

RunBud

A wearable fast-acting inhaler with Apple watch and mobile applications

by

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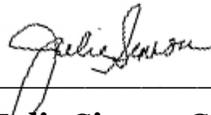
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Abstract

The purpose of my product RunBud is to combine a wearable fast-acting asthma inhaler with Bluetooth technology and mobile and watch applications to track inhaler usage including the exact mileage point(s) the user administers the inhaler. These usage details, along with the day's temperature, humidity level and pollen count will be available as daily, weekly and monthly downloadable reports. Users will be able to determine the best days to run based on these reports. The mobile and watch applications will track activity like distance, time and blood oxygen levels during the user's run. The asthma medication comes in a canister that sits inside of an actuator that has a mouthpiece from which the medication is inhaled. The canister is easily removed from the original actuator and placed into the RunBud wearable inhaler.

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| | |
|---|-----------|
| RunBud | 1 |
| Table of Contents | |
| Introduction | 4 |
| Rationale | 5 |
| Research Questions | 7 |
| Literature Review | 7 |
| Medical Research | 7 |
| Defining Asthma | 7 |
| Benefits of Managing Controlled Asthma | 8 |
| Defining Exercised-Induced Asthma | 10 |
| Common Responses | 13 |
| Product Research (Medical) | 14 |
| Fast-Acting Inhaler Types: MDI verses DPI | 14 |
| Fast-Acting Inhaler Types Currently on the Market | 16 |
| Wearable Medical Devices for Asthmatics Currently on the Market | 17 |
| Wearable Fast-Acting Inhalers for Physical Activity | 19 |
| Product Research (Fitness) | 19 |
| Features of Popular Activity Trackers/Sports Watches | 19 |
| Wearable Tech Market Reports | 22 |
| Interview | 23 |
| Dr. Jody Tversky, Allergy and Clinical Immunology | 23 |
| Target Audience/Personas | 25 |
| Methodologies | 26 |
| Branding | 28 |
| Mood Board | 28 |

| | |
|--|-----------|
| RunBud | 2 |
| Product Name and Tagline | 28 |
| Logo | 29 |
| Print and Web Typefaces | 29 |
| Colors | 30 |
| Icons | 30 |
| Packaging | 31 |
| Delivery | 31 |
| Initial Identified Limitations | 31 |
| How RunBud Evolved | 32 |
| 3D Prototype | 33 |
| Mobile and Watch Applications | 34 |
| Informational Video | 38 |
| Website | 38 |
| Outcome | 39 |
| My Personal Reaction | 39 |
| RunBud Testing Report Summary | 40 |
| User Testing Feedback (Asthmatic) | 40 |
| User Testing Feedback (Non-Asthmatic) | 42 |
| Revisions to Mobile and Watch Applications After Testing | 43 |
| Areas for Product Expansion | 44 |
| Next Steps | 45 |
| Appendix A – Target Audience/Personas | 46 |
| Appendix B – Final Logo | 49 |
| Appendix C – Icons | 50 |

| | |
|--|------------|
| RunBud | 3 |
| Appendix D – Athletic Common Colors Research | 52 |
| Appendix E – Mood Boards | 53 |
| Appendix F – Packaging Design | 54 |
| Appendix G – How RunBud Evolved | 55 |
| Appendix H – 3D Prototype Breakdown | 56 |
| Appendix I – Mobile and Watch Applications | 58 |
| Appendix J – Downloadable Report | 59 |
| Appendix K – Video Script and Storyboard | 60 |
| Appendix L – Final Informational Video | 68 |
| Appendix M – RunBud Project Website | 78 |
| Appendix N – IRB Research Certificate | 79 |
| Appendix O – Preliminary Product Survey Consent Form | 80 |
| Appendix P – Preliminary Product Survey Questions/Responses | 82 |
| Appendix Q – Preliminary Product Survey Testing Video | 89 |
| Appendix R – Secondary Product Survey Consent Form | 93 |
| Appendix S – Secondary Product Survey Questions/Responses | 94 |
| Appendix T – Secondary Asthma Product Testing Website | 105 |
| Works Cited | 107 |

Introduction

In fifth grade, my love for running came and went quickly due to my limited supply of oxygen. I remember the gym class one beautiful spring afternoon that I went outside to run a lap. I decided it was the day I was going to give running my all. My gym teacher blew the whistle, and my classmates and I were off! To my surprise, halfway around the field, I was in the lead—then I just stopped because I had an asthma attack. I went to the nurse to take my fast-acting inhaler. Needless to say, I came in last in the race. After that day, I avoided physical activity for a couple of decades. In my early thirties, I started working out at a local gym. Within two years, my walking turned into running on the treadmill. In the fall of 2011, I ran my first 5K, and never stopped or walked once. After that, I was hooked. Through it all, I have always had to keep my asthma issues front and center. I control my asthma the best I can by taking two inhalations of asthma medication 5 to 10 minutes before a race starts, and I always carry my inhaler with me. However, since I started running, I have wished for a wearable fast-acting inhaler product that was less bulky and easier to transport during my races.

I decided to develop this product when I began running road races. My everyday fast-acting inhaler is inconvenient to carry on long runs due to its awkward shape and large size. To accommodate carrying my inhaler and car key securely, I found myself purchasing more expensive running pants that have a zippered pocket in the back of the waistband. However, it is difficult to get my inhaler in and out of my pocket during a run. Another issue is that the inhaler cannot lay flat, so it juts into my lower spine and causes discomfort.

The purpose of my product RunBud is to combine a wearable fast-acting inhaler with Bluetooth technology and mobile/watch app to track inhaler usage including the

exact mileage point(s) the user administers the inhaler. These usage details, along with the day's temperature, humidity level and pollen count will be available as daily, weekly and monthly downloadable reports. Users will be able to determine the best days to run based on these reports. The mobile/watch app will track activity like distance, time and blood oxygen levels during the user's run. My product will include 3 components; the Apple mobile/watch app and the wearable inhaler. The asthma medication canister can be easily removed from the original actuator and placed into the RunBud wearable inhaler.

Through the research I have conducted, only a few wearable inhalers exist. However, none combine a fast-acting inhaler with an Apple watch and mobile application with tracking applications. My findings and research are important because this product will simplify the physically active lifestyle of many adults and athletes with asthma. The problem my research intended to solve is to meet the need for a convenient, wearable fast-acting inhaler with Apple watch and mobile application with the ability to track inhaler usage, asthma symptoms and triggers and blood oxygen levels during a run.

Rationale

Over the past few decades, asthmatics have become more involved sports than in previous decades. With advancements in medications and knowledge of environmental triggers and how to control asthma, asthmatics have more freedom to participate in physical activities, largely without incident.

Avoiding asthma symptoms during physical activities does take some preparation prior to exercise and could require attention during exercise. Warming up ten minutes

before exercising with a fast walk or high-intensity intervals has helped some asthmatics experience a two-hour symptom-free window. A warmup in combination with using a fast-acting inhaler five to ten minutes prior to physical activity may also reduce symptoms up to two hours because the medication relaxes the muscles that surround the airway, allowing the airways to open up. If an asthmatic is exercising outside on a day with poor air quality or high pollen count, this may also trigger asthma symptoms (O'Brien). Having a solid understanding about environmental irritants and how they can impact physical activity, even after warming up and using a fast-acting inhaler, will greatly benefit the individual with asthma. It is very important that asthmatics always carry a fast-acting inhaler because symptoms may arise at any time. This could mean the difference between life or death, depending on the severity of the asthma symptoms.

After examining literature on medical and product research, my project is uncommon because it combines a few very important tools that do not currently exist as one product on the market to make an asthmatic successful during physical activity.

My project is important because a wearable fast-acting inhaler with Apple watch and mobile application to track inhaler usage and environmental triggers will simplify the lives of physically active asthmatic adults. The wearable product will make engaging in sports activities easier by: (1) providing a fast-acting inhaler that is easy to inhale on the move, (2) being less cumbersome, (3) tracking simple sports-related tasks such as distance and time, (4) tracking daily environmental irritants such as pollen count, humidity level and temperature, (5) tracking inhaler usage during the run, (6) tracking asthma symptoms after the run and (7) showing blood oxygen level averages per mile ran. My wearable fast-acting inhaler with Apple watch and mobile application cannot cure asthma, but it will benefit many adults and athletes with the disease.

Research Questions

1. How can a wearable fast-acting inhaler with technology featuring a sports watch and activity tracking and climate monitoring mobile application benefit the market—technologically and medically?
2. What are the most effective environmental tracking device technologies on the market to benefit my product development?
3. What design elements are necessary to develop an effective wearable inhaler product for asthmatics during physical activity?

