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Endotracheal Tube Adaptor for Aerosolized Medication

Abstract

The goal of this project is to develop an endotracheal tube adaptor that can be used to consistently deliver aerosolized medication directly to an anesthetized patient during surgery by the anesthesiologists at the UW-Hospital. Aerosolized medications such as Albuterol and Ipratropium, are routinely used to control the symptoms associated with asthma attacks and bronchospastic disease. While a patient is anesthetized they may require this aerosolized medication during surgery should they have a sudden asthma attack. The adaptor will act as an interface between the anesthesia circuit and the patient and will be available to deliver either of these types of medication should the need arise. The device should not impede the anesthesia circuit and should solely act as a port to deliver medication should it be needed during surgery. Our client would prefer an adaptor that either works with the patients plastic canister housing dispenser, directly with the new metered dose inhaler (MDI; Albuterol or Ipratropium), or as an addition to his current adaptor. This device should also be a long lasting and able to withstand multiple cleanings with MetriCide disinfecting solution.

Problem Statement

For nearly 30 years our client, along with other anesthesiologists at the UW-hospital, has used an adaptor called the Bronchodilator Tee which is

manufactured by Boehringer labs. This adaptor allowed them to directly deliver highly concentrated aerosolized medication (Albuterol or Ipratropium) to their intubated, anesthetized patient through the patient's endotracheal tube. However, a new change to the aerosolized medication canisters used at the UW-hospital has rendered the Bronchodilator Tee ineffective at delivering medication. The new canisters have been fitted with a non-removable actuation counter to aide in patient awareness as to how much medication is left in their personal MDI. No other adaptors on the market have addressed this new MDI canister design so there is no way for our client to calm an asthmatic patient during surgery. This presents a large safety issue to all patients with a history of asthma attacks. Our goal throughout the semester is to design and fabricate a new adaptor that will allow a quick and effective means of delivering medication from this new MDI canister design.

Background

Our client is Dr. Mark Schroeder, an anesthesiologist at the UW Hospital and an Associate Professor of Anesthesiology at UW-Madison. Our client sees dozens of patients monthly. Of these patients, only about 2-3 require the administration of nebulized medication during surgery due to complications related to asthma or bronchospastic disease. These patients will be hooked up to an anesthesia circuit similar to the one shown above. The gas will flow

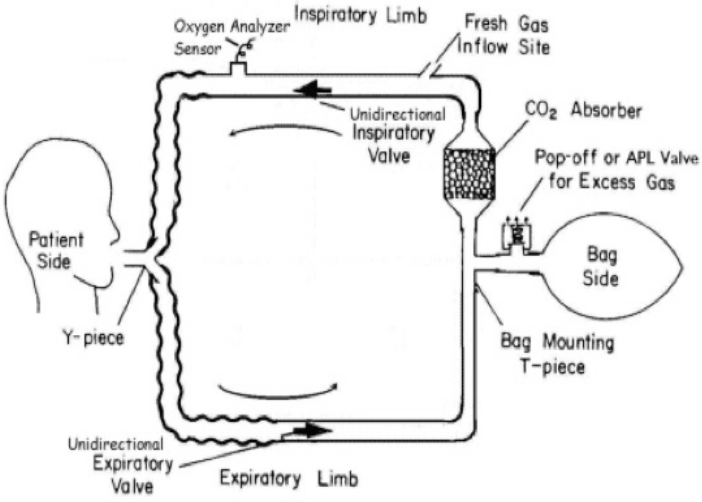


Figure 1: Anesthesia circuit

counterclockwise through the system, and the patient will inhale and exhale through the Y-piece in the figure. In order to allow medication to be introduced to the system, an adaptor must be incorporated into the circuit. One port of the adaptor will connect to the Y-piece, with the other connected directly to the endotracheal tube which runs down the patients throat. This provides an easy and direct way for the nebulized medication to travel to the patient's lungs.

All endotracheal tubes have a standard ISO connector with an outer diameter of 15 mm. This connector will fit into the inner diameter of our adaptor. Additionally, the tubing which runs from the Y-piece into the adaptor has an outer diameter of 13 mm. Thus, the inner diameter of the side port of our adaptor will be 13 mm. Our adaptor must be compatible with these dimensons.

Problem Motivation

Patients on mechanical ventilators sometimes need aerosolized medication delivered to them while in an operation. They are connected to the anesthesia circuit though the endotracheal tube which cannot be taken out from their mouths. This problem can be solved by annexing an adaptor to the circuit, although the adaptor must maintain a closed circuit to ensure no net gas flow leakages. Anesthesiologists at the U.W Hospital, previously mentioned, use an adaptor with such features, called the Bronchodilator Tee.

Figure 2: Bronchodilator Tee

This adaptor has 3 ports of which one connects to the anesthesia circuit, one to the endotracheal tube and one where the MDI canister fits in to deliver the

medication. This adaptor works really well with the anesthesia circuit for several reasons. Firstly, it delivers the medication effectively without comprising the efficiency of the circuit. It doesn't impede the pre-determined minimum gas flow rate of 4-5L/min, so that there are no abnormalities in the anesthesia circuit system. Moreover it maintains the closed circuit since the port where the MDI canister fits in has an attachable cap to it, which can be closed after the medication has been delivered. Hence, the Bronchodilator Tee prevents the dilution of the anesthesia mixture, which is extremely advantageous as then the patient is much less likely to wake up during an operation.

Why a new adaptor is needed

Recently, the FDA banned the use of MDI canisters that used chlorofluorocarbon (CFC) gases as propellants, since they are damaging to the environment. These types of canisters are aimed to be completely removed from the market by 2010. Medical companies now have been designing a new canister with an eco-friendly propellant. GlaxoSmithKline is a relatively known company for producing such a canister. The propellant

Figure 3: New MDI canister

they, as well as other companies now, use is a hydrofluoroalkane (HFA) and has been deemed environmentally safe. However, not only have the propellants of the new canisters been changed, but also its geometry. The canister now has an actuation counter built on the cap of the canister for the purpose of letting the patient know how many doses they have left within the canister. The counter has led to the cap becoming more bulky. Since the cap is irremovable, the new canister cannot fit into the MDI canister port of the Bronchodilator Tee. This is mainly due to the nipple piece being incompatible with the port, unlike the old canister, which did not have a bulky hindrance from its surrounding large cap. So, we need a new adaptor which can fit this type of canister into its port, as well as connect to the anesthesia circuit and to the endotracheal tube all together while maintaining a closed circuit.

