylinder. The green band indicates 10-15 cmH_2O, yellow is 15-25 cmH_20, and red is over 25 cmH_2O.

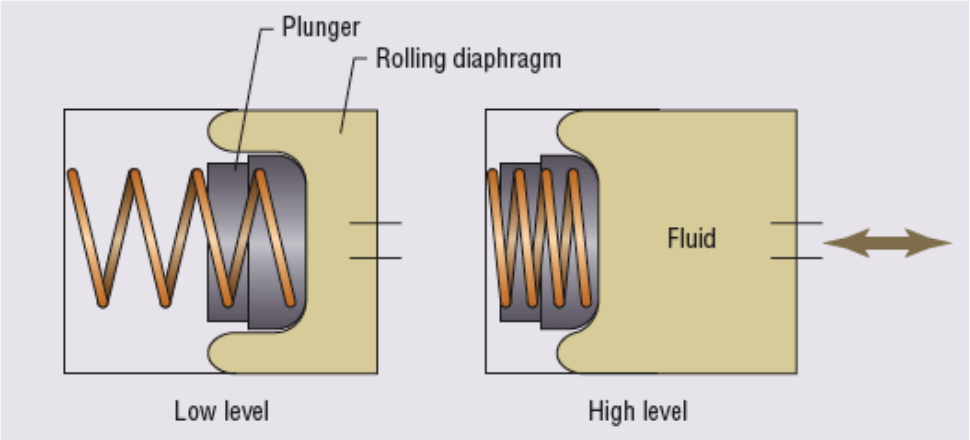

Figure 8 Rolling Diaphragm

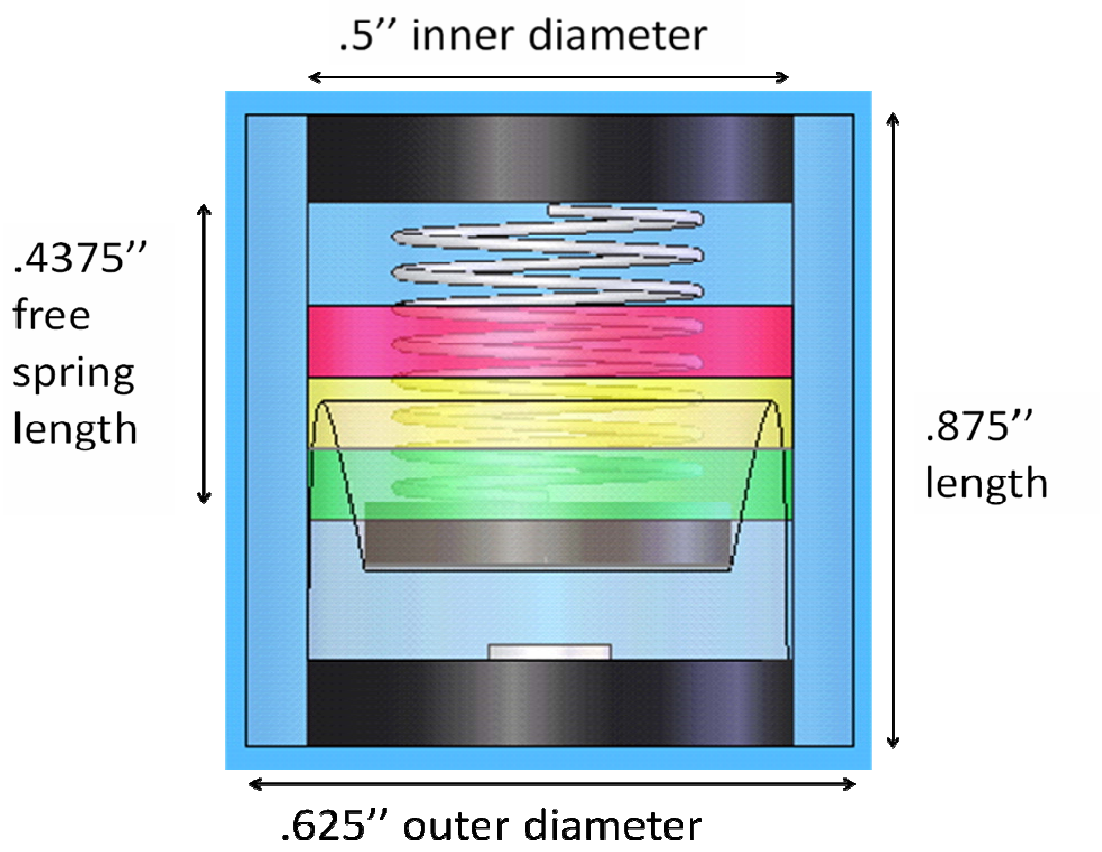

Figure 9 Revised mechanical spring design incorporated with the inflatable balloon design.

Construction

Parts were acquired from Home Depot, McMaster-Carr, Dorn Hardware, EMS Industrial, Qosina, Halkey-Roberts, Online Labels.com, and the University Hospital. The clear PETG tube used for the primary cylinder was cut in the Engineering Centers Building Machine Shop to a length of 1 inch, and all other parts were fashioned by the team. The only adhesive used on the device is glue holding together the top rubber stopper and spring, all other parts can be completely hand assembled. Difficulties included the small size of the device being hard to work with, obtaining a spring with a small enough spring constant, and finding proper material for the diaphragm. Spring constants were calculated with a simple scale and weights. The final spring is stainless steel with a constant of 0.3 (**See Appendix E)**. The material used on ET tube cuffs was

found to be primarily PVC. Based on the success of PVC in this application, the diaphragm material chosen is composed of thin vinyl from common work gloves. The plugs at both ends of the cylinder are composed of black polyurethane rod that has the same diameter as the inner diameter of the cylinder (.5 inch) which assures an airtight system. The indicating disk is composed of the same material as the plugs, with a smaller diameter (.375 inch). The device is attached directly to a T-valve that combines a syringe injection port and the ET tube pilot balloon port. The indicating lines on the outside of the cylinder are clear plastic labels that are colored on an inkjet printer. The final device's dimensions are 1 inch long, 5/8 diameter, and it attaches directly to the ET tube in an unobtrusive fashion resembling the client's requirements. The budget was maintained, as costs totaled $78.08, and the final cost per unit, as calculated from bulk prices is $0.70.