Literature Review

This literature review discusses the existing scholarship in both the medical and product research areas which relate to asthma. This research advances a product design solution for my wearable fast-acting inhaler with Apple watch and mobile application to promote and support the importance of controlling asthma while involved in daily physical activities and tracking related environmental issues, inhaler usage, asthma symptoms and blood oxygen levels during the run. The absence of a product like this on the market affects physically active adults and athletes with asthma because the disease is not only exercise induced but it is widely triggered by environmental issues such as humidity levels, pollen and mold counts, etc.

Medical Research

Defining Asthma

Asthma is a chronic inflammatory disease that makes breathing difficult and causes inflammation and temporary narrowing of the airways that send oxygen to the

lungs (Dryden 36). Approximately 300 million people worldwide suffer from asthma. The most recent studies show that asthma in 2017 affected 7.8% adults in the United States in comparison to affecting 7.6% in 2001. Allergens and exercise may cause swelling of the airways and trigger symptoms such as decreased oxygen intake, chest tightness, wheezing, coughing and thick mucus. Asthma may be deadly if not properly controlled and monitored during exercise (“Asthma Facts and Figures”).

It is difficult to pinpoint the exact causes that trigger an asthma attack, but the environment can be a significant culprit. For asthmatics, one or more of the following triggers may lead to an attack: exercise, air pollution, mold and mildew, cold temperatures, dry air, smoke, feather bedding, dust mites, cockroaches, animal dander or saliva, respiratory infections or colds and emotional stress or excitement (Holland).

Benefits of Managing Controlled Asthma

Understanding the definition of asthma, what triggers it and to how to control it, are essential to properly managing the disease. Dr. Tyra Bryant-Stephens, M.D., and Caroline West, MPA, both from The Children’s Hospital of Philadelphia, Philadelphia, PA, conducted a study on 76 families with children whose asthma led to frequent emergency room visits. The study showed that, following hospital discharge, these children went back into environments that lacked care coordination in poorly-resourced environments. Providing awareness of how to manage asthma care by practice-based asthma navigators improved asthma control for the children and young adults (Bryant-Stephens). The results from this study showed that asthma education, care coordination resources and proper use of asthma inhalers reduced emergency room visits.

This area of scholarship is important in my project because it examines how controlling asthma allows for the individual to participate in physical activities more often without a major incident. According to Katie M. Buston and Stuart F Wood, contributors to the medical journal *Family Practice*, “Asthma is a substantial health problem among children and adults. Optimum drug treatment and good care can convert it from a major handicap to a minor inconvenience, yet it continues to be an important cause of morbidity and mortality (Buston).” Patient self-management on a day-to-day basis is extremely important if the asthmatic wants to maintain a “normal” lifestyle, which includes physical activities such as running, biking, hiking, and other sports-related exercise.

However, when we look at the benefits of controlling asthma with medicine and the environment, we understand how these benefits enhance the physical activity level for the asthmatic. *The Importance of Physical Exercise Training in Asthmatics*, a journal article written by Alain Varray, Ph.D. and Christian Prefaut, M.D., suggests that asthma patients benefit from physical exercise. Years ago, sports activity was avoided in the asthmatic community because exercise-induced bronchospasm was thought to be an exacerbation of the disease (Varray 1992). In 1984, RO Voy conducted a study that included 67 asthmatics on the United States Olympic team. The resulting figure corresponds to the total percentage of asthma patients in the United States population. An impressive 61% of the Olympic asthmatics have won medals (Voy 1984).

To effectively manage asthma, for non-professional athletes, an exercise recommendation of approximately 30 minutes, 4 times a week at 60% to 85% of the maximum heart rate will greatly improve lung function. Improved physical activity reduces airway reactivity and medication use (Disbella). Dr. Vincent N. Disabella, DO,

FAOASM, Double Board Certified, Fellowship Trained Primary Care Sports Medicine Physician, states, “The capacity to exercise, however, requires good general control of asthma, including use of inhaled corticosteroids and avoidance of triggers. In addition, patients must be taught to prevent exercise-induced bronchoconstriction by using inhaled medications and strategies like avoiding cold-weather exercise.” Asthmatics who practice techniques to help control asthma show improvement during physical activities. However, no techniques are foolproof.

Defining Exercised-Induced Asthma

Regular physical activity is encouraged, but there are a few drawbacks asthma patients must consider and understand. The term EIA (exercise-induced asthma) is derived from airway obstruction following exercise among patients with underlying asthma issues. The term EIB (exercise-induced bronchoconstriction) refers to post-exercise asthma-like symptoms observed particularly in athletes who do not have pre-existing asthma (Dryden). Dr. Moira Chan-Yeung, says the severity of airway constriction during exercise is associated with the level of ventilation. With normal nasal breathing, inhaled air heated to the body temperature is entirely saturated with water in the initial airway branches. However, there is an increase in minute ventilation (volume of air that can be inhaled or exhaled during one minute) during and after strenuous exercise. The nose is unable to adapt to the increased volume of air. The downside to both EIA and EIB is that the acute airflow obstruction rapidly spikes 3 to 15 minutes after exercise stops and may remit immediately 20 to 60 minutes later. The severity of episodes varies among individual asthma patients due to multiple factors. Dryden states 60% to 90% of asthmatics considered exercise to be a major cause of their asthma

attacks (Dryden). Below is a chart that highlights the factors that influence the severity of asthma symptoms such as environment, duration of exercise, overall control of asthma and physical health, current respiratory infections, time since last exercise activity, concurrent medications and common allergen foods eaten before physical activity (Dryden) (see fig. 1).

| Factor | Decrease EIB/EIA | Increase EIB/EIA |
|--|--|---|
| Environmental conditions | Warm temperatures (34-37° C) ¹²⁴ High humidity (100%) Absence of allergens Low air pollution | Cold temperatures, dry air ^{124,125} Airborne particles and pollutants, allergens, moulds, dust Irritants: automobile exhaust, sulphur dioxide, nitrogen dioxide, smoke, ozone, ¹²⁶ chlorine ¹²⁷ |
| Type, intensity, duration of exercise | Short episodes of fast/slow running with brief rests ¹²⁸ VO ₂ max <40% predicted ¹²⁹ <3 minutes continuous exercise | Continuous activities that require near maximum aerobic capacity VO ₂ max ≥60% predicted 6-8 minutes continuous exercise |
| Overall control of underlying asthma and BHR | Good control: FEV ₁ >70% predicted Fall in BHR ¹³⁰ | Poor control: FEV ₁ <65% predicted Increase in BHR ¹³⁰ |
| Physical conditioning | Good physical conditioning Warmup and cooldown sessions | Poor physical conditioning Sudden burst of activity Fatigue ¹²⁶ Emotional stress ¹²⁶ Athletic overtraining ¹²⁶ |
| Respiratory tract infections, especially viral | No respiratory tract infections | Presence of respiratory tract infections ¹²⁶ Sinusitis ¹³⁰ Rhinitis |
| Time since last exercise | If within 40-90 min may benefit from refractory period ¹³⁰ | >2-3 hr |
| Concurrent medications | Maintenance anti-inflammatory bronchodilator medication | Salicylates, NSAIDS, β-blockers ¹³⁰ |
| Pre-exercise foods eaten | None | Peanuts, celery, shrimp, grain, carrots, bananas ¹³⁰ |

BHR = bronchial hyperresponsiveness

Fig. 1. EIB/EIA chart from: Dryden, Donna M. *Exercise-Induced Bronchoconstriction and Asthma*. US Department of Health and Human Services Agency for Healthcare Research and Quality, 2010.

Research shows exercise-induced asthma appears to affect children more than adults. Not all individuals with EIA develop post-exertional (worsening of symptoms) bronchospasm after demanding exercise. Physical activity induced air-way obstruction in asthma patients is associated with the bronchospasm of the large and small air passages, resulting in increased airway resistance (Dryden). According to Dr. Alfred Bove, M.D., Ph.D. at the Lewis Katz School of Medicine, intermittent activities such as baseball, football, weight-lifting and tennis were better tolerated than continuous physical activities such as running, soccer, boxing, cycling or basketball. (Bove). Additionally, contributing author Ken D. Fitch, for the journal article Specificity of Exercise in Exercise-Induced Asthma, researched the breathing function after running, cycling and swimming in 40 asthmatics and 10 with control subjects. Each activity was performed for 8 minutes. No control subject showed any significant breathing capacity after the physical activities. However, in uncontrolled asthmatics, EIA was observed after 72.5% of running tests, 65% of cycling tests and 35% of swimming tests (Fitch).