Existing Models

There are three main types of existing technologies available to assist the deliverance of aerosolized medication to a patient on a mechanical ventilator. One is the Bronchodilator Tee, which is currently the best option on the market and is being used by the U.W Hospital.

Figure 4: Nebulizer

The second type, sometimes used by the hospital, is the nebulizer. The nebulizer is a device used to administer medication to people in the form of a mist that is to be inhaled into the lungs. This device takes the medication in a liquid state and vaporizes into a gaseous form. The reason this is done is so the medication can travel to the respiratory tract which speeds the onset of the

medication and decreases the chance of side-effects from occurring. The nebulizer, however, is very inefficient. This large because it uses much more gas flow than when the bronchodilator tee is used (around 7L/min) which also means more amounts of the medication is needed. Also, the nebulizer can result in the patient having a higher risk of tachycardia (increased rate of heartbeat) during the procedure.

The third type of technology is the syringe and the MDI adaptor. This adaptor is placed in a breathing system circuit between a manually operated bag-valve-mask or an automatic ventilator and the patient airway circuit. The medication is released downstream through the nozzle of the canister into the center of the breathable gas flow. The MDI is actuated by manually squeezing against the adaptor to release a spray of medication. This technology is different from the first two as it has a lock system integrated into it. A Female Luer lock tapered to the bore surface and a male Luer lock on an outer end of the injector conduit.

Figure 5: Syringe and MDI adaptor

Although there are only 3 main types of existing technologies for aerosolized delivery in anesthesia systems, there are numerous patents in the market for devices that do the same job. The difference is that these devices have some properties that are tweaked up, so that they differ from the original existing technologies. However, all these devices have one thing in common. They are incompatible with the new type of canister. Indeed we have yet to come across a technology that takes the geometry of the new MDI canister into account. The goal of our design project is to produce an adaptor that can accommodate the structure of the new canister as well as deliver the aerosolized medication with the same efficiency that contemporary adaptors do.

Client Specifications

Through out the course of the semester we have had several meetings with our Client, Dr. Mark Schroeder, in order to better understand the basics project objectives and create a list of client requirements. As an outcome of these meetings we have been able to divide his requirements into two main categories: Essential Features and Desirable Features.

Essential Features: These are the client requirements that the adaptor must contain in order to achieve basic functionality. These items are considered non-negotiable.

- **Compatibility:** Our elbow adaptor must be compatible with the new, HFA propellant, MDI canister from GlaxoSmithKline. This is currently the canister and propellant used by the University of Wisconsin-Madison hospital.
- **Air Flow:** The adaptor must be able to maintain the 4-5 L/min air flow rate through the ventilator circuit. The adaptor can not diminish or restrict this level of air flow without potentially causing harmful affects to the patient.
- **Drug Deliverance:** 70% of the administered dosage (per actuation of the canister) must be delivered into circulation.
- **Reusability:** Dr. Schroeder has given us the option to design the new adaptor as either a reusable or a single use device. However, if it is designed for reusability, it must be compatible with the hospital's current sterilization solution, MetriCide.

Desirable Features: These are features that based on experience Dr. Schroeder has found to be highly desirable but, since they do not directly affect the adaptor's functionality, they will ultimately be evaluated based on their overall cost to benefit ratio.

- **Geometry:** Dr. Schroeder has expressed a strong preference that the geometry of the adaptor allow for the medication to be delivered at a 180 degree angle to the endotracheal tube (that is, directly down into the tube opening). This would allow for what he feels is optimal performance by decreasing the possibility of rain off caused by turns in the air flow.
- **Universal:** While the adaptor must work with the GlaxoSmithKline HFA MDI Canister, Dr. Schroeder would like it to also work with the canisters from as many other manufacturers as possible. This would provide flexibility in case the hospital decides to switch suppliers.
- **Cost:** Dr. Schroeder would like the prototype to cost less than $300.

Materials

The adaptor must be made from a material that is both compatible to the current cleaning solution used by the UW Hospital, MetriCide, and with the HFA propellant based medications used in today's metered dose inhalers. Along with being compatible with the medication and cleaning solution the material must be ridged and durable so that it can have a standard shelf life of around 1 year. With these basic qualifications in mind we were able to create a short list of metals and plastics that we feel would do more than an adequate job. These possible candidates include: aluminum, brass, stainless steel, high density polyethylene (HDPE), and acrylonitrile butadiene styrene (ABS). Although, the final decision about the material we use will be made with input from the manufacturer, we feel that the use of either aluminum or high density polyethylene would work the best for our design.

From the stand point of metals, aluminum encompasses all of our requirements while adding a few benefits of its own. It is known to be a soft, yet sufficiently durable, metal. This is beneficial to our design because it is strong enough to

withstand everyday use at a hospital but is soft enough to allow for easy fabrication. Along with being durable aluminum is lightweight which ensures it will not be too heavy for the endotracheal tube to adequately support. The final few reasons aluminum is a quality choice is that it is compatible with MetriCide, it is relatively cheap, and most importantly, due to its ability to oxidize, it is considered to be one of the most corrosive resistant metals available.

High density polyethylene (HDPE), much like aluminum, is a quality choice because it fulfills all of our requirements. It is compatible with MetriCide. It is sufficiently ridged to be able to with stand the decompression of the canister. In comparison to ABS, it is more fracture resistant, and it is compatible with the medication used in the MDI's. Perhaps one of HDPE's most valuable attributes is its non porous surface. This non porous surface serves two functions in our product: it prevents substances from sticking to it, which facilitates the efficient delivery of the medication into the circuit easier cleaning and sterilization of the adaptor.

