

1Haler: The Pocket Rescue Inhaler Revolutionizing Asthma Care

Taylor Agnello^{*1}, Laura Alderfer^{*2}, Chantel Charlebois^{*2}, Stephen Choi^{*3}, and Melissa Mendoza^{*2}

^{*}All authors contributed equally

¹Department of Industrial and Systems Engineering, ²Department of Biomedical Engineering, ³Department of Mechanical Engineering, Rochester Institute of Technology (RIT), Rochester, New York, 14623

Abstract

Asthma is a chronic respiratory disease in which airways become inflamed, narrowed, and swollen, making it difficult to breathe. It is estimated that as many as 334 million people are affected by asthma globally [1]. In the United States alone, about 25.7 million people have asthma, which translates to 1 in 12 people [2]. Asthma prevalence and severity is highly connected with poverty, city air quality, indoor allergens, not enough patient education, and poor health care [3]. While there is no cure for asthma, it can be controlled with proper prevention and treatment. The most common treatment for this medical condition is utilizing an inhaler either daily (maintenance) or for emergency asthma attacks (rescue) [2]. Based on Ganguly et. al, it was reported that asthmatic patients chronically use their inhaler incorrectly. The research study with 31 patients using dry-powder inhalers demonstrated misuse ranging from 45% to 84%, even after showing patients how to use the devices [4]. The most prevalent impedance to proper prevention and treatment is the lack of access to inhalers due to cost, low-compliance and improper-use. Figure 1 demonstrates the current prototype for the novel device that contains three doses of albuterol sulfate asthma medication. The dimensions emulate the size of a credit card, making it convenient to carry in a pocket.



Figure 1. Device Design (A) Closed device (B) Open device with removable sealant doses

Given that this device will use a different dry-powder drug-delivery method than inhalers used on the market,

validation of the product's efficacy is vital to patient safety. As detailed in U.S. Pharmacopeia 29, all inhalers must undergo the Delivered-Dose Uniformity testing to ensure that patients will receive the target-delivered dose. Following these guidelines, a similar model was built as shown in Figure 2 to determine the content of active ingredient emitted from the mouthpiece of the built dry powder inhaler [5].

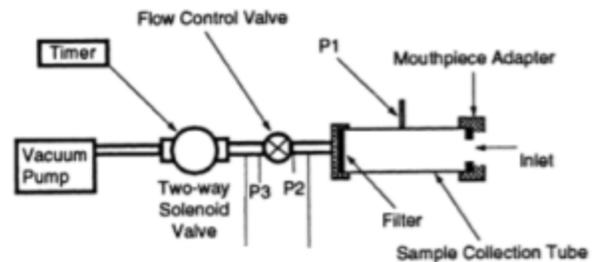


Figure 2. Sampling apparatus for dry powder inhalers model from US Pharmacopeia specifications [5].

A general full factorial design in Minitab Statistical Software was used to determine the number of trials needed to gain statistically significant results. As this project is still in progress, there are no current results from the testing apparatus. Current progress is also underway to survey patients under Rochester Institute of Technology Institutional Review Board to ensure that design is both convenient and easy to operate with pictorial instructions and a demonstration video. Potential markets include those who incorrectly use their inhalers, those that infrequently use inhalers and are looking for a cheaper emergency device, those in low income settings, and those that may desire to keep multiple inhalers in different locations for convenience. There is currently no intellectual property protection for this product; however, the team has discussed patent options with guidance from The Simone Center for Innovation and Entrepreneurship at RIT. Overall, the main goal for this novel device is to reduce cost, increase patient compliance, and increase convenience for inhaler users globally.

Acknowledgement

This material is based upon work supported by the National Science Foundation Innovation-Corps grant through The Simone Center for Innovation and Entrepreneurship at Rochester Institute of Technology. Authors acknowledge the support and guidance from Michael Zona and the Kate Gleason College of Engineering Multidisciplinary Senior Design program. Authors also acknowledge Mary Parkes Asthma Center at University of Rochester Medical Center in Rochester, New York.

References

- [1] Global Asthma Network and International Union Against Tuberculosis and Lung Disease. The Global Asthma Report 2014: Global Burden of Disease Due to Asthma, 2014.
- [2] Centers for Disease Control and Prevention, Asthma in the US Vital Signs, May 2011.
- [3] Centers for Disease Control and Prevention, US Department of Health and Human Services. Trends in Asthma Prevalence, Health Care Use, and Mortality in the United States, 2001–2010. NHCS Data Brief, no. 94, May 2012.
- [4] A. Ganguly, A. K. Das, A. Roy, A. Adhikari, J. Banerjee, and S. Sen. Study of Proper use of Inhalation Devices by Bronchial Asthma or COPD Patients Attending a Tertiary Care Hospital. J Clin Diagn Res, Oct 2014.
- [5] U.S. Pharmacopeia 29. Metered-Dose Inhalers and Dry Powder Inhalers. <601> Aerosols, Nasal Sprays, Metered-Dose Inhalers, and Dry Powder Inhalers. April 2014.