

Summary

Our team is working with Dr. Philip Zapanta on project Modified Inhaler Adapter, or M.I.A. There are over a million patients diagnosed with a neuromuscular disease and over 500 million people over the age of 65 around the world. Many of these patients have difficulty using a standard inhale due to its design where one must apply all the force on a very small contact area. These individuals usually require assistance to operate these inhalers. M.I.A. solves this problem by designing an ergonomic and easy to use inhaler that can be attached to the modern medication canisters for inhalers. Our design incorporates a two side wedge system where patients can use their whole hand to activate the inhaler instead of just one finger. M.I.A. will help millions of people get the medication they need.

Anticipated Regulatory Pathway

- Class II Product
- Aiding delivery of a drug
- Implications of the device not working properly
- The Intercenter Agreements defines aerosol delivery device as a drug product regulated by the Center for Drug Evaluation and Research (CDER).
- Required to submit a 510(k), not needing full "FDA-approval."

User of Product

- People who suffer from neuromuscular diseases
- People who require aid in using their asthma inhaler
- Children who prefer our canister to a prescribed one
- Market Size ~ 1 Million People
- 5 Million in US have muscular dysfunction of some type
- 20% of these people have asthma symptoms / respiratory diseases

Competition

3 Competitors :

- MyPurMist machine (Bulky and Costly)
- Accuhaler (Powder inhalation medication, not a direct competitor)
- Aeronex Inhaler (Slightly bulkier and complicated to use)

Our inhaler allows a more ergonomic means of use to dispense with either one or two hands, requiring lower force to use than our competitors.

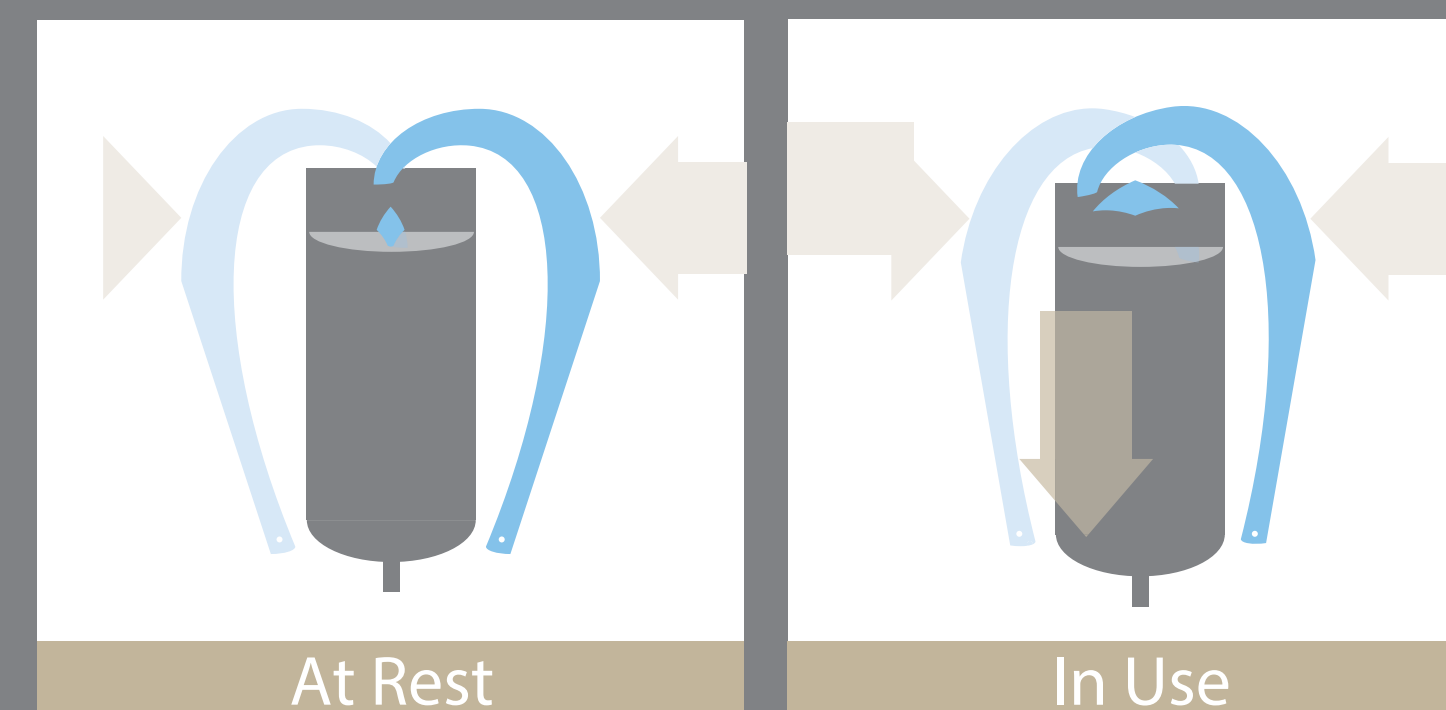
Ease of Use

Using the actual prescribed medical canister allows multiple means of use, each using the entire hand rather than a single finger. This allows for less dexterity to be required with use.

