

Speech and Humidification in Tracheostomies

Tala Habbab,^{1,2} Gayatri Paranjape,^{1,3} Allison Caron,^{1,2} Tahj Spigner,^{1,4} Rachel Kim,⁵ Gaurav Balakrishnan^{1,2}

Biomedical Engineering, Materials Science and Engineering, Chemical Engineering, Mechanical Engineering, Design - Carnegie Mellon University

INTRODUCTION

Background

- Tracheostomies are surgical procedures to relieve an obstruction to the airway¹
- 3 million patients currently live with tracheostomies in the US²
- Patients suffer from excess of mucus buildup in their tracheostomy tube caused by dry air

Problem

- There is no current technology that allows tracheostomy patients to speak while directly addressing humidification of breath.

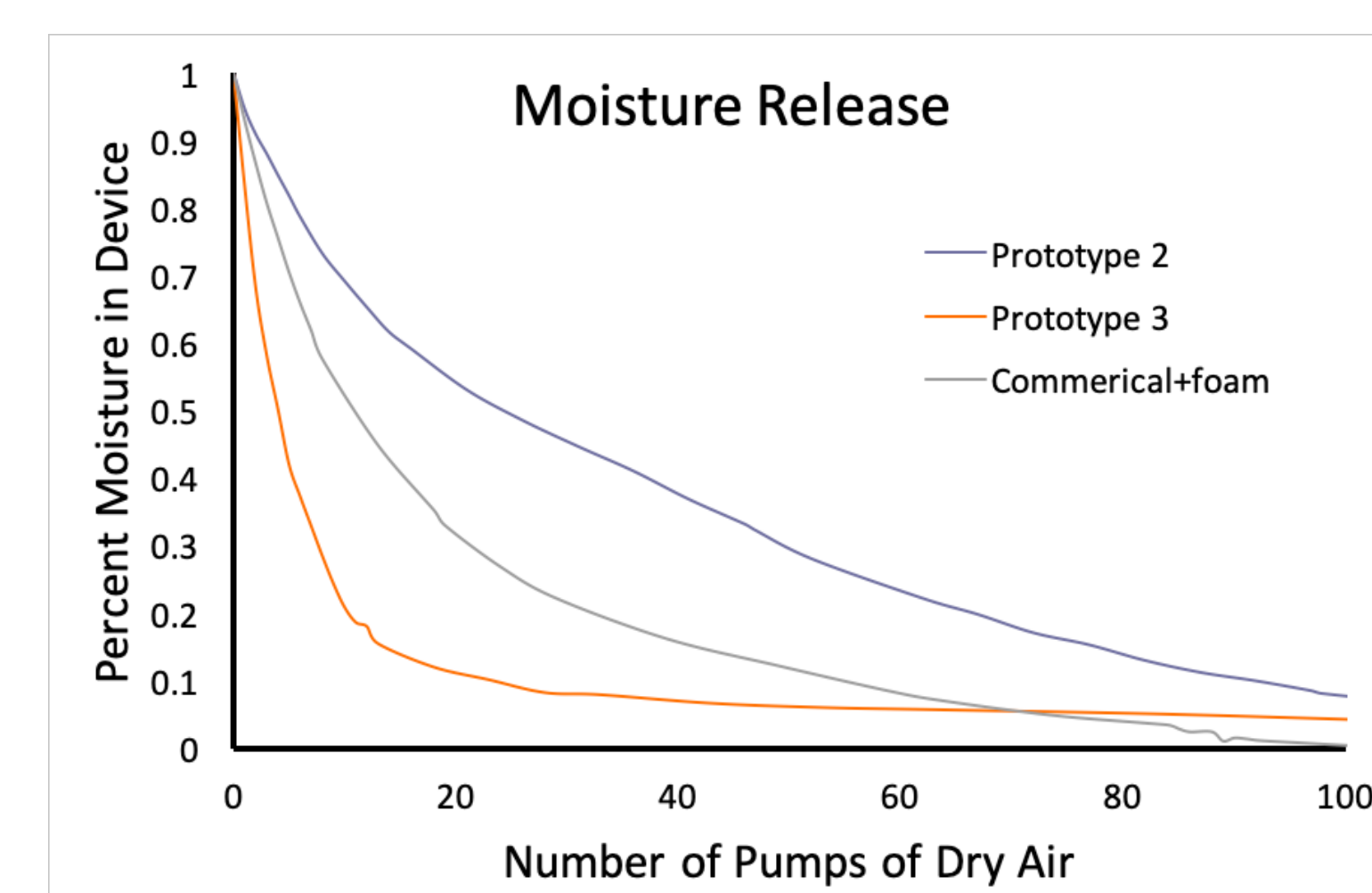
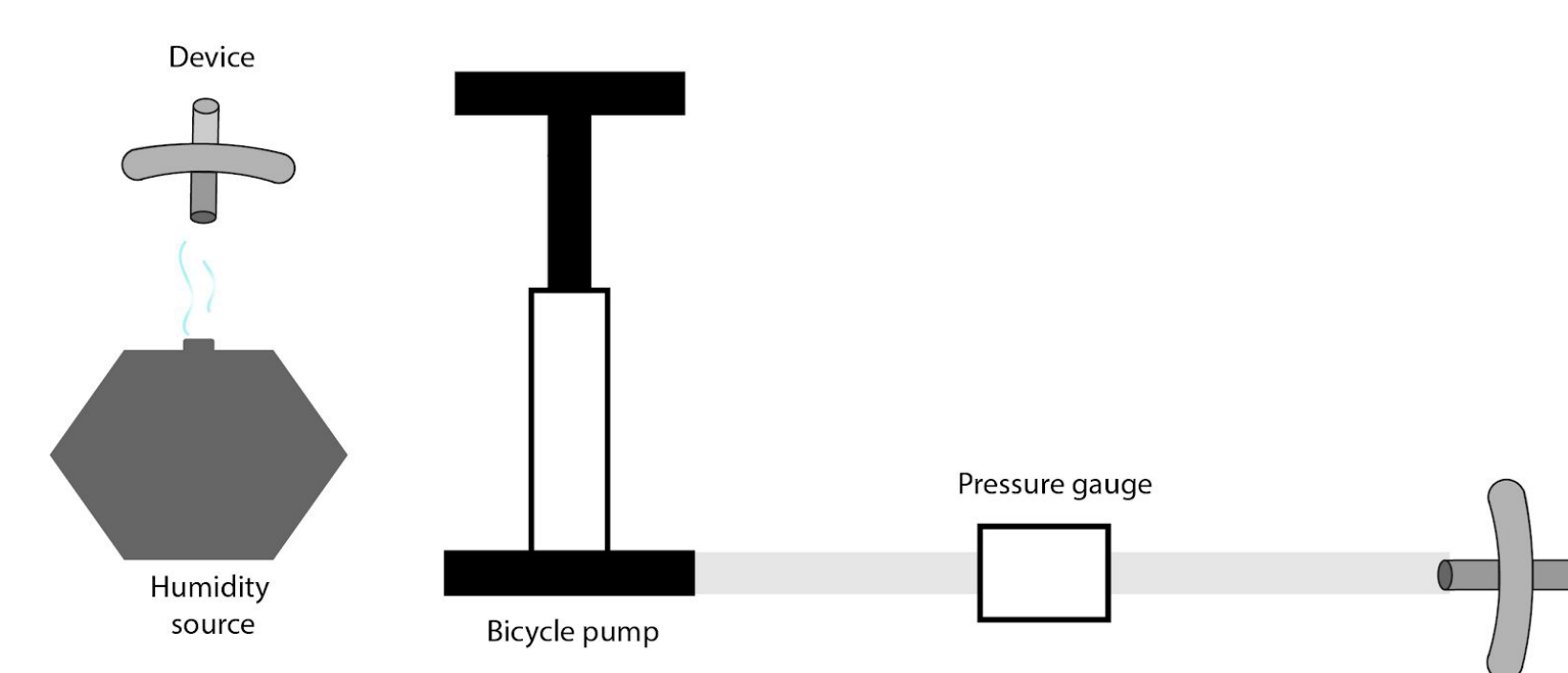
Need Statement

- A reusable device that allows tracheostomy patients the convenience of switching between speech and humidification, while maintaining low risk of infection.