Proposed Designs

To meet the client specifications and address the new aerosolized medication canister cap, we have developed the following designs:

1. "The Syringe"

This concept is actually quite different from any of the currently existing MDI adaptors that we found on the market. The basic concept behind this model is that it allows for the healthcare professional who

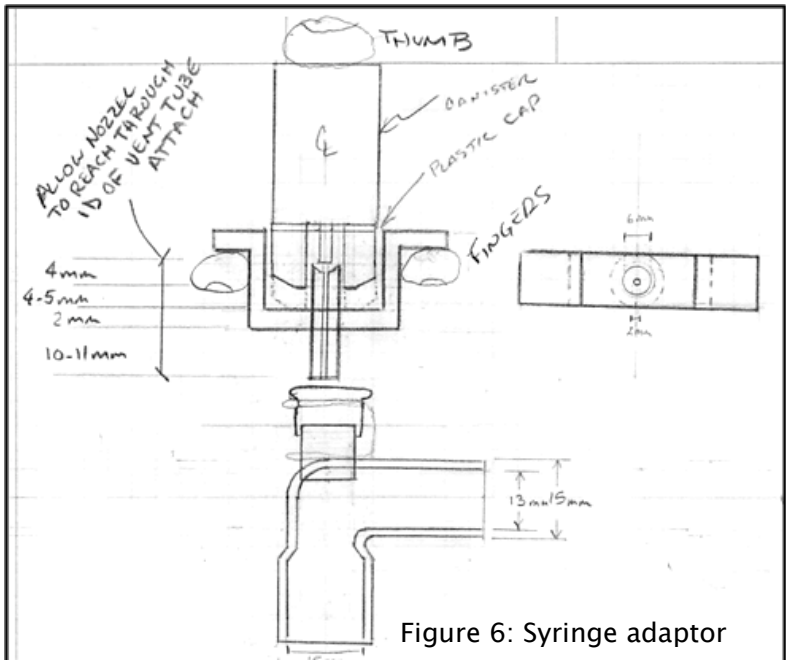


Figure 6: Syringe adaptor

is administering the aerosolized medication to “syringe” it effectively into the ventilator circuit. This is accomplished by making use of a female “Luer” port on the elbow that connects the ventilator to the endotracheal tube and a corresponding male port on the “syringe” canister adaptor (a “Luer” taper port is an industry standard fitting used to make leak free connection of small fluid lines including hypodermic syringe tips, needles, and glass bottle stoppers). The use of the Luer port to deliver the medication into the circuit ensures that the medication and anesthesia gas will not escape the circuit during actuation, and also, since it is an industry standard fitting, guarantees that the syringe style canister adaptor is compatible with the anesthesia circuit.

There are several advantages to this particular design. The most significant of these is that our syringe system can be designed and manufactured to fit an already existing and widely used elbow adaptor. This has obvious cost benefits since we only have to manufacture the smaller and simpler syringe piece rather than the entire elbow. Another significant advantage to the “syringe” alternative is that it can almost certainly be designed to work effectively with a wide range of MDI canisters. This is possible because our design affectively eliminates the complex geometry associated with differing canister styles and instead engages the canister through its most universal feature, the aerosol nipple. This potentially provides the doctor with the flexibility of using our syringe with MDI canisters from a wide variety of drug suppliers so that they can choose the best and lowest cost drug without worrying if the canisters are going to be compatible with the hospital’s elbow adaptors. Finally we feel that the “Syringe” design allows for a better delivery of medication into the circuit because it delivers the medication into the adaptor at gas flow level, meaning that there is no gap between where the medication enters the elbow and where it meets the anesthesia gas. This should provide a better opportunity for the gas and

medication to adequately mix, and should help to prevent rain out along the sides of the elbow.

Although, the "Syringe" design is our best alternative, and we feel the pros far out weight the cons, it does have two main drawbacks. First, since the nozzle interface and Luer port portion of the syringe are small and have relatively complex geometries, fabrication of that piece could be difficult and, therefore, more expensive than some other approaches. This could in turn make this design harder and costlier to mass produce through injection molding. Secondly, our design requires two distinct and separate pieces, the syringe and the elbow. This increases the probability of someone misplace the syringe and, thereby, rendering the system useless.

2. Canister Tee

The canister model is very similarly to the Bronchodilator Tee in both design and function. It will work exactly as the Bronchodilator Tee did by administering the MDI from a 180 degree angle above the endotracheal tube. At a 90 degree angle to the endotracheal tube and MDI port will be the connecting tube for the anesthesia gas flow mixture. The geometry for the top will be redesigned to accommodate the new MDI canister actuation counter but the bottom portion of the adaptor will have the