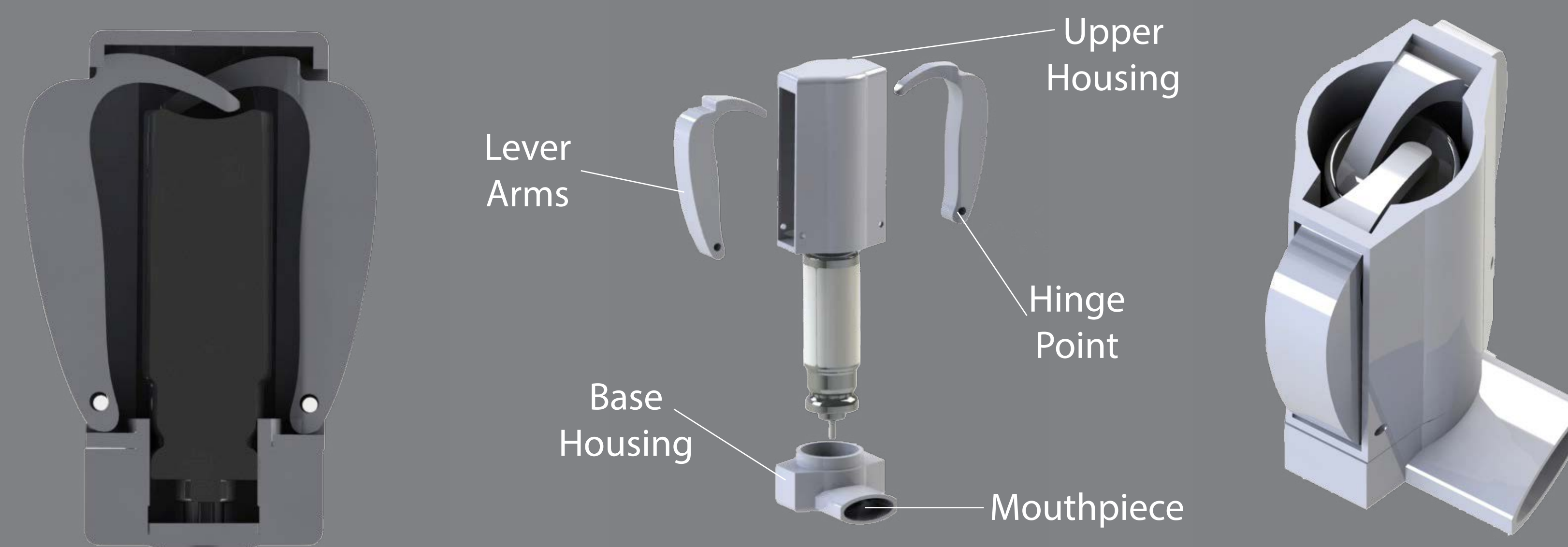
At 6.29 pounds of required force, our inhaler design is more efficient than the standard inhaler by 15%.

M.I.A. ASSISTED INHALER

M.I.A aids inhaler use for those with low hand dexterity by allowing the user's full hand or two hands be used, and lowers the force needed to dispense the medication.



The design uses two "hooks" hinged at the base of the inhaler that, when squeezed, forces the canister down into the base sprayer to release the medication.



Inner mechanics of the inhaler consist of two hook-like arms, which hinge inward to push at an angle on the vertex of the canister's domed top.



One-handed dispense

Two-handed dispense

BME Design, 2014-15

Thank you for the continued support and mentoring from Dr. Zapanta, Wayne Chung, and Madeline Cramer

Morgan Fritz- Industrial Design, Engineering Studies Minor
Conor McGuire - Materials Science & Engineering
Jessica Uphoff- Industrial Design
Tommy Vandenberg- Mechanical Engineering

Cost of Production

- Purchased by the patients themselves
- Insurance companies in mind when dealing with manufacturing and marketing costs
- Device is covered by insurance if the physician prescribes
- Product estimated cost at \$25 with mass production manufacturing.
- Hope: Large clinical need will promote immediate purchase

Potential Market and Impact

- User of product:
 - People who suffer from neuromuscular diseases
 - People who require aid in using their asthma inhaler
 - Children who prefer our canister to a prescribed one
- Market Size ~ 1 Million People
 - 5 Million in US have muscular dysfunction of some type
 - 20% of these people have asthma symptoms / respiratory diseases
- Distribute to local pharmaceutical stores
- Speak with various doctors in hopes of implementing a bundle purchasing system
- Group price for inhalation medication and our product at a discount

Clinical Use

- Elderly and patients with neuromuscular diseases can have very hindered voluntary movements.
- The loss of motion is due to degenerating neurons in the body, from age or disease.
- Current inhalers on the market are not easy to use for these patients due to their top-down push design where one must apply pressure to the top of the inhaler to activate the device.
- Currently in the market, if assistance isn't available for patients there is a possibility that they could die from not obtaining the medicine they need to breathe.

Market Analysis

- In total, there are approximately 36 million people who fall under our market.
- Estimated 2.3 million people have multiple sclerosis in the world.
- 30,000 people in the United States are diagnosed with Amyotrophic lateral sclerosis.
- About 15 out of every 100,000 people suffer from DMD. One in five people have allergy or asthma symptoms.
- About 40% of patients with neuromuscular disorders are under the age of 18.
- We can estimate overall that about 5 million people in the US have a type of muscular dysfunction and 20% of these people have asthma symptoms or other respiratory diseases.
- Additionally, there are over 500 million in the world over the age of 65 and approximately 7% are diagnosed with asthma.