**Endotracheal Tube Adaptor - Product design specification**

**Group Members:**
Evan Joyce
Ryan Childs
Timothy Barry
Ozair Chaudhry

**Function:**
The goal of this project is to make design changes to an endotracheal tube adaptor that was fabricated last semester for product optimization. The adaptor works as an interface to introduce aerosolized medication (e.g. Albuterol) from a pressurized canister into an anesthesia circuit to an intubated patient. This project was initiated due to a recent change in the Albuterol canister used by the UW-Hospital. The new canisters have been fitted with a non-removable, plastic, actuation counter resulting in a mechanical incompatibility with the old adaptor used at the hospital.

Last semester a prototype adaptor was produced that was universally compatible with all aerosolized medication canisters and also compatible with a specific gas sampling Luer port. It acts as a syringe to dispense medication in a simple fashion, with one hand, into the Luer port. This semester's objectives are: make the adaptor compatible with all Luer ports, adjust the size of the aperture at the distal end of the prototype for optimal medication delivery, and thoroughly test the prototype to ensure efficacy. The prototype will also be designed and constructed in a way such that it can be injection molded.

**Client Requirements:**

- Must be compatible with both new aerosolized medication canisters (with actuation counter) and with old style canisters (sans actuation counter).
- Should reliably deliver aerosolized medication to patient.
    - Particle size should be comparable or smaller than those observed last semester with Brochodilator Tee and patients Multi-Dosed Inhaler (MDI).
- The final prototype for this semester may be made of metal, however, the final design should be injection molded. The one time use, plastic adaptors should cost between $1.50-3.00 per unit.
- Adaptor should be compatible with the hospitals cleaning solution, MetriCide.
- Must be compatible with all femal Luer ports (distal 7.5mm of Luer port) on plastic, anesthesia elbows.
    - Must not disturb the 4-5 L/min airflow from anesthesia circuit to patient.

**1. Physical and Operational Characteristics**

**a.) Performance requirement:** The device should consistently deliver Albuterol particles between 0.5-10 microns in diameter to ensure maximum absorption by the

lungs. The adaptor should work in conjunction with all styles of Albuterol canisters and should also be compatible with the distal 7.5mm of all female Luer ports.

**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. If made of plastic, the adaptor should be able to withstand the force required to actuate the canister.

**c.) Accuracy and Reliability:** The adaptor should administer Albuterol droplets that range from 0.5-10 microns in diameter. In addition, it should be comparable or exceed the particle size observed with the patient's hand-held MDI and the Bronchodilator Tee adaptor used by the hospital.

**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 into the female Luer port with only a nominal force. All sharp edges of the existing prototype should be rounded off to maximize user safety. The housing area for the medication canister's nipple should be sized appropriately to form a snug fit between the nipple and the housing (3.1mm). The adaptor should be able to be comfortably used with one hand.

**h.) Size:** The prototype should fit the first 7.5mm of the female Luer port and should be kept at a maximum of 36mm wide by a maximum of 55mm long (this includes reducing the current length of the distal nozzle).

**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 medical grade plastic, stainless steel, or aluminum and should also be compatible with MetriCide.

**k.) Aesthetics/Appearance:** 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 for use by our client. Further production of additional units will be determined by our client and will be done via injection molding.

**b.) Target Product Cost:** The product should cost between $1.50-$3.00 if it is injection molded and disposable. Also, prototype re-design costs should be limited to $500.

**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.) Consumer:** 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. General modifications he would like made to our current prototype include: orifice size change, rounded corners, shortened nozzle/punch out and replace nozzle, addition of actuation counter stud, and file for FDA 510(k) approval.

**c.) Patient-Related Concerns:** Any material used on the device will have to withstand repeated exposure to the HFA propellant without chipping or flaking off into the patient's lungs. The particle size should consistently fall within the above mentioned range to ensure patient safety.

**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, some companies also redesigned their canisters, making them incompatible with the current adaptors due to a non-removable actuation counter cap. The market for MDI adaptors is very large and diverse, but most of these products are compatible with the old canisters (those lacking the actuation counter cap). 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). Nebulizers also exist that can be used to nebulizer Albuterol, but these are much different in form and function from our device and have significant patient-related safety concerns.