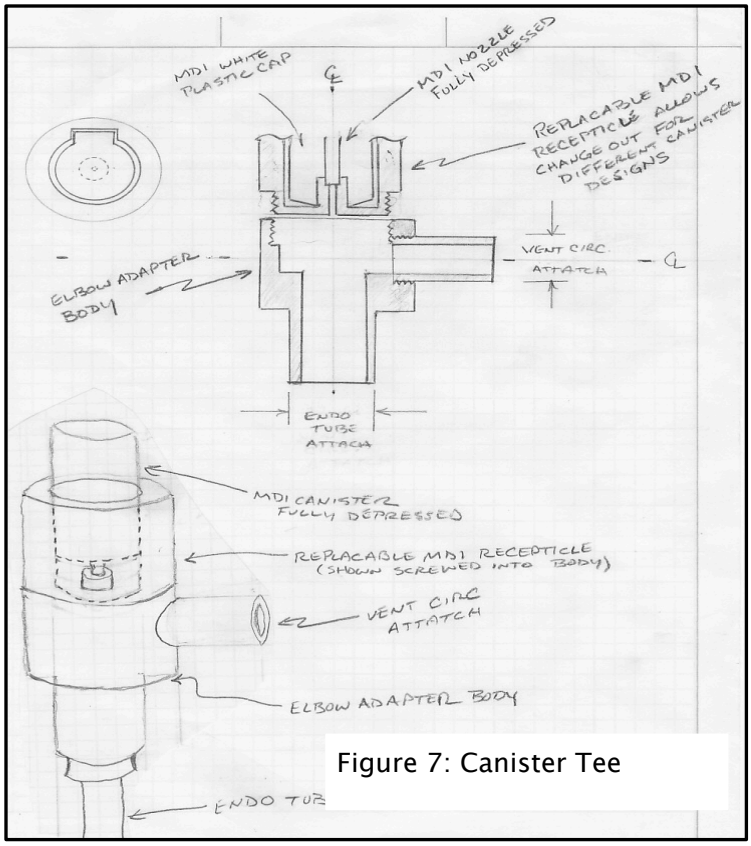


Figure 7: Canister Tee

same geometry of the Bronchodilator Tee. This adaptor will have a cap to seal the circuit off when not in use.

The two advantages to this design are that it is our “failsafe” method and all of the geometries needed for internal and external diameters are known. “Failsafe” refers to the fact that since there will only be minor changes from the Bronchodilator Tee to the Canister Tee, we can assume that the flow rates will be relatively unchanged. The UW-hospital used the Bronchodilator Tee for nearly 30 years so a similar model that fits the new MDI canister would be widely accepted without much reassurance of its efficacy. Also, as mentioned above, all of the geometries are known for the bottom portion of the adaptor. Knowing these geometries will be of greatly assistance in making the SolidWorks model that is needed by companies for fabrication purposes.

Although this is our “failsafe” design, it still has inherent disadvantages including a lower level of efficiency, difficulty in fabrication, and a high cost. Both this model and the Bronchodilator Tee have a somewhat large gap between where the medication canister is depressed and where the medication from the canister actually incorporates itself into the anesthesia gas flow. This gap is slightly larger on the new Canister Tee design. We feel that this ~1 cm gap will allow the medication to “rain out” or collect along the far side (far left side on diagram above) of the internal body of the adaptor. This rain out will lead to a lower amount of medication being delivered to the patients lungs, even though the amount incorporated into the gas flow will be relatively high. Another concern with this alternative is the higher cost due to a large amount of materials needed and the small and intricate pieces that are needed to correctly fit the new actuation counter. The device would need to be fabricated from multiple pieces of stock material since one tube comes off at a ninety degree angle. In addition to this, pieces will need to be threaded together thus leading to even more assembly work.

3. The "Y" Adaptor

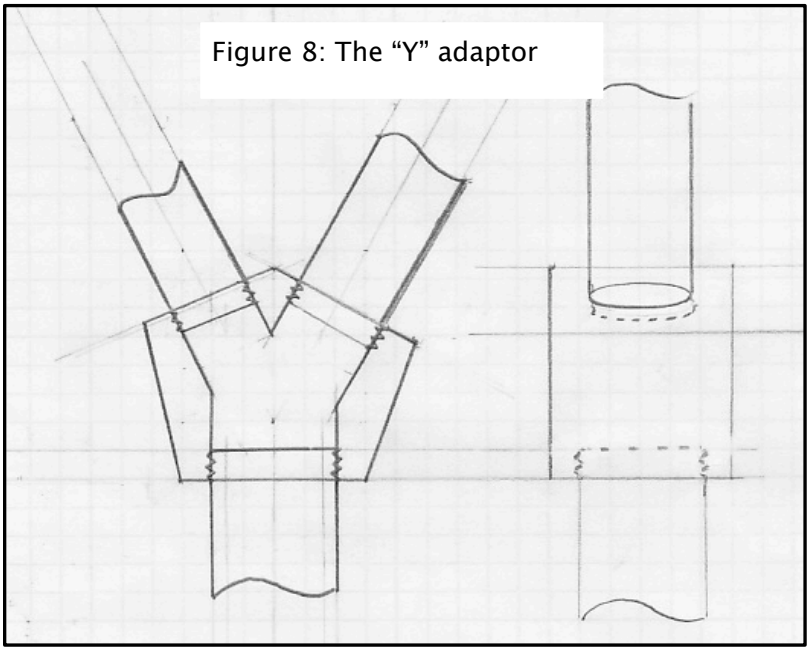


Figure 8: The "Y" adaptor

Our third design is called the "Y" adaptor. This adaptor is a twist on the other designs that we thought of due to the angle that the anesthesia gas flow and MDI canister medication mix at. Instead of a 180 degree angle between the MDI canister and endotracheal tube there would be closer to a 150-160 degree angle. Similarly, there would be only a 40-60 degree angle between the anesthesia gas flow and the MDI canister port versus the 90 degree angle of all of the other designs. This shallower angle would lead to a more efficient mixture between the gas flow and medication thus leading to a more efficient deliverance of medication particles into the patient.

This type of adaptor has two main advantages; adaptability and better efficiency. As noted on the diagram below, there is not a specified delivery method for the medication. A Syringe port or Canister Tee type design could be modified to fit on the MDI end of the adaptor making it nearly as adaptable as the two previous designs. In addition to the adaptability this geometrical change would lead to a more efficient means drug delivery to the patient. In an experiment by Fadl et al. it was demonstrated that the angle an MDI is administered at can greatly affect the extent to which the medication is delivered to the lungs, where it is able to calm an asthma attack. This is due to

the velocity that the medication leaves the canister at. At a more shallow angle (20 degrees was ideal according to the article) the velocity is less so the medication is better able to maneuver around sharp turns without condensation occurring. This is shown in a model of a human throat below.