The scholarship highlighting the importance of using fast-acting inhalers before exercise helps stress that asthmatics' physical activity would be very limited without this medication. Dr. Alfred Bove, M.D., Ph.D. suggests that asthmatics use asthma inhalers or bronchodilators prior to exercise to prevent the occurrence of more severe asthmatic symptoms during physical activity (Bove). Fast-acting beta-2 agonists, such as albuterol, which is a quick-relief medication that belongs to a class of drugs known as bronchodilators, may be taken 5 to 10 minutes prior to the start of physical activity to control EIA and EIB symptoms, increasing airway responsiveness ("Albuterol Sulfate Inhalation"). Asthmatics should never be restricted from exercise in order to avoid triggering. Instead, asthmatics should follow an appropriate treatment regimen to

reduce the number of asthma occurrences. In fact, exercise will greatly improve physical activity tolerance because overall conditioning raises the exertion threshold for bronchospasm (Bove).

Common Responses

The benefits of managing controlled asthma are highlighted in an interesting study on athletes at the 2016 Olympics in Rio. The study published in *Respirology*, suggests that when asthma was well-controlled, breathing attacks were not a hindrance to athletic success (Levai, 2016).

Elite swimming and boxing require athletes to achieve relatively high minute ventilation. The combination of a sustained high ventilation and provocative training environment may impact the susceptibility of athletes to exercise-induced bronchoconstriction (EIB), according to Irisz Karolina Levai, MD, from the School of Sport and Exercise Science at the University of Kent in England, and her colleagues.

However, the prevalence of EIB was nine times higher in Olympic swimmers (68%) than boxers (8%) due to the differences in environments in which the athletes train. Levai and her colleagues state, “We attribute these findings to more demanding environmental exposures including the combination of pool chemicals and high respiration rate requirements while swimming.” Overall, asthma control was enhanced due to optimization of airway health (Levai).

Exercise is Associated with Improved Asthma Control in Adults, a journal article written by Shilpa Dogra and her colleagues, suggests a structured exercise intervention can improve asthma. Dogra and her colleagues conducted research over 12 weeks on

male and female (not pregnant) adults who were currently taking asthma medication and physically inactive. There was a significant improvement in asthma control and breathing quality in asthmatics who exercise regularly, because such activity reduces airway inflammation and increases asthma control (Dogra).

While previous research has concluded that exercise leads to improvements in medication use, the frequency of exercise-induced asthma and lung function, this study is the first to show that regular exercise participation can lead to a change in overall asthma control, Shilpa Dogra adds.

The findings in this scholarship support improved breathing control in asthmatics who have physically active lifestyles, take their medications regularly and use fast-acting inhalers before exercise and during, if needed.

Product Research (Medical)

Fast-Acting Inhaler Types: MDI verses DPI

Fast-acting inhaler types closely correlate with the importance of asthma control. This information is pertinent to my project because it defines which inhaler type is easier for an asthmatic to use. Professor, Dr. J van der Palen conducted a study on the adequacy of inhalation techniques among adult asthmatics using different types of inhalers. He tested three hypotheses: (1) asthma patients using only one type of inhaler demonstrated an adequate inhalation technique; (2) individuals using dry powder inhalers (DPIs) demonstrated correct inhalation techniques more often than those using a metered dose inhaler (MDI); and (3) some inhaler combinations are more prone to inhalation technique errors. Out of 208 asthmatics tested, 68% of those using the dry powder inhalers performed the inhalation techniques correctly versus the 54% of

asthmatics using the metered dose inhaler. The research concluded that DPIs are the most error-proof devices (Palen). The Diskhaler® is a DPI that has a cartridge filled with small blisters containing a medicine dose in each blister. The Diskhaler® punctures each blister by raising the device lid so the medication can be easily inhaled. The cartridge is replaceable with the Diskhaler® (see fig. 2). Another version of the DPI is the Diskus®. It features a built-in counter so the patient will know how many inhalations are left. To activate the medication, the user slides the lever until a click sounds. This device does not have a replaceable cartridge, and is thrown away monthly (“Diskhaler”) (see fig. 3). Another positive feature of DPIs is that they do not need to be shaken before inhalation.

Once the blister is open, the DPI is ready for immediate use (Palen). Dry powder inhalers are the most error-proof devices and will be considered in the design of my product prototype.



Fig. 2. Diskhaler® from: “Diskhaler.” *Asthma Canada*, 2018, www.asthma.ca/get-help/asthma-3/treatment/diskhaler/.

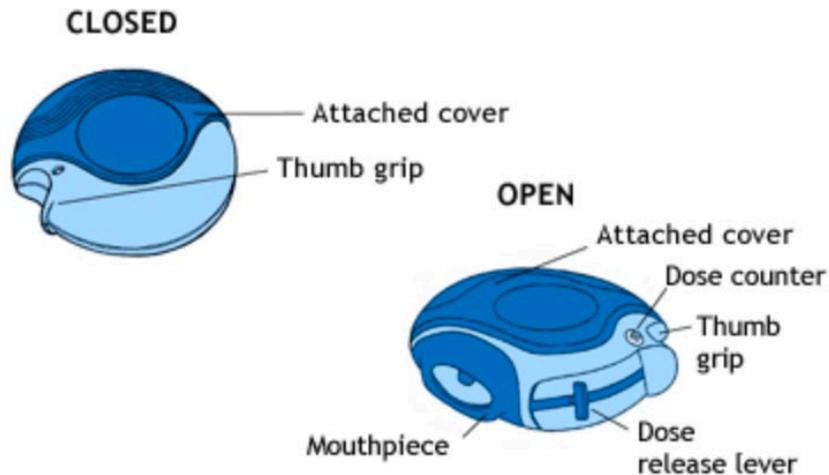


Fig. 3. Diskus® from: “Diskhaler.” *Asthma Canada*, 2018, www.asthma.ca/get-help/asthma-3/treatment/diskhaler/.

Fast-Acting Inhaler Types Currently on the Market

As I develop my project, I must keep abreast of what is currently on the market in the product/medical category for fast-acting inhalers so I do not develop something that has already been produced. Having insight into what products have been developed but didn't succeed is also a key factor in the success of my product. The most common types of fast-acting inhalers are beta-agonist bronchodilator. "Standard albuterol is probably one of the most frequently used beta-agonists," says Richard Honsinger, MD, a spokesman for the American Academy of Allergy, Asthma and Immunology. In 1980, the first beta-agonist, albuterol, was approved by the FDA under the trade name Ventolin. Also known as albuterol, Ventolin is marketed under other brand names such as ProAir

HFA and Proventil HFA. These are all albuterol sulfate inhalation aerosol inhalers (Hatfield).

In 2015, the Food and Drug Administration (FDA) approved the first fast-acting beta-agonist (SABA) albuterol sulfate inhalation powder under the trade name *ProAir RespiClick* from Teva (Brooks). The inhaler was released in the U.S. in late 2016 (“ProAir RespiClick”).

ProAir RespiClick is the first and only breath-actuated, dry-powder rescue inhaler to be approved by the FDA for the treatment of acute asthma symptoms.

ProAir RespiClick is significant as it eliminates the need for hand-breath coordination during inhalation, according to a company news release that quoted David I. Bernstein, M.D., from the division of immunology, allergy and rheumatology, University of Cincinnati College of Medicine in Ohio.

Additionally, through this scholarship, I have discovered the significance of eliminating asthmatics' need for hand-breath coordination during inhalation as this reduces the risk of misuse by eliminating the timing factor altogether.

Wearable Medical Devices for Asthmatics Currently on the Market

General “wearable” fast-acting inhalers are essential to my project. Despite the fact that the devices mentioned in this section are not specifically wearable or lack a patent, these devices reflect the thoughts and ideas of the asthmatic community.

Learning what asthmatics believe will make their daily lives better will help me develop my project. During my research, I reviewed many patents related to my project and found one that closely correlated to my project. Inventor Mark Garon (patent/publication #US6223744B1), patented his idea of a portable aerosol delivery

apparatus that can be worn by asthmatic who require fast-acting medical treatment. Aerosol delivery, metered dose inhalers (MDIs), have a few problems that Garon identified: (1) the usage technique is complex; (2) the MDI dosage canister is bulky; (3) once empty, the canister must be replaced; (4) MDIs are not convenient to carry; and (5) the plastic inhaler, cap and mouthpiece must be cleaned periodically to avoid clogs in the small opening. According to Garon's research of existing MDIs (reference is made to U.S. Pat. Nos. 5,404,871 and 5,655,516 issued to Goodman et al) that are actuated by the inspiratory effort of the user's breath, these inhalers release a dose when the inspiratory effort moves a mechanical lever to trigger a release valve. Unfortunately, aerosol delivery remains bulky for a wearable device, is expensive to manufacture and is in the testing stages (Garon).

Another "wearable" device for medicine bottles and asthma inhalers, from the startup company Amiko, will inform, alert and remind the asthmatic user to take the right dose of medication. It also alerts the user through a mobile application when medication is low. This is not a wearable device for asthmatics to access easily for their fast-acting medication during physical activity. However, the idea behind automatically collecting data about usage, helping asthmatics stay on track with their medicine and eliminating errors due to prescription timing and dosage is helping individuals get closer to controlling their asthma (Walker).