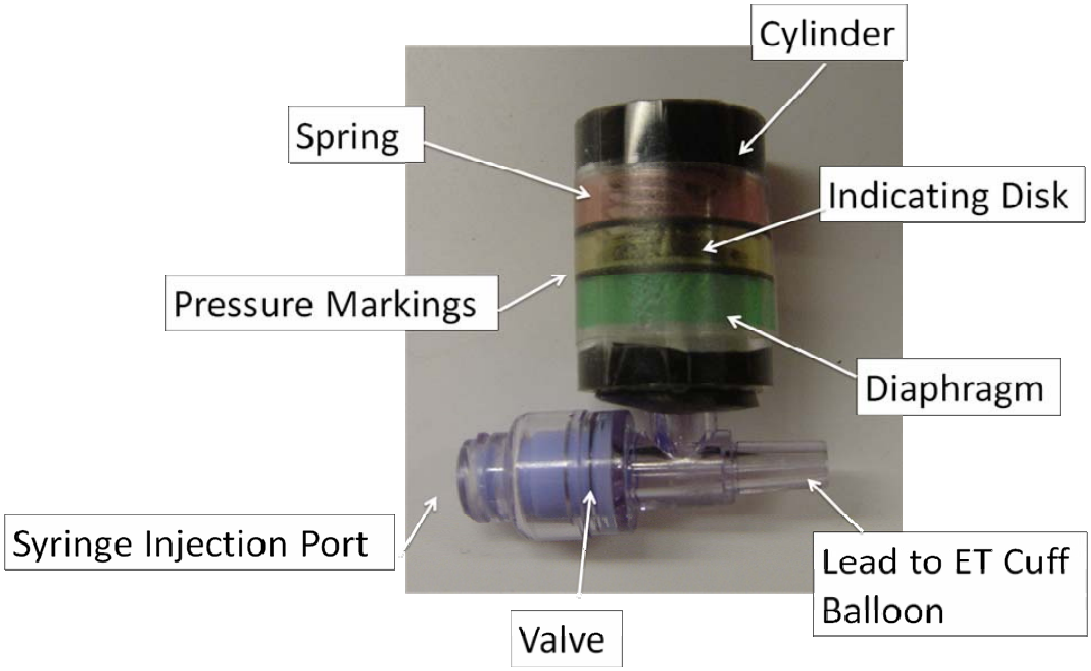

Figure 10 Image of device with mentioned parts

Testing

Multiple tests were performed to assure the integrity of the materials used in the device and that it is safe for its prescribed purpose. In order to calibrate the device, an extra valve was added between the device and the ET tube so that the manometer could be connected to the system to measure the pressure. A recorded number of cubic centimeters (cc), or milliliters, of air was injected into the system, causing an inflation of the diaphragm, pushing the indicating disk up the cylinder. The displacement of the indicator up the cylinder was measured with a ruler. The pressure in the system was also recorded. This process was repeated for ET tubes with 4.0, 5.0, 7.0, 7.5, and 8.5cm diameters to ensure the device's versatility with all size cuffs. This produced a linear calibration curve shown below in Figure 11. The range increments calculated were 3/32" that will correspond to the green, yellow, and red partitions on the cylinder. The standard error from this calibration is +/- 0.02078 in.

The first test on the actual device was to ensure material integrity. The client expressed the desire of the device to withstand a sterilization process that includes temperatures up to 180 degrees Fahrenheit. To meet and exceed this temperature, the device was submerged in boiling water for up to six minutes in 3 separate tests. No deformations were observed. The next test was a stress test. A five pound weight was dropped on the device axially from differing heights of 3' and 4.5'. These 22 Newton and greater forces would exceed any normal situation the device would experience in a hospital setting. The monitor did not deform after the 3' drop, but one end of the device bent down approximately 1/16" after the 4.5' drop. The device was also thrown against a concrete wall with a force of approximately 1.3 Newtons. The force here was so low because the device weighs only 5.88g. No deformation occurred. The next test was to ensure the device was air tight. It was submerged in a tank of water for 45 minutes to see if any air bubbles

escaped. No bubbles were observed, so no leaks were present. In addition, the visibility of the colored ranges were also tested and found that the indicator could be clearly seen in the green and red increments from about 7' away, and the yellow region about 9' away. This is much farther than the physician who is inputting the air and using the device will be positioned. Finally, the consistency of the device was tested. Air was inputted into the device and inflated the ET cuff to the red range. The syringe was removed and the manometer was inserted to measure the pressure to assure the colors were accurately reading the internal pressure. A +/- 1cmH_20 average was recorded around each separating line, within the required +/-2cmH_20 cushion.