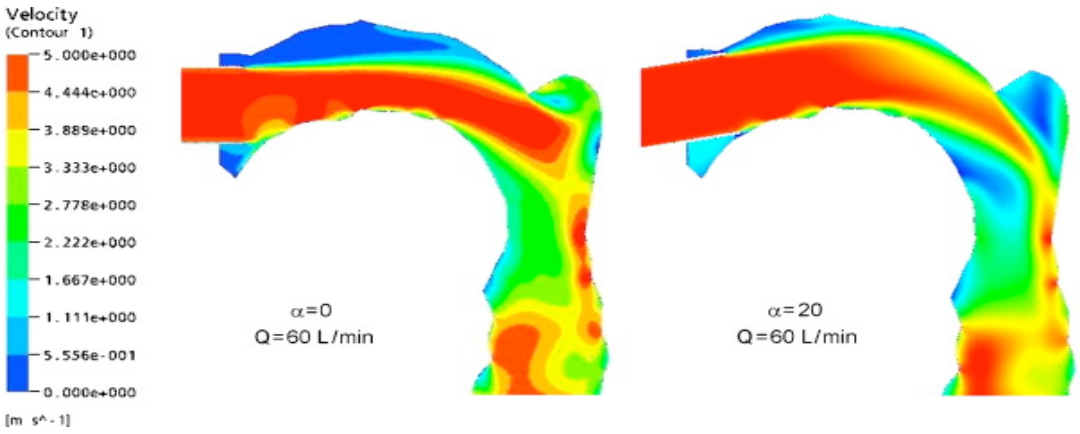


Figure 9: Image depicting velocity patterns at different mouthpiece entrance angles.

The “Y” design did however have two negatives that outweighed its positive attributes. The first disadvantage is that it is too bulky to be used effectively in a situation as crowded as the operating room. The anesthesia circuit already has a plethora of cords, tubes, and wires that connect in various places to ensure both the safety of the patient and a smooth operation from start to finish. Since this alternative is made of four pieces (three threaded tubes and a central block to house them) it will take up too much room. Also the more aggressive angle could lead to inadequate room to both connect the wye-piece of the circuit while still being able to deliver medication from the MDI canister. This was the main Achilles heel of the “Y” alternative. Another disadvantage is the inability to sterilize this design effectively due to the complexity of how parts fit together and how many threaded parts are involved.

Design Selection

	Efficiency .3	Adaptability .25	Ease of Use .15	Fabrication .1	Sterilization .2	Total 1.0
Syringe	**8** (2.4)	**10** (2.5)	**9** (1.35)	**8** (0.8)	**9** (1.8)	**8.85**
Canister Tee	**7** (2.1)	**5** (1.25)	**7** (1.05)	**3** (0.3)	**4** (0.8)	**5.5**
The "Y"	**10** (3.0)	**7** (1.75)	**6** (0.9)	**4** (0.4)	**6** (1.2)	**7.25**

To evaluate which of these three designs would best meet the needs of our client, a design matrix (see Table 1) was created to evaluate each design. The three designs were evaluated on five different criteria to determine the best design for the adaptor. The five criteria were efficiency, adaptability, ease of use, fabrication, and sterilization. Each criterion was assigned a weight based on its importance for the design. Then each design was given a rating of 1-10 for each criterion. These ratings were multiplied by the weight and summed together to give the total rating for that design.

The most important criterion in the matrix was the efficiency of the adaptor. We defined efficiency as the percent of the dose from the MDI that would successfully travel through the adaptor into the anesthesia circuit. The further the medication would have to travel through the body of the adaptor, the less efficient we think it would be at delivering medication into the circuit. The

greater distance traveled would increase the chance of medication getting caught on the inside body of the adaptor.

The second most important criterion in the matrix was adaptability. We defined this as how well our adaptor would work with the wide range of HFA canisters available on the market. For example, the GlaxoSmithKline canister used by the UW Hospital has a large actuation counter, while other HFA canisters lack this bulky cap. The more canisters our adaptor would work with the better, and ideally it would work with every single HFA canister currently approved by the FDA.

The third criterion in the matrix was cleanability. We defined this as how well the sterilization solution MetriCide would work with the design. Since our adaptor will be repeatedly used on patients in an operating room, it is essential that it can be effectively sterilized by the methods employed by the University Hospital. After meeting with Professor Thompson, we determined that threaded components are much harder to sterilize and contain small microscopic areas behind the threads which are impossible to sterilize with a solution.

The fourth criterion in the matrix was ease of use. We looked at several factors when defining ease of use. First, we determined whether each design would require one or two hands to use. Second, we considered how the size of the adaptor would interfere with the rest of the anesthesia circuit and if this would cause any complications.

The final criterion in the matrix was fabrication. We defined this as how easily we could machine and build each design. Any design containing multiple threaded components would be more difficult and time-consuming to fabricate than a one component design. Additionally, designs which contained complex

and intricate geometry would also be difficult and require more time to fabricate.

Canister Tee

The lowest scoring design in the matrix was the canister tee. It received very low scores for both fabrication and sterilization. Since this adaptor would consist of 2 threaded components, it would be more difficult to fabricate, and as mentioned previously it would be impossible to fully sterilize certain areas behind the threads. Additionally, the top part of the adaptor resembling an MDI would have to be very precisely machined, and this would also increase the difficulty of fabrication. The adaptor received a 7 for efficiency. The distance traveled by the medication through the adaptor would be slightly more than in the bronchodilator tee, and thus less efficient. Additionally, with the intricate top MDI portion of the adaptor, this design would most likely only be compatible with a specific type of HFA canister, and thus it received a lower score for adaptability. Overall, the Canister Tee received a 5.5/10.

The "Y"

The "Y" design was the runner up in the design matrix. It scored a perfect 10/10 in efficiency due to the decreased angle at which the medicine would be introduced into the flow of air from the anesthesia circuit. However, like the canister tee, the "Y" consists of multiple threaded components, and thus it received lower scores for both fabrication and sterilization. This design would also be the bulkiest of the three, so it received a lower score for ease of use. We didn't specify how the medication would be administered into the "Y" adaptor, and thus the value for adaptability is arbitrary. We could elect to use the syringe method or the canister method with a Y-shaped adaptor, which would determine the score for adaptability. Overall, the "Y" received a 7.25/10.