University of New South Wales design graduate, Katherine Kawecki developed a wearable patch that operates as an acoustics sensing monitor to detect respiration-related inflammation. The device gives the individual a haptic touch as soon as it detects the user becoming short of breath. The system also includes a "smart" fast-acting inhaler that connects to a phone via Bluetooth to track medication usage through a mobile

application (Charara). The technological advances in this area of scholarship help me understand what can and cannot work—thereby helping shape my project into a final prototype.

Wearable Fast-Acting Inhalers for Physical Activity

I have found two very remarkable capstone projects from the students at the University of Washington, in Seattle, and the College of Creative Studies, in Detroit, Michigan, that successfully present a fast-acting wearable inhaler for children and young adults. Tess Manthou, a student at the University of Washington, developed the Pod, a wearable fast-acting inhaler that children can wear as a clip, bracelet or necklace. The child-friendly design is both fun and fashionable and alleviates the social challenges kids face when taking their medications. The Pod has an associated mobile application that tells parents the location and time their child takes the fast-acting inhaler (Manthou). Muge Ozturk, a student at the College of Creative Studies, developed Breathy. This wearable inhaler allows children to access their inhaler quickly, but it not associated with a mobile application. The device uses the dry powder inhaler technology with the replaceable blister packaging. When the inhaler's nozzle is pushed upward, it punctures the blister to allow for one dosage to be inhaled (Ozturk). These wearable fast-acting inhalers most closely resembles my product.

Product Research (Fitness)

Features of Popular Activity Trackers/Sports Watches

The health benefits and accuracy ratings of the most popular tracking devices with mobile applications reveal that the step counting technology is important. The

consumer's preference for a sense of community/social element increases motivation for the successful physical activity of active adults and athletes with asthma demands. Allen G. Taylor, a lifelong runner, practitioner of a healthy diet and author of *Get Fit with Apple Watch, using the Apple Watch for Health and Fitness*, states:

The Apple Watch contains a comprehensive suite of built-in applications that perform many functions that people are accustomed to performing on their smartphones, enabling watch wearers to tailor their daily, weekly and monthly health and fitness programs to their own individual needs.

The common features of the Apple Watch are as follows: digital crown, retina display with force touch, heart-rate sensor, accelerometer, gyroscope, ambient light sensor, speaker, microphone, Wi-Fi (802.11b/g/n), 2.4GHz, Bluetooth 4.0, 18 hours of battery life and water resistance. According to Taylor, these sensors and communication features offer a variety of useful functions that may be performed by many mobile applications (Taylor).

Another popular activity tracker is Fitbit. David Cooper, a reporter with Sport360, states, "There are 4 key principles behind the Fitbit— successful piece of technology; features, practicality, software and design." One of the most striking features of the Fitbit technology is the ability for its internal accelerometer to track steps and activity with flawless accuracy. The practicality of the Fitbit is durability and a back light that ensures information is visible for individuals engaging in nighttime activities. A universal charging cable charges the Fitbit watch and synchronizes with the mobile application via Bluetooth. The software gives an analysis of the user's pace, heart rate, distance and calories burned. It also gives up-to-date information about step count and sleeping

patterns. The overall design of the Fitbit—part fitness band, part GPS watch—is both comfortable and fashionable with a high degree of analysis and functionality. The Fitbit is also water-resistant (Cooper).

The Garmin Vivofit4 is another popular activity tracker that has a surprising one-year battery life—unlike the Fitbit and Apple Watch that must be charged approximately every 18 hours. The downside to the Garmin Vivofit4 is that heart rate monitoring is not available. However, the device has other common features such as: water-resistance, time, date, timer, stopwatch, alarm clock, distance, calories burned, sleep patterns monitor and step counter. The device also comes with its own mobile application, Garmin Connect, to save, share, plan and get involved in social challenges with friends and family (Chowdhary).

Activity trackers that track user engagement, build awareness and help with management of asthma. According to Dr. Emil Chiauzzi, Ph.D., as activity trackers become more consumer-accessible, they will be used for patient engagement to follow activity in the management of chronic diseases, such as pulmonary rehabilitation among asthmatics. Engaging patients as advocates in their own activity monitoring builds awareness and offers physicians daily assessments of their patients' activity habits (Chiauzzi). On average, the user will have 700 more steps per day when friends and family share the same app. Recently, a new guidance tab was added to the Fitbit app. For example, if the user ran 5 or more miles, the app may suggest a workout session to rest the legs and concentrate on an abdominal exercises (Granziano). Wearing activity trackers promotes a sense of community/social element that increases motivation and is beneficial to an individual's overall health.

Wearable Tech Market Reports

Wearable tech market reports provide insight into market needs, which will help me develop my product(s) accordingly. In the article, “Small gains in fitness, brighter future possible,” Senior Technology Analyst Billy Hulkower reports that the adult population owning a fitness tracker or smartwatch grew by 4% from June 2016 to June 2017. The slow pace in consumer growth suggests fitness tracker devices may remain a niche product market mainly only appealing to people who are fitness enthusiasts and those with medical conditions. The issue with fitness trackers and smartwatches is that they contain many features smartphones already have, such as pedometers, GPS, email and text notifications, heart rate monitoring and sleep trackers to name a few. Hulkower suggests, “With each added health feature, a new group of users might be brought into the fold: for example, dieters, diabetics, and hydration measurement would appeal to distance runners.” In Q1 of 2017, the Apple Watch was the leading fitness device sold globally with 3.5 million units purchased. In the same time frame, fifty-one million iPhones were purchased (Hulkower).

Jeannette Ornelas, Social Media Analyst, mentions in her report, “Wearable Health and Fitness Trends,” that from August 2016 to August 2017, an online discussion involved 4 million mentions about wearable technology stressing the role of health. These online topics account for one-third of health-related issues (Ornelas) (see fig. 4).



Fig. 4. Wearable tech infographic from: Ornelas, Jeannette. *Digital Trends: Fall Social Media, US, September 2017*. Mintel, 2017, pp. 1–1, *Digital Trends: Fall Social Media, US, September 2017*.

Most fitness trackers perform all of the same duties, but vary in accuracy and certain features. However, in my research, none of the mobile applications tracked environmental issues that could widely affect asthma triggers in athletes and physically active adults.

I developed my wearable fast-acting inhaler with Bluetooth technology and mobile/watch application prototypes based on the literature review research presented. Additionally, I refined and redesigned my product based on further research and user testing.

Interview - Allergy and Clinical Immunology

I met with Dr. Jody Tversky, former Clinical Director, Allergy Clinical Practice and Assistant Professor of Medicine, at Johns Hopkins in February of 2019 to present my idea of the wearable inhaler with mobile and watch application. Dr. Tversky's most

important advice to me: “the first entry level step to designing a successful medical product is to initially design something that does not require high level FDA evaluation clearance. Identify a clear market and then design your product or device using existing technologies and/or items that have already been approved by the FDA.” This makes the process more palatable for those just getting into the biomedical design world. More advanced entrepreneurs or companies have the resources to tackle uncharted waters, more life-threatening disease processes and/or novel or invasive testing devices. During our discussion, I asked Dr. Tversky a few questions regarding the overall design and idea for asthmatic runners. He thought the product would be useful for asthmatic runners and he provided helpful feedback. He suggested building a prototype for initial testing to see if it’s a marketable item and to identify potential problems and opportunities. This testing would identify technical constraints as well. He stressed the importance of using dosing that pharmaceutical companies already use. Since a lot of the mobile application technologies that I planned to use in my mobile/watch application already exist, he suggested that I tap into other existing technologies from Apple or android marketplace and adapt them into my product.

Dr. Tversky is also a researcher and inventor. He shared with me the eight steps he follows when creating a new product. His eight steps are as follows: (1) Conduct pre-market research to identify problems and opportunities; (2) Determine technological validity to identify technical constraints; (3) Identify the steps to execute the early business model which involves contractual thinking; (4) Build a team with expertise to execute the plan; (5) Prototyping and customer discovery to identify the essential features needed; (6) Conduct a small pilot for users to test the product and give feedback, learn if the product is safe, and for the Institutional Review Board to conduct research

and the FDA to test and use surveys to gather patient information and data without actually holding the product; (7) Have users interact with the design and modify the product as needed; and (8) Develop a plan for funding – identify the market size, how much to produce, lead time, FDA restrictions, whether it works, and what your story is, and then reach out to investors.

Using Dr. Tversky's expert advice combined with my current research on MDI (metered dose inhaler) versus DPI (dry powder inhaler), I decided MDI needs to be used for my product. The MDI actuator, an easily replaceable component from the user's existing inhaler, will be easily removed and placed into the RunBud wearable inhaler that replicates the inside design of the asthmatic runner's existing inhaler canister.