Current Solution



MOISTURE RELEASING TESTING



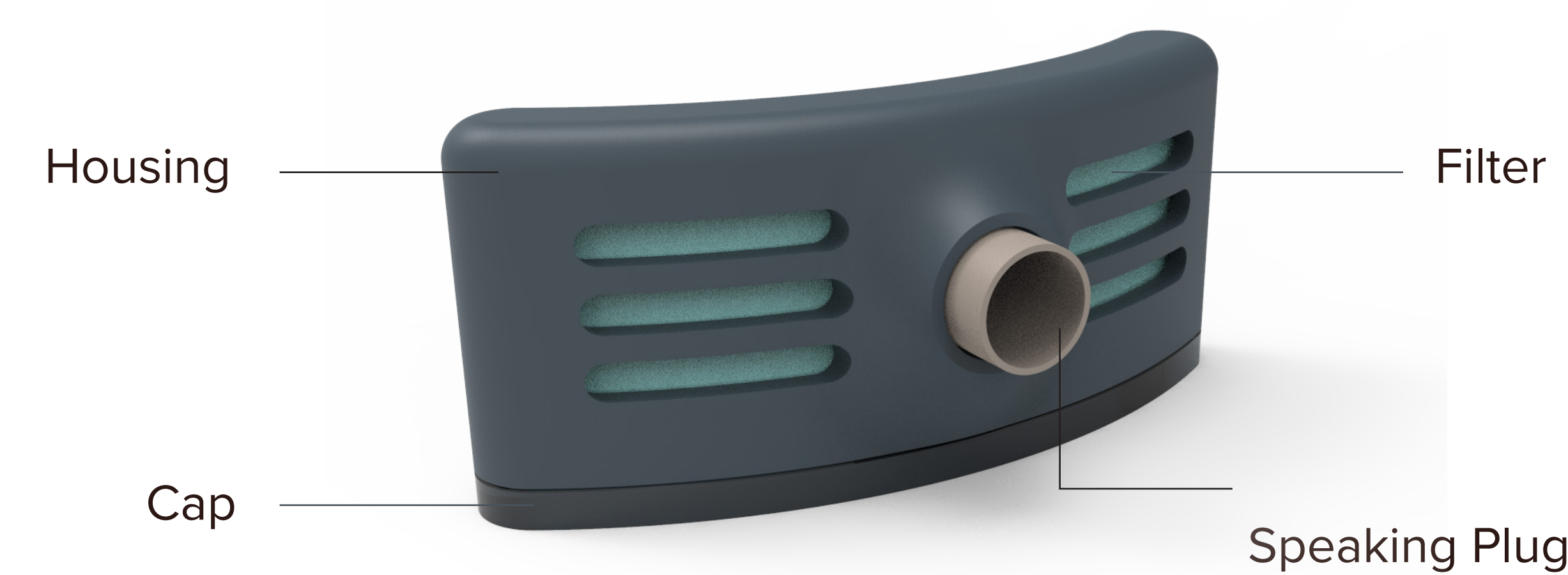
Methods

- Multiple pumps of air travel through the filter, releasing moisture from device.
- Commercial HME and several prototypes were tested using this method.