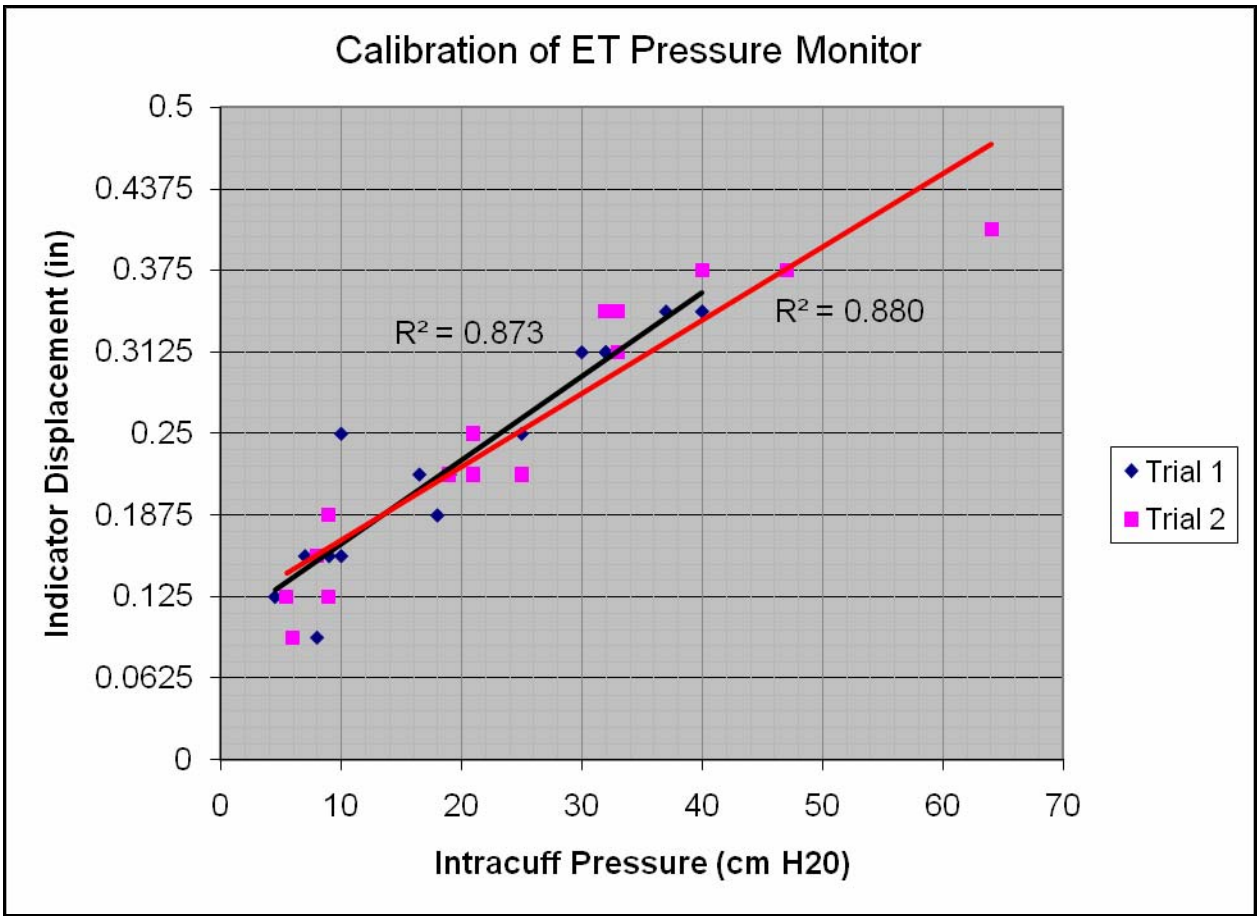

Figure 11 Graph of Calibration of ET pressure monitor

Future Work

For manufacturing purposes, the device could be scaled down even smaller with machine assembly. Custom materials for each of our parts would help perfect the mechanics of the device. These materials include a smaller diameter spring with a more precise spring constant and using a rolling diaphragm with a specific manufactured shape. Currently, a finger of a vinyl glove is being used, which in an accurate, but not exact shape of the cylinder. Also, a small amount of glue was used to attach the spring to the top black polyurethane cap. This was to lessen movement of the spring and maintain device rigidity. If parts with more precise dimensions are used, there would be no need for glue because all the parts would fit together perfectly. This would aid the manufacturing process in reducing time, cost, and materials needed for production. Finally, taking our device into a different direction, implementing a bellows (Figure 12) instead of the diaphragm and spring system would make the device smaller and accurately indicate the pressure in the system when inflated. Material of the bellows would have to be investigated.