Target Audience/Personas

I identified the target audience for my wearable fast-acting inhaler with Bluetooth technology and mobile/watch application from my original proposal. My target audience consists of anyone, eighteen or older, who has been diagnosed with asthma and enjoys participating in non-competitive to extreme running activities. Other sporting exercises that involve running (soccer, baseball, football, ice/roller skating) or continuous moment (such as boxing) that require a fast-acting inhaler to control asthma symptoms were also researched. However, for the purpose of this thesis project, only asthmatic runners were tested. The minimum age of the physically active adults and athletes with asthma is at least 18 years of age to avoid parental consent to use the product once developed. These individuals care about my product due to asthma diagnoses increasing. One of the biggest issues facing these individuals is the increase in asthma prevalence from 7.3% in 2001 to 8.4% in 2010, resulting in 25.7 million persons

with asthma. This increase is largely due to lack of healthcare use and environmental triggers (Akinbami). As a result, my findings and research were important because this product will simplify the physically active lifestyle of many adults and athletes with asthma.

A medical professor and physician, in the field of asthma, found my project useful and interesting. Medical professionals appreciate how I have gathered and categorized the medical and product research on fast-acting inhaler types to understand what and why it works best in a wearable device. Ultimately, the results of my product will make it easier for physically active asthmatic adults and athletes to manage their asthma.

[\[Appendix A – Target Audience/Personas\]](#)

Methodologies

The research I collected for this project is historical. According to Wiersma, “this type of qualitative research involves examining past events to draw conclusions and make predictions about the future.” This idea guided me to formulate an execution plan after analyzing and gathering data for my project.

The established methods I used are: (1) interviews, (2) usability testing and (3) survey/testing.

I conducted interviews on a few competitive and non-competitive runners with asthma. During my research, I have come across a few runners with asthma who have written articles on this subject. These articles are beneficial because they give other runners with asthma points of view on how to deal with asthma symptoms while engaging in physical activity. Liza Howard, author at iRunFar.com, director at the non-profit Band of Runners and a fellow asthmatic runner, would prove a useful source

because she provides useful guidelines for asthmatic and non-asthmatic runners.

Gathering information like this from reporters in the field or actual runners who have asthma would help shed more light on my product and the importance of developing it.

After completing the IRB research training, I conducted usability testing for the product prototype (3D prototype testing) and the mobile and watch application (preliminary usability testing consisting of a walk-through video coupled with survey questions and final usability testing through Proto.io, which I recorded through Zoom) to make sure the product and application are functional for the general public. All preliminary and final testing participants accepted the survey consent form.

[\[Appendix N – IRB Research Certificate\]](#)

[\[Appendix O – Preliminary Product Survey Consent Form\]](#)

[\[Appendix P – Preliminary Product Survey Questions/Responses\]](#)

[\[Appendix Q – Preliminary Product Survey Testing Video\]](#)

Through the RunBud usability testing recorded through Zoom, I was able to show testers the overall design and layout. This enabled me to receive constructive feedback on the importance of the packaging and branding of my fast-acting inhaler with Bluetooth technology and mobile/watch application that tracks inhaler usage and climate monitoring application. The color scheme, logo design, package design, product design, mobile application design, product and application name and tagline must be well thought out to bring awareness about the importance of these products. A short informational video was developed to market the final products to potential users.

Branding

Mood Board

I initially created a mood board filled with upbeat colors, watch packaging, existing fitness watches, two wearable inhalers created for children with asthma and currently marketed asthma medication designs. The mood board helped me gather my thoughts on design and allowed me to view on one board what and how things have been done in the past.

[\[Appendix E – Mood Boards\]](#)

Product Name and Tagline

The product name RunBud originated from my experiences with my albuterol inhaler when I first started running races in 2011. I named my inhaler product RunBud because I never left home without my running buddy. From running errands to running races, my inhaler has always been my buddy. Hopefully, one day, many others like myself who are asthmatic runners will have a RunBud to make their own running experiences easier.

The tagline “Forget the wheeze. Run like the breeze.” is a reminder that running with asthma doesn’t have to be difficult. Having this wearable fast-acting inhaler with Bluetooth technology and mobile/watch application to track inhaler usage details, the day’s temperature, humidity level and pollen count, as well as distance, time and blood oxygen levels during the user’s run, will make running a bit easier. It will allow for the runner to know when it’s a good day/time to run and lessen potential health risks.

Logo

I chose the typeface TimeBurner to create the RunBud logo because of the typeface's continuous curves, reminiscent of a running path. Using all lowercase letters, I manipulated the typeface to form one continuous path for my RunBud logo design. The tagline in the logo also uses TimeBurner. In the beginning of my logo development, I created a handful of logos with a more rectangular logo design and made the "U" in both run and bud reflect the silhouette of "runners." After initial user testing, the original logo designs weren't aesthetic. I redesigned the RunBud logo to the clean, rounded version I am currently using.

[\[Appendix B – Final Logo\]](#)

Print and Web Typefaces

For print and web, I used two primary typefaces for this project: Lato and TimeBurner.

Lato –Semi-rounded details give this font a sense of warmth while the strong structure provides stability and seriousness (Łukasz Dziedzic). This legible sans-serif font is perfect for the mobile and watch application.

TimeBurner – Cool, modern and clean, this sans-serif font is based on very simple geometry. The font works well for text details on packaging and the tagline.

These fonts complement each other because of their clean, strong structures. Lato is one of the Google Fonts, which is another reason I chose it for my mobile and web application. According to Google, Google Fonts are easy to add to many web services and Lato supports 100+ Latin-based *languages*, and 50+ Cyrillic-based *languages*. This is

important because I want to make my mobile and web application as universal as possible.

Colors

The colors I chose were important to maintain the energetic, gender neutral vibe of the brand. I researched many athletic websites to learn of popular, gender neutral colors commonly used, and then chose my own combination to build my RunBud brand. The primary colors I chose for my brand are: PMS Blue 072, PMS 312, PMS 354 and PMS 123. The secondary color is PMS Cool Gray 6. According to Jacob Olesen from colormeanings.com, the positivity of yellow, the positive mental energy of teal and the good health of green made a perfect combination of colors to create my RunBud logo. The trust and confidence of blue was a great choice for the wearable inhaler product, the main color of the mobile and watch application, video and website. These colors clearly convey to users that this is a product you can confidently trust. Gray, the secondary color is neutral, conservative and avoids attention. That makes it an ideal color for the tagline, text and other design aspects as it doesn't compete with the primary colors used for both the RunBud logo and product.

[\[Appendix D – Athletic Common Colors Research\]](#)

Icons

The RunBud icon created for the watch application is a circle filled with PMS Blue 072 and the lowercase letters “rb.” Since the watch is relatively small, I used only the “rb” to reflect the brand and make it easy for the user to recognize.

For both the mobile and watch applications, I created very clean, geometric and easily recognizable icons using the primary brand colors. The icons include blood oxygen levels, inhaler usage, weather related, allergens, and graph shapes for best times to run and blood oxygen. All icons were created to be quickly and easily identified, as they should be for an on-the-go application.

[\[Appendix C – Icons\]](#)

Packaging

The RunBud inhaler product packaging will be a rigid 4 inch x 4 inch box with a magnetic flap closure. The outside of the box will be PMS Blue 072 with the RunBud logo and tagline on the front. The magnetic flap will feature the informational text “wearable inhaler caddy for asthmatics” in PMS 123, in the TimeBurner font. The inside of the box will feature the “inhaler taken map with check” icon. The RunBud wearable inhaler caddy product will be inset and flush inside the box with PMS 123 as the backdrop to make the product pop.

The RunBud wearable inhaler caddy product features the full color logo running vertically down the front and horizontally on the back clip. The overall RunBud product color is PMS Blue 072.

[\[Appendix F – Packaging Design\]](#)

Delivery

Initial Identified Limitations

The first limitation I identified was the development of a mobile/watch application prototype, as this process is fairly new to me. My only previous experience

was developing a mobile application prototype using Axure RP 8 in Interaction Design in the fall of 2017. As I moved forward in the development of my RunBud application, I researched Proto.io, an application prototyping platform that does not require coding, and decided to use this tool to help me create my mobile and watch applications. The second limitation I identified was the development of a 3D prototype to create my wearable fast-acting inhaler. I originally designed the wearable inhaler in Illustrator and was unsuccessful at creating it through Tinkercad. Due to my lack of 3D design skills, I reached out to ZVerse. Caitlin Buckalew and Darian Graham, design engineers with ZVerse, created my 2D wearable inhaler design into a 3D printable file. When they found out I was an MFA thesis student, they graciously provided it to me pro bono. I took the 3D file and had Shapeways print it for use in my informational video.