Results

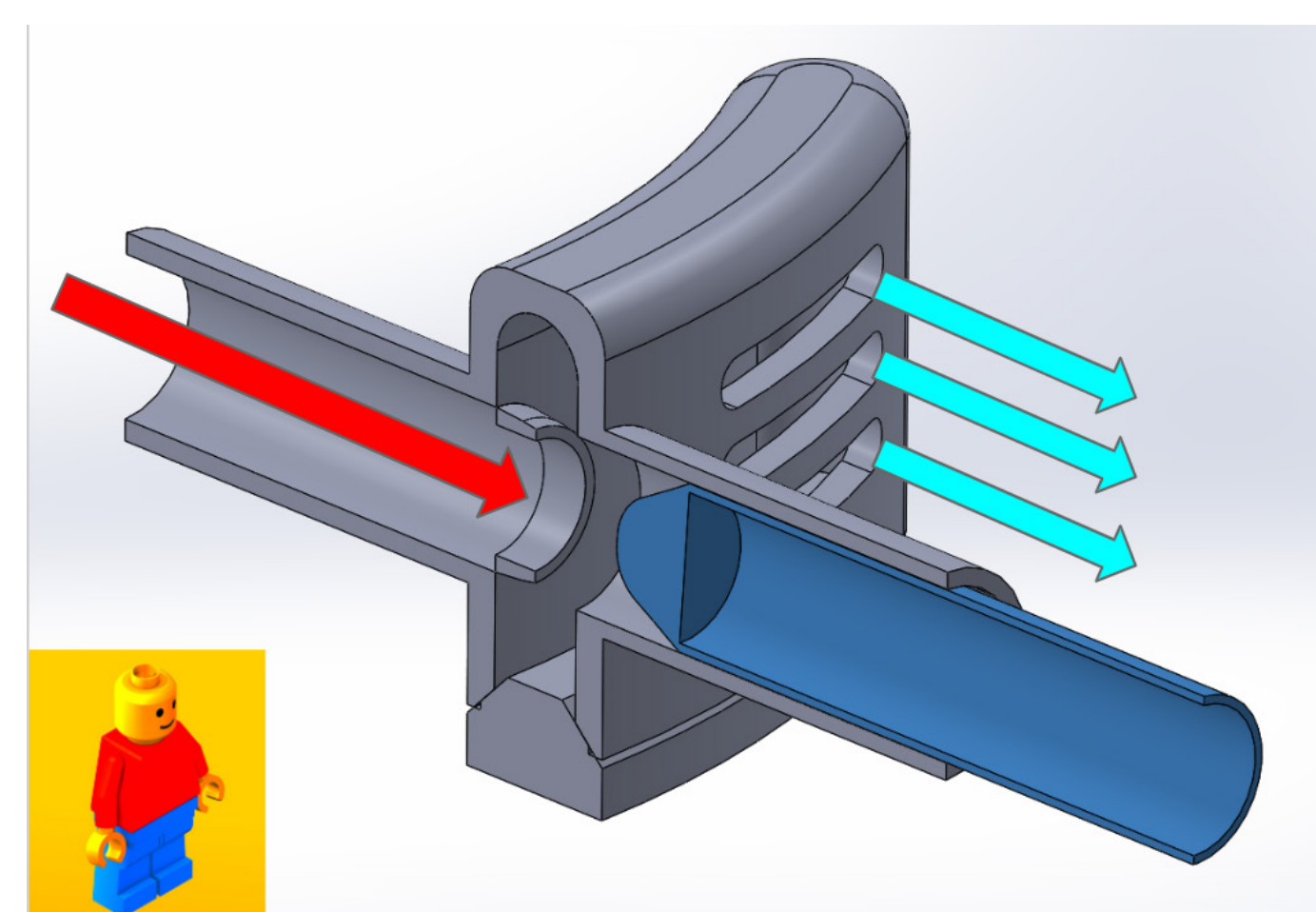
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PROPOSED SOLUTION