Figure 12 Tiny bellows: http://www.dsrubber.com/products_page_2.htm

Dr. Proctor also wishes for a patent to be pursued on the device and presented to Kimberly Clark.

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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 Specifications

Endotracheal Tube Pressure Monitor
Client: Dr. Lester Proctor
Advisor: Dr. Paul Thompson

Team Members
Val Maharaj (Leader)
Colleen Farrell (Communicator)
Andrew Bremer (BWIG)
Deborah Yagow (BSAC)

Function:
The purpose of this project is to construct a pressure monitor that will be permanently attached to the endotracheal tube. This indicator will let the doctor know, qualitatively, the pressure level inside the cuff on the end of endotracheal tube that is inflated inside the patient's trachea.

Client requirements:

- **Monitor the cuff valve pressure consistently using qualitative markers**
- **Device is as small as possible (pencil eraser size)**
- **Permanently attached to the endotracheal tube**
- **Versatile enough to function on any type/size ETT**
- **Low manufacturing cost**
- **Disposable**

Design requirements:
1. Physical and Operational Characteristics
a. *Performance requirements*: Pressure monitor must perform at a level equivalent to competing devices.

b. *Safety*: Must be FDA approved for humans. Device cannot be made out of any latex material due to allergies.

c. *Accuracy and Reliability*: Must be very consistent, qualitatively. Accurately measure three pressure ranges (10-15 cm H2O, 15-25 cm H2O, and above 25 cm H2O). Can be +/- 2 cm H2O away from actual pressure.

d. *Life in Service*: Must last for duration of patient intubation, (short or long term). Disposable.

e. *Shelf Life*: Device should last as long as the endotracheal tube. Because both the endotracheal tube and the pressure monitor will be sealed in a sterilized package, package can last one year.

f. *Operating Environment*: Even though the product will be made as a disposable, it should be able to withstand the temperature (180°F) and chemicals used (ethylene oxide) during sterilization. Product can otherwise be used in any hospital setting.

g. *Ergonomics*: Easy to use and read, and must not get in the way of patient or any hospital staff

h. *Size*: Ideally, as small as possible. Target size: 1 inch length, 0.5 inch diameter.

j. *Materials*: Cannot be made out of latex due to allergies. It would also be preferred if none of the parts were made out of ferrous material, since iron can distort MRI scan data. Also, because this will be a disposable product, productions materials must not leave bad footprint on environment.

k. *Aesthetics*, *Appearance, and Finish*: Smooth, clean appearance. Device should be easily readable by anyone.

2. Production Characteristics
a. *Quantity*: one working prototype.

b. *Target Product Cost*: during mass production, less than $0.50.

3. Miscellaneous
a. *Standards and Specifications*: FDA approval required for commercial product.

c. *Patient-related concerns*: No need for product sterilization because it is disposable. However, should the need arise; the product will be able to withstand the sterilization process.

d. Competition:

Rusch Inc Monitor Cuff Endotest Rusch.

Cufflator Endotracheal Tube Cuff Pressure Monitor by Posey.

Brandt TM tracheal tube.