How RunBud Evolved

Initially, RunBud was a wearable fast-acting inhaler sports watch with mobile application. The sports watch and wearable inhaler combination was an all-in-one unit. As the project progressed, combining a wearable inhaler and sports watch as one unit proved to be cumbersome and would make the watch a competitor of the Apple watch. Asthmatic runners would be forced to choose between wearing the wearable inhaler and sports watch combination or their Apple watch. No one would want to wear both. The project was then broken down into three main products: the wearable inhaler, mobile application and watch application. Each of the three products may be used together for maximum benefits or can interact independently. The wearable inhaler may be used alone if the user prefers. However, then the user would have to personally keep track of

his or her inhalations. If the user doesn't need a fast-acting inhaler, the user can take advantage of the mobile and watch applications without the wearable inhaler.

[\[Appendix G – How RunBud Evolved\]](#)

3D Prototype

The wearable inhaler product was designed to fit the existing metered dose inhaler (MDI) albuterol canister that originally fits the asthmatic runner's inhaler. Adapting the product to the already FDA-approved canister, would save a lot of time and money as it would avoid FDA involvement in developing RunBud. The overall dimensions of the product are 2.5 inches high and 1.25 inches wide. The front and back of the albuterol canister would fit flush inside the wearable inhaler. The dimensions of the inhaler canister are 0.75 inches in diameter, 2.25 inches in height and 1 inch in width. Only the sides of the canister would show about .5 inches. The albuterol canister will be easily replaced when empty. However, when adding the albuterol canister to the wearable inhaler, the number of inhalations remaining in the canister will need to be added into the mobile application, in settings under metered doses so it can be tracked when used during running. Among the advantages of using the MDI (metered dose inhaler) over the DPI (dry powder inhaler) is that the MDI doesn't require a deep, fast inhaled breath, and accidentally breathing out (and wasting medication) isn't a problem. This provides freedom for the asthmatic runner to keep moving while taking the inhaler at the same time.

The overall design of the wearable inhaler is a rectangle with rounded edges, dark blue in color with the RunBud logo running vertically down the front and a small horizontal RunBud logo located on the clip on the back. The clip design is similar to the

iPod shuffle 4th generation clip. The clip is secured with metal retaining clips for a strong hold while running. The wearable inhaler will use rechargeable lithium-ion battery technology similar to what is used in the iPhone, with a Bluetooth chip sensor. The battery and chip will be located toward the rear, inside the inhaler. An iPhone charger will have the ability to charge the RunBud wearable inhaler. Bluetooth technology will track inhaler usage by sending the information to the watch – which will be communicated to the user via alert from the icon with a yellow check mark in a blue circle, along with haptic feedback in the form of a tap on the wrist. The information will also populate to the user's iPhone. The inhaler icon will appear on the map to show exactly where, when and how many inhalations were taken. Bluetooth technology will keep track of how many inhalations are left in the canister.

The original actuator that houses the albuterol canister has a built-in metering valve to keep track of how many doses are in the canister. Once the canister is removed from the original actuator and placed into RunBud, the user will have to input the number of doses last indicated by the metering valve into the settings section on their phone. There is no way to manually reset a metering valve, so one cannot be added to the RunBud actuator because that would make the RunBud disposable and, thus, cost prohibitive. Actuators that come from pharmaceutical manufacturers are made to be disposable. RunBud needs to be a one-time purchase.

[\[Appendix H – 3D Prototype Breakdown\]](#)

Mobile & Watch Applications

The mobile application prototype currently only works with the Apple iPhone. The mobile application has four main sections: warm-up, cool down, breathe and run

schedule. The watch application also has four main sections: warm-up, cool down, breathe and let's run.

The warm-up section of both mobile and watch applications consist of three activities: a guided ten-minute warm-up that includes a four-minute walk, two-minute march and a 4-minute jog. The user has the option to participate in one or all three activities, or skip the warm-up and go right into the run. Once the user is ready to run, he or she may select the "Let's Run" icon start button to begin tracking.

The mobile portion of the cool down section consists of a five-minute cool down. The "inhale through your nose" and "exhale through your mouth" will guide the asthmatic runner through a five-minute cool down walk. The watch application uses the same structure as the mobile application; however, the watch uses haptic feedback, tapping on the wrist when "inhaling through your nose" and no taps when "exhaling through your mouth."

The breathe section of the mobile application consists of three sub-sections: oxygen level, inhaler usage and track symptoms. The watch application consists of two sub-sections: oxygen level and track symptoms. The oxygen level is tracked through the Apple watch application during the user's run and populates to the mobile application to display more detailed information to the user. Unfortunately, only the Apple watch 6 has this technology. When I was initially working on this application, this was a "future enhancement" option. On the mobile application, it shows an oxygen level screen featuring the blood oxygen level average with a green, yellow or red scale. Green represents a blood oxygen level of 95% to 100%, which is average. Yellow represents 91% to 94%, which is below average. Red represents 90% or less, and indicates the user should consult a doctor. The user can click on the "run average results" button to view

the oxygen level results graph that tracks where their oxygen level average was at each mile. If the user's blood oxygen level dropped below 95%, the user would have the option to click on the yellow or red bar, depending on which one appears. Once the user clicks on the bar for more detailed oxygen level specific results, he or she will be able to view oxygen level, heart rate, and at what mile the breathing issue occurred. On the watch application, only the blood oxygen level average of the total mileage ran is shown with a green, yellow or red scale.

Inhaler usage is tracked using Bluetooth technology when the user uses his or her wearable inhaler during a run. The Apple watch application starts tracking once the inhalation is taken. Simultaneously, a check mark icon on the watch face and a haptic feedback tap on the wrist let the user know when the inhaler is used. On the mobile application, a map of the user's run is generated using information from GPS filtering technology similar to map my run, and the check mark icon appears on the map at the exact mileage point the user takes his or her inhaler. The user can click on the check mark icon for details on how many inhalations were taken, and at what time and mileage point. A "running report" button is also available on the screen under the map that provides usage details, along with the day's temperature, humidity level and pollen count. All of this information is available as daily, weekly and monthly downloadable reports.

Under the track symptoms subsection for both the mobile and watch applications, the user is able to indicate whether he or she experienced the following asthma symptoms during the run: wheezing, coughing, chest tightness and shortness of breath. The symptoms will also be noted on the downloadable report.

The run schedule section of the mobile application consists of a Monday through Sunday graph that pulls data from the user's setting section under asthma triggers. Asthma triggers has three subsections: allergies, seasons and temperature. The user can go through each section and swipe the on/off switch to green to activate that particular asthma trigger. The options for allergies include: molds, pollen, grasses and weeds, trees, air pollution and animal dander. Seasons options are spring, summer, fall and winter. Temperature includes hot, humid air and cold, dry air. A weekly running report in the form of a graph includes the asthma triggers noted by the user, along with the day and times the user is available to run. Using the weather and seasonal related information provided by the asthmatic runner in the settings section, a personalized weekly run schedule is generated in the graph format under run schedule. Run graphs are created using hourly and daily information pulled from the weather.com application, which is subject to change as weather and seasonal information updates. The watch application portion, called "let's run," consists of a reminder that pops up on the watch based on the information from the mobile application. The user can "accept" or "dismiss" the reminder. If the user "accepts," the "let's run" timer pops up so the user can immediately start his or her run.

The bottom navigation of the mobile application consists of the home, let's run, inhaler, search and settings icons. I selected these particular sections to make it easier for the user to be able to quickly navigate to the sections most important in the application. Home, search and settings are essential in all applications. However, let's run and inhaler are essential to the asthmatic runner who will be relying on this application to make his or her runs easier. The let's run icon allows the user to skip all warm-ups by going directly into the run tracking mode once clicked. The inhaler icon

allows the user to go directly to their last run map to view exactly where he or she took their inhaler during the run.

[\[Appendix I – Mobile and Watch Applications\]](#)

[\[Appendix J – Downloadable Report\]](#)

Informational Video

The informational video serves as one of my two forms of media. The short informational video was developed to market the final products to potential users. The video highlights the wearable inhaler with mobile and watch application and is approximately one-minute in length. The video begins by showing the asthmatic runner using the wearable inhaler as she is running. This shows the ease of use. The 3D prototype for the wearable inhaler is shown in the next scene morphing from the front, side and back. The next scenes include the important features of both the mobile and watch applications. Music and text screens in between video sections help the user understand what each section has to offer them as an asthmatic runner.

[\[Appendix K – Video Script and Storyboard\]](#)

[\[Appendix L – Final Informational Video\]](#)

Website

The website is another product developed as one of my two forms of media. The website will house the mobile and watch applications, 3D prototype, informational video, user testing (initial testing with video and survey and final testing with product testing through Proto.io and recorded on Zoom), target audience (extreme athlete, non-competitive runner and Asthma Specialist), Marketing (logo, tagline, color scheme,

packaging) and final paper and presentation. The website is branded to complement the RunBud look and feel, using the brand colors, fonts and logo. The homepage uses a clip from the informational video of the asthmatic runner taking the inhaler while running for visual interest and consistency.