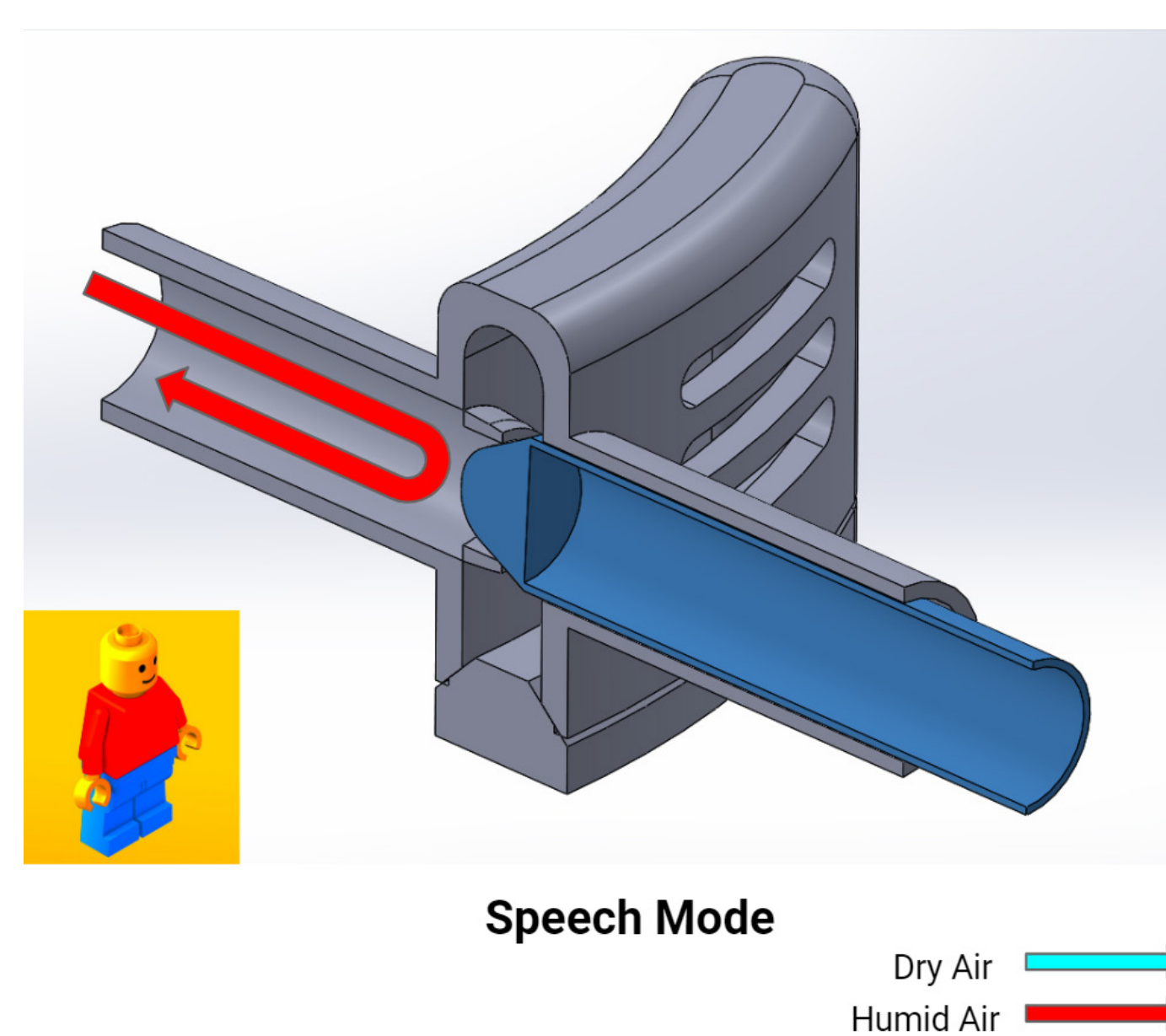
Final Design

- Features a sleek and portable design inspired by the natural profile of the human neck, gently curving to reduce its outward profile.
- Speaking plug allows for modification of resistance in cases of heavy breathing, such as walking up a flight of stairs.