The Syringe

The syringe design received the highest rating in the design matrix. The universal shape of the handheld syringe portion of the adaptor would allow it to interface with all types of HFA canisters, and thus it received a 10/10 for adaptability. The aerosolized medication would be injected directly into the airstream of the anesthesia circuit, and thus it would be very efficient. The reason it only received an 8/10 in efficiency was attributed to concerns that air could leak out of the adaptor when the nozzle was inserted into the Luer port of the elbow. The syringe was the only design in the matrix which could be operated with one hand, allowing the anesthesiologist more freedom while treating a patient. This led to a very high score for ease of use. Since the elbow portion of the adaptor is already widely available, we would only have to fabricate the small handheld syringe portion. Fabricating one component with little complex geometry would be very simple, and this threadless component would also be easy to sterilize. The syringe received an 8.85/10. Of the three designs, it was the most adaptable, the easiest to fabricate and sterilize, and the most ergonomically friendly. Additionally, it was very efficient. After evaluating all these advantages, we elected the Syringe adaptor as our final model to pursue and build for the remainder of the semester.

Ergonomics

Out of our three possible designs, we happened to choose the most user-friendly option. The “Syringe” model is a universal, easy-to-use design where the person who is going to deliver the medication, has to hold onto a fabricated piece that fits into the head of the canister to make a “syringe”. It requires the use of only one hand with no other complicated procedures, this minimizing the probability of user error. One vital ergonomic quality that we do have to

take account is to make sure the patient will be receiving enough medication though each actuation of the canister. A low dosage of the medication could mean that patient could potentially feel pain, which we do not want. So we must take the mechanics of the actuation of the canister into deep consideration, such as, does the canister fully actuate every time it is pushed or does it always need an extra force to fully actuate? Does the actuator give a higher dosage than the amount it is supposed to release for every actuation? Although our client has said a higher dosage does not usually harm the patient, we must still take into account for the well-being of the patient.

Future Work

For the rest of the semester, the concentration is going to be placed on making a working model of the adaptor. The main goal from this point on will be sketching a SolidWorks or other form of auto CAD model. This will supply us with all of the specifications and geometries that will for an outside company to make a prototype. A computer model also ensures accuracy and reliable outcomes when working with a company. We hope that the company will be able to recommend a final material to use, whether it is plastic or metal as mentioned above, based on the geometries and intricacy of our project. We assume that the prototype may take a few weeks to be fabricated once we find a company so finding a suitable company is currently our main concern. Once we have our working model we will be able to move onto performing tests.

There are two main aspects that we would like to test on our adaptor; gas flow efficiency and durability. By efficiency we are referring to both how the anesthesia gas flow travels through the circuit and how effective our adaptor is at delivering medication into the circuit air flow (and thus the patient). There

are various ways of testing this aspect including SolidWorks simulations, outside companies who specialize in gas flow analysis, and fluid dynamics specialists such as professors here on campus. If we choose to send our prototype off to a company we will most likely need to contact the WARF first to ensure the safety or our intellectual property. All of the time involved in testing will amount to a few weeks so this will be the first thing done once we obtain our prototype. As for durability testing, we would like to simulated multiple cleaning cycles and wear-and-tear type situations it may encounter while at the UW-hospital. This can be accomplished by using the same cleaning solution (MetriCide) that our client uses.

Conclusion

In conclusion, we have selected a design that uses a syringe type administration method to deliver the medication to the patient. The design is ergonomically friendly, universal to many MDI canisters, and fits an already existing elbow that has a Luer lock port. We hope to have a working prototype that has been thoroughly tested by the end of the semester.

References

1) http://www.osha.gov/dts/osta/anestheticgases/fig05.gif
2) http://www.boehringerlabs.com/broncho.htm
3) Picture from client interview with Mark Schroeder
4) http://www.myrespiratorysupply.com/images/nebulizer%20kit.JPG
5) http://www.patentstorm.us/patents/7207329/description.html
6) Sketch by Mark Childs
7) Sketch by Mark Childs
8) Sketch by Mark Childs

9) Fadel A, Wang J, Zhang Z, and Cheng YS. Effects of MDI spray angle on aerosol penetration efficiency through an oral airway cast. Journal of Aerosol Science. 38-8; August 2007. Pages 853-864