I started thinking about this project years ago during one of my many road races. Today, I have had the opportunity to research and develop a product that will potentially help many physically active adults with asthma achieve their goals, including myself.

[\[Appendix M – RunBud Project Website\]](#)

Outcome

My Personal Reaction

Creating this product gave me a greater appreciation for how far I have advanced with my running. I have long had a love for running. However, running wasn't possible for me during my adolescent years. As a child, I was on medications so strong that they sometimes made me shake. It wasn't until my early thirties that I started going to the gym regularly and began building up my lungs. In 2011, I ran my first 5K. I finished in 36 minutes and 22 seconds without stopping for a breathing issue. Throughout the race, I held onto my inhaler, which I have called RunBud ever since.

Having the opportunity to create a product for myself and fellow asthma runners has been dream come true. Thanks to the M.F.A. Integrated Design Program at the University of Baltimore, my product has the potential to become a reality. I am further motivated to move forward with my product due to positive feedback from the asthmatic runners that participated in my user testing. It is inspiring to know that I have the potential help so many people dealing with asthma.

While my asthma has been an inconvenience throughout my life, I have learned that by controlling it with the proper medications and continuing to run when my asthma, the day's temperature and allergens allow, I will continue to persevere. I will push through the tough runs and celebrate the easier runs. My thesis project has also taught me to keep pushing myself even when I didn't feel like I had anything more to give. I learned to say to myself, "game face on, Kelly; you can do this."

RunBud Testing Report Summary

Overall, testing was conducted from August 4, 2020 to August 28, 2020. I tested ten participants, six asthmatic runners and four non-asthmatic runners. The participants' ranged in age from 32 to 72 years old, and consisted of nine Caucasian females and one Latino male. Further testing needs to be conducted to include a wider range of ethnic and gender groups. However, for the purpose of this thesis project, the small group I was able to connect with will have to suffice. The testing included the mobile and watch applications usability testing and 3D wearable inhaler review. All participants took the usability testing on either a desktop or laptop computer, were recorded through ZOOM and accepted the product survey consent form.

[\[Appendix R – Secondary Product Survey Consent Form\]](#)

[\[Appendix T – Secondary Asthma Product Testing Website\]](#)

User Testing Feedback (Asthmatic)

My asthmatic runner participants all described their asthma severity as mild to moderate. All but two of my participants took medication daily to breathe. They all used their fast-acting inhalers before or during running.

The usability problems I observed ranged due to generational gaps. The younger participants seemed to click on everything and the older participants seemed reluctant to do the same. However, the common usability problems are on mobile: unclear what pulse oximeter means, unclear what Rx icon means on the map, unclear they need to click on yellow graph bar for more detailed pulse oximeter information and unclear what inhaler taken means. For the watch, the pulse oximeter is missing a back button and the watch always needs to go back to the home screen – not the “RB” icon. The comments from usability testing were reviewed and the changes were applied to make the applications more user-friendly.

The positive feedback I received from my asthmatic runner participants on “features most usable” are as follows: the inhaler taken section, including the map and inhaler usage tracking, the warm-up and cool down sections and the Let’s Run section – likes best times of the day to run. Other positive feedback includes: the wearable inhaler conceals medication and looks less medical; the design is clean and simple to understand; great, new technology for asthmatics to track symptoms and inhaler usage; design is clean, easy to read, easy to use, sleek, on brand and not clunky; design is staggered well and loves the logo and colors; very easy to understand; wearable inhaler product designed well; easy to read environmental report snap shot; and product colors work well and are user-friendly. Overall, the feedback indicated RunBud is a valuable product that all participants would use.

The negative feedback I received from two of my asthmatic runner participants is that they would not use the warm-up section. Three participants would not use the pulse oximeter section. However, since participants’ responses were 50/50, I did not remove these sections as they are essential to asthmatic health. At the time of testing, the “Let’s

Run” section represented the best times to run and was populated by information the user added into settings. More than half of the testing participants found it confusing that the “Let’s Run” section didn’t start up the run. As a result, after testing, “Let’s Run” was renamed “Run Schedule” and “Let’s Run” was made into its own icon and moved into the bottom navigation of the mobile application to serve as the icon to start up the user’s run. The watch application was also an issue because the back button kept taking the user back to the “RB” icon. This function was corrected so the user can stay within the watch application.

User Testing Feedback (Non-Asthmatic)

My non-asthmatic runner participants were selected because they are all tech savvy. I wanted to get their opinions on the applications because this is a product that doesn’t have to be used with the wearable inhaler. This product can also help non-asthmatic runners have an easier run especially since my participants all have some sort of environmental allergies and do not run well in extreme temperatures.

My user testing resulted in the following usability problems on mobile: unclear of what pulse oximeter means; unclear about Rx icon on the map; unclear what inhaler taken means; need cool down reminder; unclear about track symptoms buttons- needs more distinct variation in color; unclear what Let’s Run means – change name; need to add disclaimers about where the information is coming from and reword share medical report. For the watch application, I received the same feedback from the non-asthmatic participants. That feedback included the following: the pulse oximeter is missing a back button and the watch always goes back to the home screen – not the “RB” icon. The comments from usability testing were reviewed and the changes were applied to make the applications more user-friendly.

The positive feedback I received from my asthmatic runner participants about “features most usable” is that the reporting aspect is beneficial for the pulse oximeter and inhaler taken sections. Other positive feedback included: design is clean and clear; color is soothing; easy to understand; likes the colors; legible, clear buttons; and easy to click. Overall, the feedback indicated RunBud is a valuable product that all participants would use even without having asthma.

The negative feedback I received from my non-asthmatic runner participants included the following: more back buttons needed; make the run calendar look more like a traditional calendar; add more options to the temperature section- hot & dry, warm/hot, cool/cold, humid, moderate or dry; design colors red on blue may be an issue; and a small learning curve with using the product. Two of my participants suggested a one- minute walkthrough video would be helpful. I did not follow the suggestion to include additional temperature sections for the mobile application. According to the research written in my literature review, most asthmatics have issues in hot, humid air and cold, dry air. The other temperature options are not needed. For one participant, the track symptoms and pulse oximeter features of the watch application have no benefit. Overall, my participants liked this feature on the watch, so it wasn’t removed.

[\[Appendix S – Secondary Product Survey Questions/Responses\]](#)

Revisions to Mobile and Watch Applications After Testing

After testing, I made the following revisions to the mobile application:

(1) reworked the Rx icon to be consistent with the yellow check on the blue circle that pops up on the watch after the runner takes his or her wearable inhaler; (2) renamed “pulse oximeter” to “oxygen level;” (3) “share medical report” was renamed “Export Full

Report;” (4) added the date to the report asthma symptoms screen under “track symptoms;” (5) added a straight-forward “let’s run” icon to the bottom navigation to be able to start running without warming up; (6) renamed “let’s run” (that took users to the calendar featuring best times to run each week) to “run schedule;” and (7) added disclaimers about the origin of the information to the liability screen.

The following revisions were made to the watch application after testing: (1) made it so the symptoms a user selects will appear darker to provide distinct variation from symptoms a user does not select; (2) added a back button to the pulse oximeter screen; (3) added functionality to go back to the home screen not the “RB” icon; and (4) enabled the “let’s start running” screen to appear so the user can go directly into his or her run.

Additionally after testing, I made the following revisions to both the mobile and watch applications: (1) added a cool down reminder, “keep walking and take long deep breaths,” to the inhale and exhale screens; and (2) renamed “inhaler taken” to “inhaler usage.”

Areas for Product Expansion

Due to time and resource limitations, I had to choose for my applications to work with either Apple or Android products. Currently, the mobile application is only available for the Apple iPhone and the watch application is only available for the Apple watch. Future product expansion includes making the applications available for Android phone users and other fitness watches, such as Garmin and Fitbit. I would also like to expand RunBud beyond asthmatic runners. Since the wearable inhaler doesn’t have to work with the mobile and watch applications, this product can be useful to non-asthmatic runners.

Non-asthmatic runners who have difficulty running in extreme weather conditions and have allergies can benefit from the tracking system built into the applications.

Next Steps

After completion of my thesis, I will investigate five options to distribute my project. The first option will be to explore entrepreneur partnerships. I will contact J.C. Weiss at the Merrick School of Business for guidance and explore Google for entrepreneurs. Google builds community hubs, which they call campuses, that give entrepreneurs creative freedom to learn, share and launch their ideas with the guidance of professionals (Horowitz). The second method will be to consult with T.J. O'Donnell to develop an intellectual property plan to protect my product before reaching out publicly to market my idea. The third option will be to research grant financing, like grant.gov to apply for a government grant and fund further development of this product. The fourth option will be to market my idea to investors to be able to expand my reach in the product development world. The fifth and final option will be to develop the mobile and watch applications to be fully functional and available to the public for download from Google Play and Apple's App Store. While the mobile application will work with the Apple watch and wearable inhaler, I also want the application to be available for all smartphones users as an everyday way to track environmental issues, inhaler usage, asthma symptoms and blood oxygen levels during runs. This last option will require the expertise of a product designer and/or engineer.