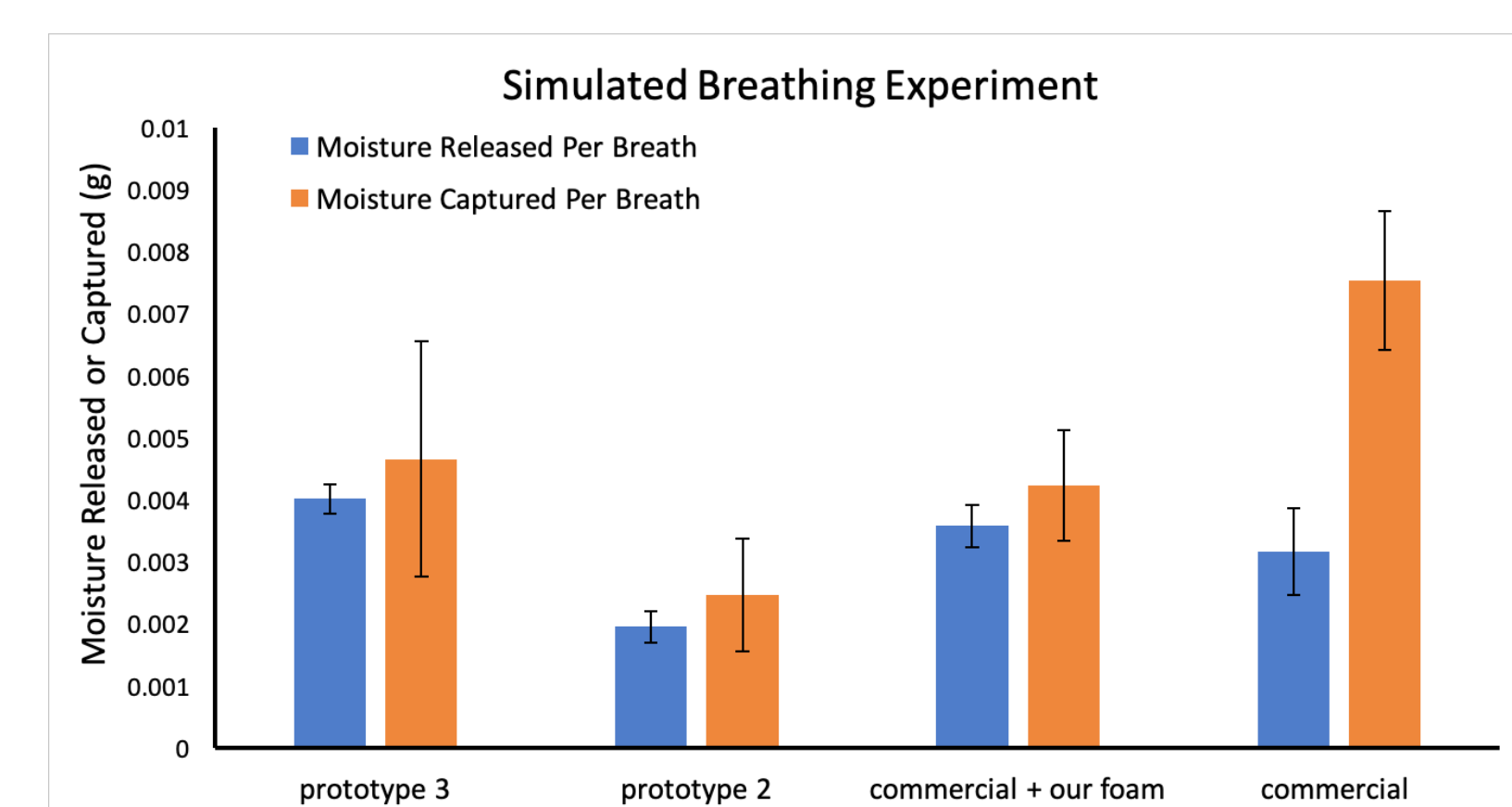