10) Picture from client interview with Mark Schroeder

11) Picture from client interview with Mark Schroeder

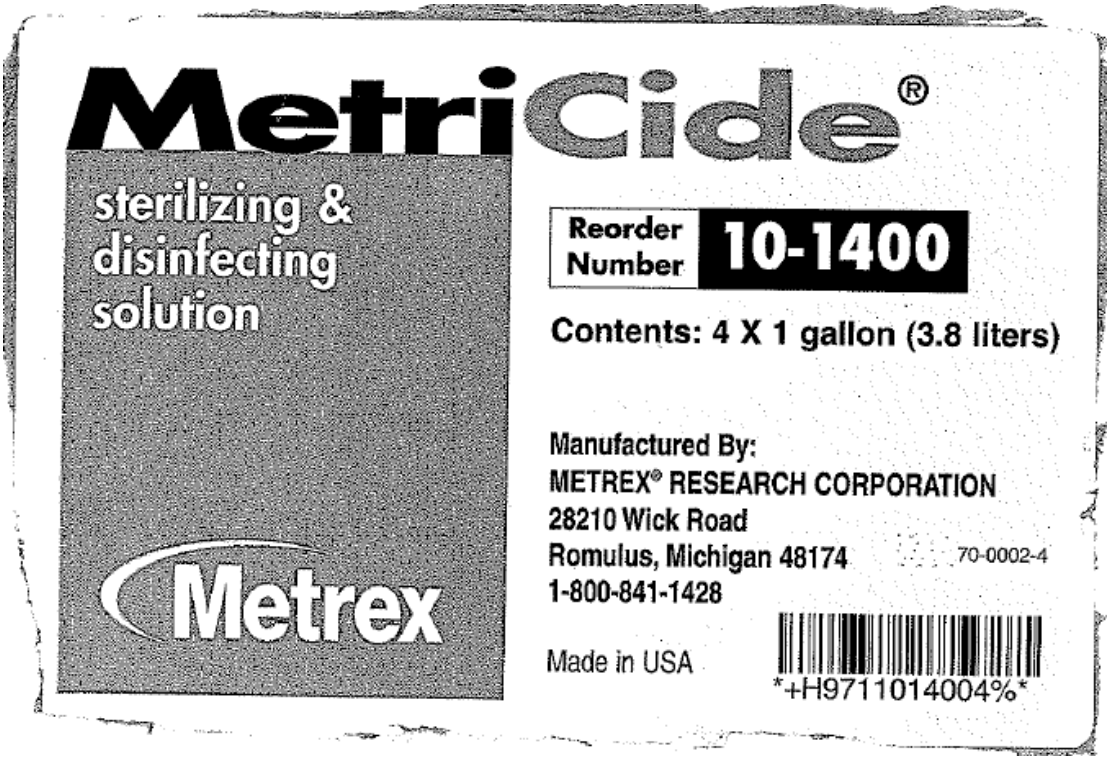
Appendices

Appendix A: Picture of old and new MDI canisters

Figure 10: New MDI canister depicting addition of non-removable actuation counter.

Figure 11: Old medication canister depicting lack of non-removable actuation counter.

Appendix B: MetriCide Compatibility Guide



INDICATIONS FOR USE:
STERILIZATION: This solution should be used for the sterilization of heat sensitive medical equipment for which alternative methods of sterilization are not suitable. Medical equipment which should always be sterilized is that which is categorized as critical (i.e., used in procedures in which contact will be made with tissue that is normally considered sterile).
HIGH-LEVEL DISINFECTION: This solution should be used for the high-level disinfection of heat sensitive medical equipment for which sterilization is not practical. Medical equipment which should always be subjected to high-level disinfection or sterilization is that which will be used in procedures categorized as semi-critical (i.e., used in procedures in which contact will be made with mucous membranes or other body surfaces which are not normally considered to be sterile).

DIRECTIONS FOR USE:
It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.
ACTIVATION: Activate the **METRICIDE®** solution by adding the entire contents of the *Activator 14* activator vial which is attached to the **METRICIDE** solution container. Shake well. When activated, solution changes color to green. Record the date of activation in the indicated space below, in a log book or a label affixed to any secondary container used for the activated solution. See label booklet attached for additional instructions and information regarding activated solution.
CLEANING/DECONTAMINATION: Blood and other body fluids must be thoroughly cleaned from hard, non-porous surfaces and objects before application of the disinfectant or sterilant. For complete disinfection or sterilization of medical instruments and equipment, thoroughly clean, rinse and rough dry objects before immersing in **METRICIDE** solution. Cleanse and rinse the lumens of hollow instruments before filling with **METRICIDE** solution. See label booklet attached for additional cleaning/decontamination instructions.
STERILIZATION: Immerse medical instruments/equipment completely in **METRICIDE** solution for a minimum of 10 hours at 25°C. Remove equipment from the solution using aseptic technique and rinse thoroughly with sterile water. See label booklet attached for complete instructions/information on sterilization.
HIGH-LEVEL DISINFECTION: Immerse medical instruments/equipment completely in **METRICIDE** solution for a minimum of 45 minutes at 25°C. Remove from the solution and rinse thoroughly with sterile water or with potable tap water. The quality of rinse water used is dependent upon the intended use of the instrument/equipment. See label booklet attached for complete instructions/information on high-level disinfection.

PRECAUTIONARY STATEMENTS:
Hazard to Humans and Domestic Animals
DANGER: Keep Out of Reach of Children
Direct contact is corrosive to exposed tissue, causing eye damage and skin irritation/damage. Do not get into eyes, on skin or on clothing. Wear goggles or face shield and protective gloves (butyl rubber, nitrile rubber, polyethylene or double-gloved latex), when handling or pouring. Avoid contamination of food. Use in well ventilated area in closed containers.

STATEMENT OF PRACTICAL TREATMENT:
In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, get medical attention. Harmful if swallowed. Drink large quantities of water and call a physician immediately.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

STORAGE AND DISPOSAL:
Store at room temperature.
Solution Disposal: Discard residual solution in accordance with federal, state and local regulations.
Container Disposal: Do not reuse empty container. Wrap container and put in trash.
Refer to label booklet attached for material compatibility information and more detailed usage/product data.

5) Material Compatibility

MetriCide is compatible with the following reusable devices and materials: Rigid and flexible endoscopes, respiratory therapy equipment, anesthesia equipment, rubber, most stainless steel instruments, plastic, most dental instruments (not including dental handpieces), many types of metals, such as stainless steel, carbon steel, aluminum, and plated metals such as nickel plating or chrome plating.

For a listing of specific device manufacturers that have reported device compatibility with **MetriCide**, see Table 1 below.

Table 1. Manufacturers Reporting Device Compatibility with **MetriCide**

Company	Instrumentation
Acoustic Imaging	Transducers
Acuson Computed Sonography	Biplane Transesophageal and External Transducers
Bard Interventional Products	Automatic Endoscope Washers (Models 000187, 000387, and 000487)
Circon - ACMI	Cystoscopes
Hewlett Packard	Omniplane TEE Probe
Instrumentation Industries	Plastics used in Respiratory Therapy
Medivators, Inc.	Automatic Endoscope Washers
Olympus Corporation	Olympus Flexible Endoscopes
Pentax Precision Instrument Corporation	Upper GI Fiberscopes, Video Duodenoscopes, Bronchofiberscopes, Video Colonoscopes
Pilling Surgical Instruments	Rubber Bougies
Karl Storz	Rigid Cystoscopes
Welch Allyn	Flexible Sigmoidoscopes

Please refer to labeling of the reusable device for additional instructions, or call the reusable device manufacturer directly.

