Endotracheal Tube Adaptor - Product design specification

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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 between $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

1. Physical and Operational Characteristics

a.) Performance requirement: 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: 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.

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.) 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. 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).