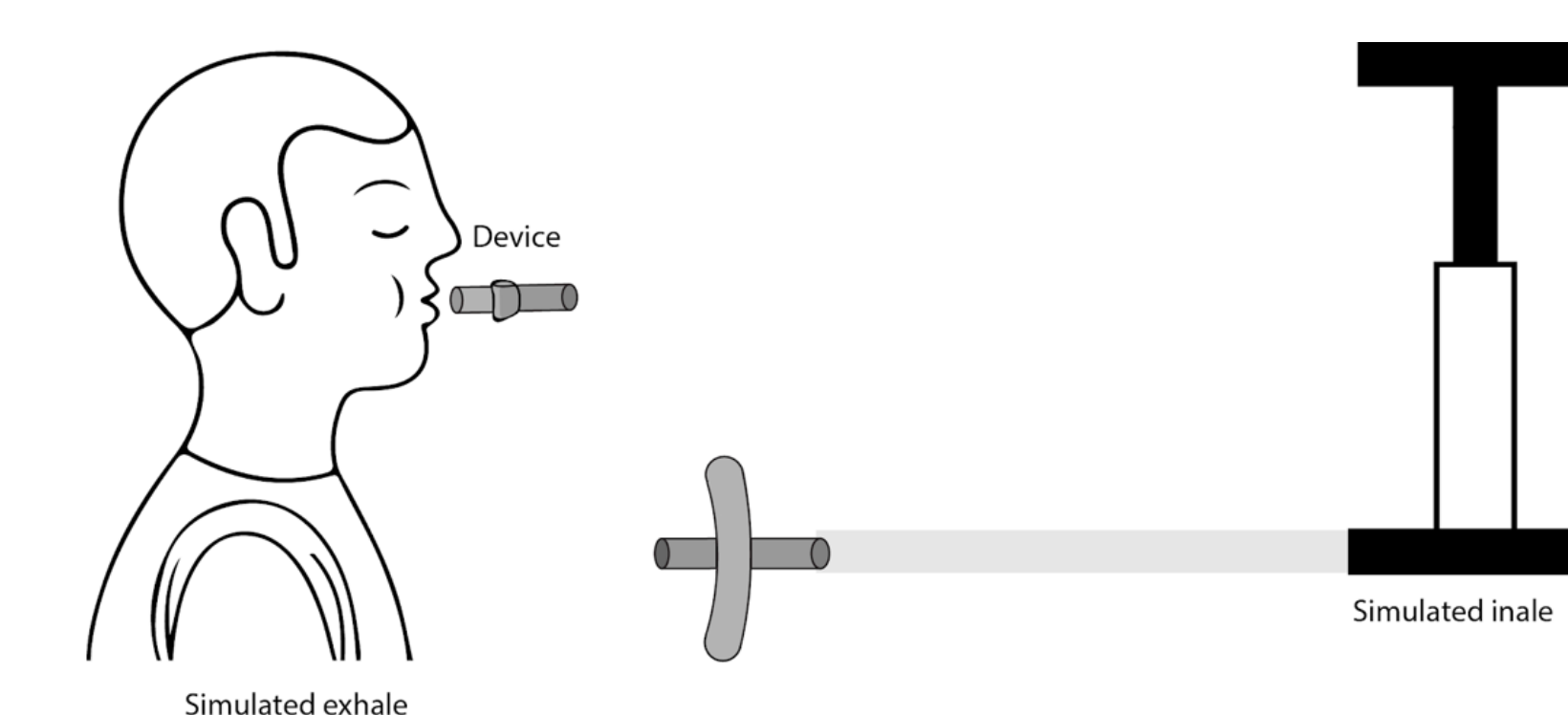
Humidification