Hi-Lo® Tracheal Tube with Lanz® Pressure Regulating Valve

Mallinckrodt Endotrol® Tracheal Tube with Controllable Tip

Appendix C: Budget

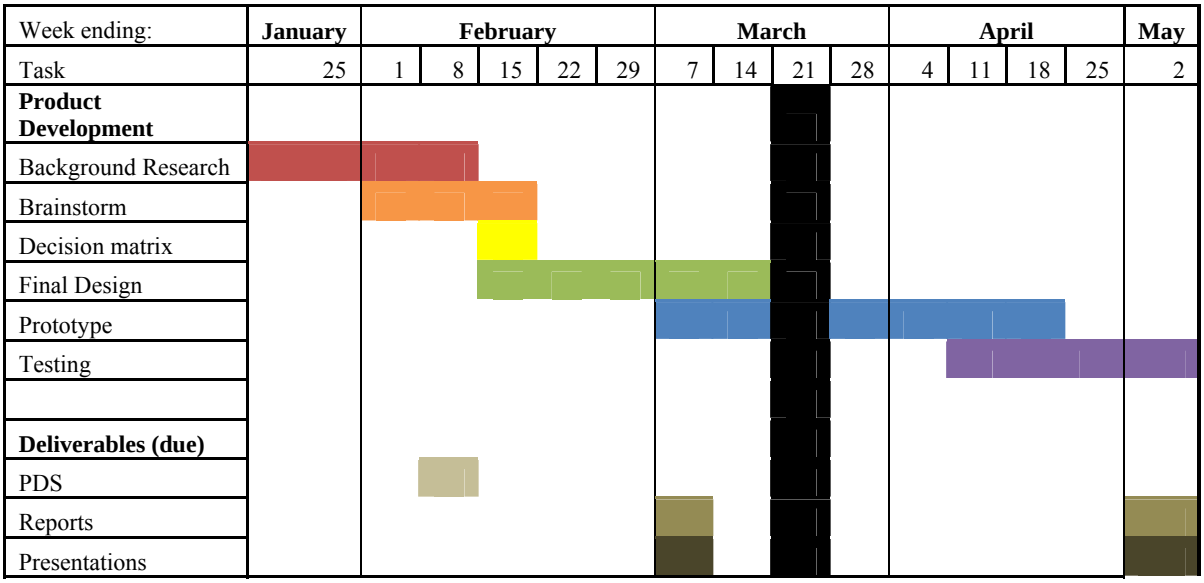
Item	Cost
Clear PETG Tubing	$27.42
Black Polyurethane Rods	$33.99
Teflon Film	$8.50
Assorted Springs	$4.19
Music Wire	$2.89
Nitrile Gloves	$1.09
TOTAL	$78.08

Approximate Cost per unit device: $0.70

Special thanks to Qosina, Halkey-Roberts, Onlinelabels.com, EMS Industrial, for supplying free parts and supplies to us.

Note: Parts include price for shipping and tax.

Appendix D: Project Timeline and Work Time



Total Time (hours cumulative)

Team Activities	42.75
Andrew	28.75
Colleen	28.5
Val	37.0
Deborah	39.75

Note Team activities include time when ALL team members are present. Individual times are for individual work as well as activities with other group members but not all group members.

Appendix E: Calculations

Spring Constant Calculation:
Force= Pressure x area
Area= cross-sectional area of cylinder
Inner diameter of cylinder = .5 in
Area= $\pi r2 = \pi(.5/2 \text{ in})2 = 0.19635 \text{ in}2$
1 cm H2O= 0.014223 psi
30 cm H2O= 0.4267 psi

Length of spring= 0.4375 in
Compressed length = 0.1875 in
Change in length = -0.25 in

Spring force = -kx
k= spring constant
x= change in length of spring

-kx= Pressure x area
-k(-0.25)= (0.4267)x(.19635)

k= .33515 pounds/inch

Force Calculations:

Force of weight dropped axially onto device:

5lbs*(1kg/2.205lbs)*(9.81m/sec^2)= 22.25 Newtons

Force against wall:

5.88g*(50 miles/hr)*(5280ft/mile)*(1meter/3.281ft)*(1kg/1000g)*(1hr/3600sec)*(0.1sec^-1)
= 1.31 Newtons

Determination of Spring Constants
Spring 1
Length =7/16 inch
7.49 g = 0.016513 lb
Compression = 1/16 inch k=0.2642 pounds/inch
11.41 g Compression = 1/8 inch k =0.2012 pounds/inch

Spring 2
Length = 27/23 inch
32.7g Compression = 7/32 inch k=0.3295 pounds/inch
11.41 g Compression = 3/32 inch k=0.2683 pounds/inch