PLEASE NOTE: **MetriCide** is incompatible with the following reusable devices and materials: Type IV dental stone impression material and Heidbrink Expiratory Valve.

Appendix C: Product Design Specifications (PDS)

The Product Design Specifications (3/11/09)

Endotracheal Tube Adaptor for Aerosolized mediation

Team Members: Ozair Chaudhry, Evan Joyce, Ryan Childs, Timothy Barry

Function:

The goal of this project is to develop an endotracheal tube adaptor that can be used to consistently deliver aerosolized medication to an anesthetized patient during surgery. Recent changes to the aerosolized medicine canisters due to environmental concerns over the propellant and an additional actuation counter have rendered current adaptors ineffective. Our client would prefer an adaptor that either works with the patients Multi Dosed Inhaler (MDI) or directly with the new medication canister (Albuterol or Ipratropium).

Client Requirements:

- Must be compatible with either new aerosolized medication canister or with new Multi Dose Inhaler (MDI).
- Should reliably deliver aerosolized medication to patient.
    - 70% of administered medication per puff of the canister should enter the anesthesia circuit.
- May be either one time use or reusable. If one time use the production cost should be from $1.50-$3.00. If reusable, prototype cost should be under $300.
- Adaptor should be compatible with the hospitals cleaning solution, MetriCide.
- Must be compatible with endotracheal tube as well as anesthesia circuit tube diameters and dimensions (15 mm).
    - Must not disturb the 4-5 L/min airflow from anesthesia circuit to patient

Design Requirements:

1. **Physical and Operational Characteristics**

a. Performance requirements:
   The device should consistently deliver 70% of administered dose per puff of aerosolized medication to a patient who is anesthetized. It should either work directly with the aerosolized medication canister or with the MDI used by the UW-Madison Hospital.

b. Safety:
   The adaptor must not restrict airflow of 4-5 L/min through the circuit. Additionally, it must be fabricated with a sterile, medical-grade material.

c. Accuracy and Reliability:
   The adaptor should administer a fixed dose of aerosolized medication per use equal to at least 70% of the 3 uL's administered by a handheld Metered Dose Inhaler (MDI). This amount isn't critical since the medicine is dosed until the patient's symptoms are alleviated.

d. Life in Service:
   The adaptor can either be single-use and made of plastic or a reusable one made of metal or plastic. If we opt for the reusable design, the adaptor should last for at least 1 year while undergoing sterilization with a solution such as MetriCide after each use.

e. Shelf Life:
   The adaptor should be sterilely packaged and have a shelf life of at least 1 year.

f. Operating Environment:
   The adaptor will be used almost exclusively in operating rooms at standard temperature and pressure by anesthesiologists and respiratory therapists. As such, there is no need to account for extreme temperatures, and there is little risk of the adaptor becoming dirty or contaminated.

g. Ergonomics:
   The adaptor should easily fit onto the endotracheal tube (15 mm) with only a nominal force, and if we opt to include a cap in our design it should be easily removed. The adaptor should be able to be comfortably used with one hand.

h. Size:
The prototype should fit tightly with the other components of the circuit to ensure the medication is being effectively delivered. This includes the 15mm endotracheal tube and the 13mm anesthesia circuit wye-piece. The prototype should take up minimal room when attached to the circuit.

i. Weight:
There are no set limitations to the weight of the prototype, however the less the product weighs the better. This will be largely dictated by material choice.

j. Materials:
The prototype must be made of either medical grade plastic or metal along with being compatible with MetriCide.

k. Aesthetics, Appearance, and Finish:
The final product can be either transparent or a clear white color if plastic. Metal is also suitable as long as it does not interfere with medication or cleaning procedures.

2. Production Characteristics

a. Quantity
One prototype should be fabricated for use by our client. Further production of additional units will be determined by our client.

b. Target Product Cost:
The product should cost between $1.50-$3.00 if it is manufactured and disposable. If the product is reusable, the cost may be more. Also, initial prototype costs should be limited to $300.

3. Miscellaneous

a. Standards and Specifications:
Since the product we are designing will be used to create an opening in the ventilator circuit to allow aerosolized drugs to be administered during surgery, it may require FDA approval if manufactured on a large scale. The device can be made out of medical-grade plastic or a light weight metal (aluminum). It must either be able to be mass-produced for one-time use or it must be

able to withstand standard medical cleaning techniques (autoclaving or MetriCide). It also must be compatible with the propellant HFA (hydrofluoralkane), and if reusable it must be able to have a shelf life of 1 year.

b. Customer:
Our client, Mark Schroeder, wants a reusable prototype that could be used as a basis for an injection-molded single-use adaptor. He does not have any preference with regards to the material used to fabricate the adaptor as long as it is medically safe. If possible he would like the device to connect directly to the canister rather then the inhaler, although he would also accept an adaptor that connects to the inhaler if it's most efficient at administering the drug. He would like the adaptor to be lightweight but rigid enough to support the HFA drug canisters.

c. Patient –related concerns:
Our prototype will need to be cleaned through standard hospital sterilization procedures before and after every use. Any material used on the device will have to withstand repeated exposure to cleaning materials (MetriCide) and to the HFA propellant without chipping or flaking off into the patient's lungs.

d. Competition:
The need for our device arose when drug companies were forced to switch aerosolized drug propellants from CFC's (chlorofluorocarbons) to HFA's (hydrofluoroalkanes) because the CFC's were dispersing ozone-depleting reagents into the atmosphere. Along with the switch in propellant, the companies also redesigned their canisters, making them incompatible with the current adaptors due to a removable actuation counter cap. The market for MDI adaptors is very large and diverse, but most of these products are compatible with the old CFC canisters and inhalers. We are currently looking at making a "syringe" style adaptor. There are several patented devices that are similar to ours, but slight differences in design make our product unique. US Patent #7207329 is an adaptor for both a syringe and MDI into the ventilator circuit, but since our product will not require an adaptor for a syringe our final design will be noticeably different. The hospital currently uses the Bronchodilator Tee designed by Boehringer Labs (US Patent #D294298).