- Humidifies inhaled air by capturing moisture from exhaled air in hygroscopic filter.



- Speech mode activated through use of speech plug.
- Manually activated by pushing into the device, allowing air to travel over vocal cords.

SIMULATED BREATHING TESTING



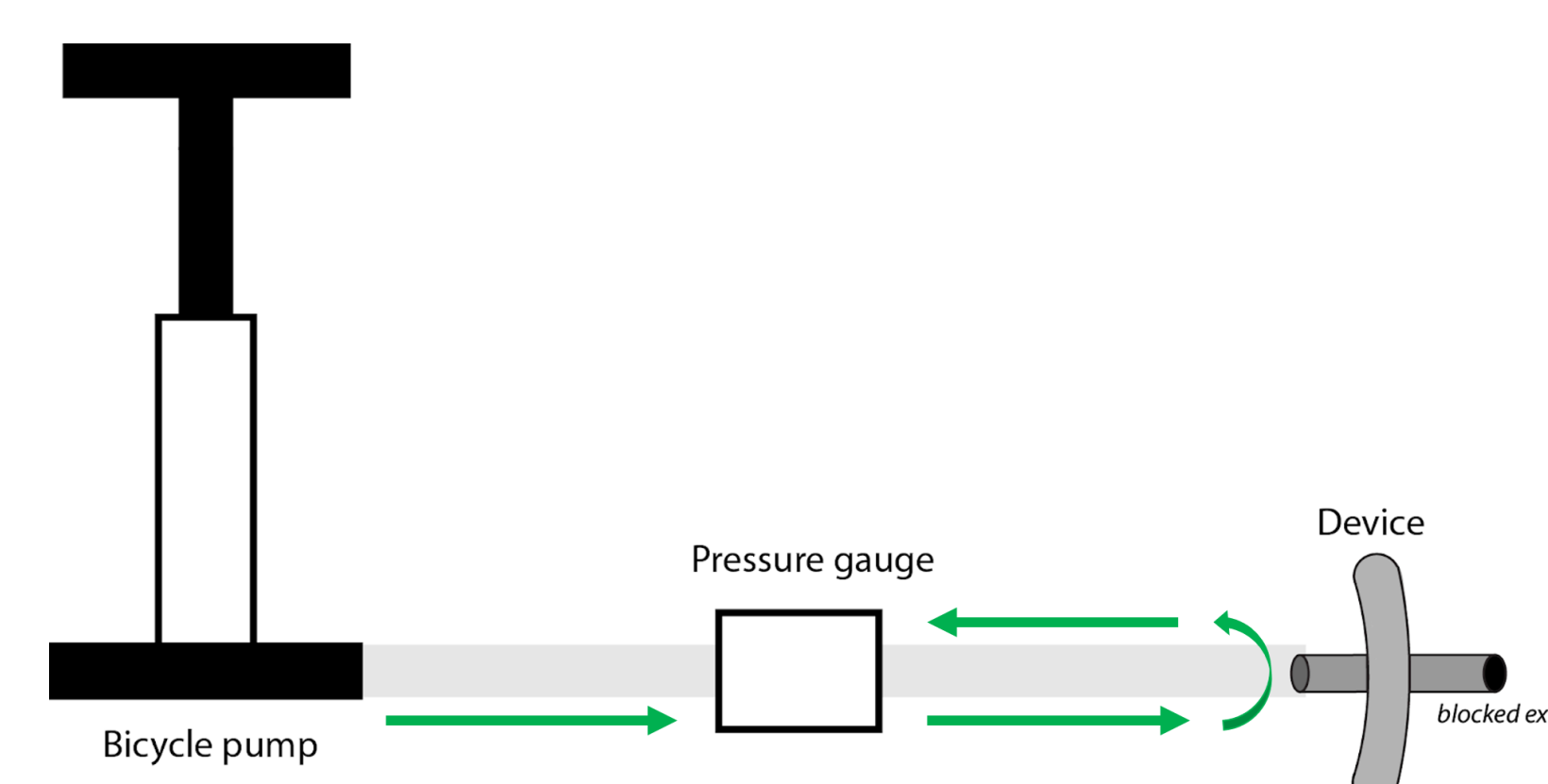
Methods

- Experimental set-up of simulated breathing shows function of device under normal conditions.
- Commercial with foam, commercial, prototype 3, and prototype 2 were tested using this method.

Results

- Prototype 3 has the most efficient form factor in capturing and releasing humidification.
- Commercial device with its own foam is better at capturing moisture but not as good at releasing moisture.
- Prototype is a better form factor than the current devices on the market.

SPEECH CAPABILITY TESTING



Methods

- Testing was done to confirm speech capability by mimicking airflow in natural airway.

Results

- If pressure increases at the gauge, the patient would be able to speak
- By performing this test, speech mode activation was confirmed (shown in video)

MANUFACTURING COST, MARKET ANALYSIS, PATENT, REIMBURSEMENT

Manufacturing Info

	ABS Plastic (LBS)	Unit-Device Yield	Unit-Device Mfg. Cost
Small Scale Mfg.	2	73	\$3
Large Scale Mfg.	2,000	73,337	\$0.005

Retail Info

	Est. Retail Cost/Unit	Est. # Units Required / Year	Est. Annual Cost
Commercial/Existing	\$2	730	\$1,460
Team 9	\$10	12	\$120

*Team 9 Pricing discloses labor, shipping, and filter pricing.

- 510(k) clearance would be most appropriate regulatory pathway for device.^{6,7,8}

Patentability

- Patent pending for this invention.
- Non-obvious as a result of slitted form factor, speech plug activation, multiple modes of adaptability.

Reimbursement

- Price of device is comparable to those currently on the market and promises a longer-term of function, it should be covered under Medicare/Medicaid.^{9,10}
- Estimated \$150/month saved by reducing amount of devices needed per month by ~80%.

CONCLUSIONS

- In comparison to current devices and previous prototypes, our final design was found to be more effective at humidification of air and successful at allowing speech.
- This prototype can significantly improve the quality of life of millions of people by reducing the need for frequent suctioning and allowing patients to easily switch between speech and humidification modes of operation.
- Provisional patent filed.
- Future work includes implementing a gasket material into the prototype and designing a manufacturing procedure for a sturdier prototype.

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