Appendix A - Target Audience/Personas

RunBud Persona 1 – The Asthmatic Extreme Athlete



Persona: Maeve Larson, Extreme Athlete

Profile: Maeve is an extreme athlete with mild to moderate asthma. She actively participates in ultra- marathons, full and half marathons. Maeve on average runs between 50 to 60 miles per week.

Gender: Female

Age: 26

Location: Colorado Springs, CO

Education: Master's Degree in Sports Medicine, Liberty University, Lynchburg, VA

Tech level: High level; uses computers daily; Maeve has an iPhone 11 and an Apple watch series 6. She keeps up with technology due to the demands of her job, as an Athletic Trainer. She prefers apps for everything because she can complete most tasks in a few easy steps. She uses social media (Facebook, Twitter, LinkedIn) every day to post about subjects important to her and keep current in her professional and athletic life.

Limitations: Asthma hinders PR (Personal Record) which is important because Maeve competes to win.

Goal: Maeve wants to maintain her PR in her marathons but wants to be better prepared for running days when environmental triggers are at their worst. Maeve wants a wearable inhaler with mobile application that provides medicine usage details, along with the day's temperature, humidity level and pollen count. She will be able to determine the best days to run based on this knowledge.

Frustration: Maeve participates in marathons and goes on long daily runs. Her bulky, fast acting inhaler must come with her. She struggles every race on how to secure it properly so she doesn't lose it and can easily access it when she needs to use it during the run.

RunBud Persona 2 – The Asthmatic Non-Competitive Runner

Persona: Michael Perez, Non-Competitive Runner

Profile: Michael is a non-competitive runner with moderate to severe asthma. He participates in 5K and 10K races a couple of times in the Spring and Fall. Michael on average works out at the gym 3 times per week for approximately 1 hour.

Gender: Male

Age: 58

Location: Baltimore, MD

Education: High School Diploma

Tech level: Mid-level; uses computers daily to input job descriptions and billing for his electrical business. He uses apps to track mileage during his races and at the gym. Michael has an iPhone 8.

Limitations: Asthma affects how fast he can run during his races and while on the treadmill at the gym. Asthma also affects him during the day at work if he exerts himself too much when the weather is extreme.

Goal: Michael wants a wearable inhaler that tracks his inhalation activity during his races and when he is at the gym.

Frustration: Michael participates in short races, goes to the gym on average 3 hours per week and has a physically demanding job. All of these things require him to have his inhaler available at all times. Whether Michael is at work or participating in physical activity he needs to easily access his fast-acting inhaler. His main complaint is his inhaler digs in his leg while he is at work because his tool belt presses on it.

RunBud Persona 3 – The Medical Professional



Persona: Dr. Johnathon Steinburg, Asthma Specialist

Profile: Dr. Steinburg is an asthma & allergy specialist practicing in White Marsh, MD. His asthma patients range from young adults to senior citizens with severe to mild asthma. Dr. Steinburg's intention with the product is to make it available to his patients. Dr. Steinburg can also relate to his patients and their need for a wearable asthma device because he is also a runner who suffers from moderate asthma.

Gender: Male

Age: 60

Location: Baltimore, MD

Education: Medical Degree in Asthma & Allergy, Johns Hopkins University, Baltimore, MD

Tech level: High level; uses computers daily; Dr. Steinburg has an iPhone 10. He keeps up with technology due to the demands of his job.

Limitations: No solid wearable inhalers to offer his physically active asthmatic patients.

Goal: To provide research and monitoring of new and improved medical advances to his asthma patients. He also wants to communicate results of these new medical breakthroughs to his colleagues. He wants to offer the product to his physically active asthmatic patients and use the product himself.

Frustration: Wearable tech and pharmaceutical companies don't see eye to eye when combining products to create wearable inhalers with mobile application to appeal to physically active asthmatics. Dr. Steinburg wants fast-acting inhaler options for his active patients.

Appendix B – Final Logo

Primary Colors



Secondary Color



Appendix C – Icons



Run SpO2 Average



3 Total Inhalations

76°
Degrees



65%
Humidity

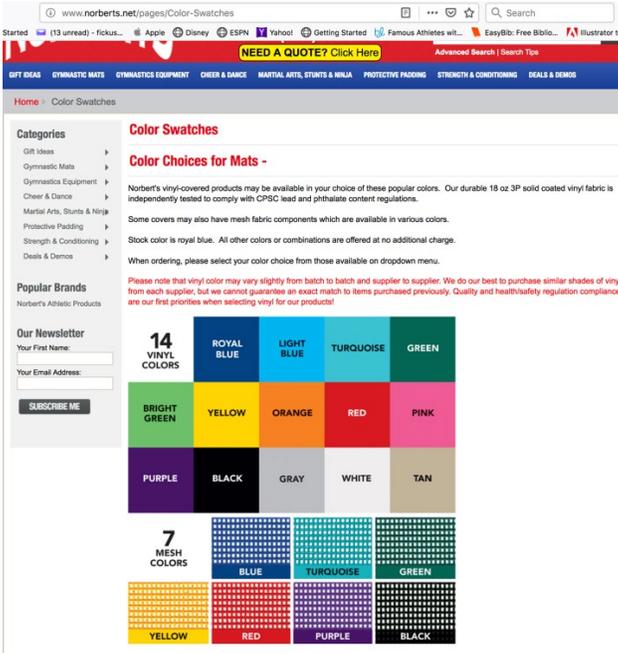
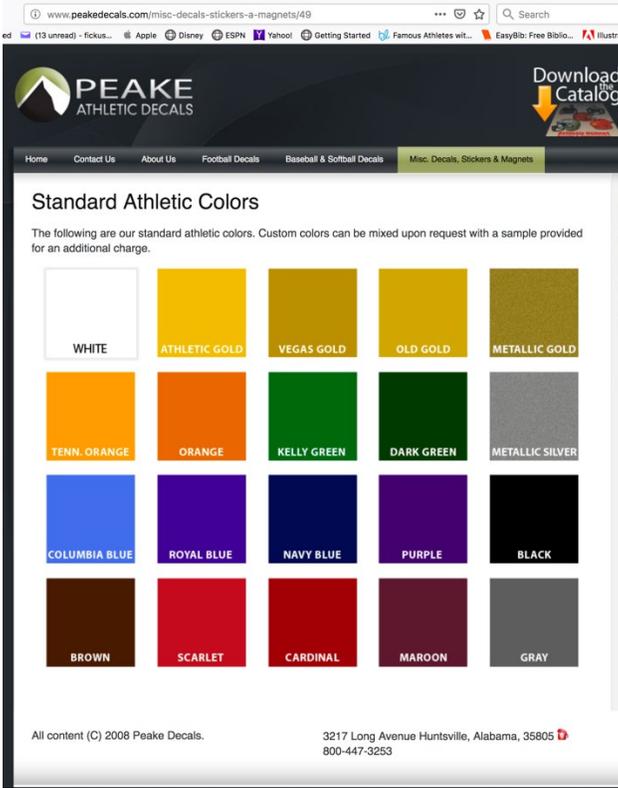
30% Grass

52% Molds

98% Weeds

23% Trees

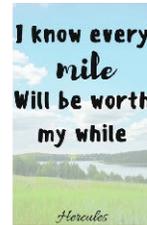
Appendix D – Athletic Common Colors Research



Appendix E – Mood Boards



earth + peace of mind = running
 environmental irritants - use environmental colors - but keep in mind target audience are male & female.
 running can give you a sense of peace.



Running makes me feel:



product develop ideas



product packaging ideas



medical packaging ideas



Appendix F – Packaging Design



Appendix G – How RunBud Evolved



Appendix H – 3D Prototype Breakdown

Design Thoughts: Detachable Wearable Inhaler with Bluetooth Technology

Notes from Dr. Jody Tversky - "the first entry level step to designing a successful medical product is to initially design something that does not require high level FDA evaluation clearance . Identify a clear market and then design your product or device using existing technologies and/or items that have already been approved by the FDA." With that being said and with my current research on MDI (Metered dose inhaler) versus DPI (dry powder inhaler) is clear: MDI needs to be used for the wearable RunBud product.

The Bluetooth technology will track inhaler usage by sending the information to the watch - a green check mark will pop-up on the watch, along with a tap on the wrist. The information will populate to the iPhone. The inhaler icon will drop on the map exactly where and when the inhale was taken.

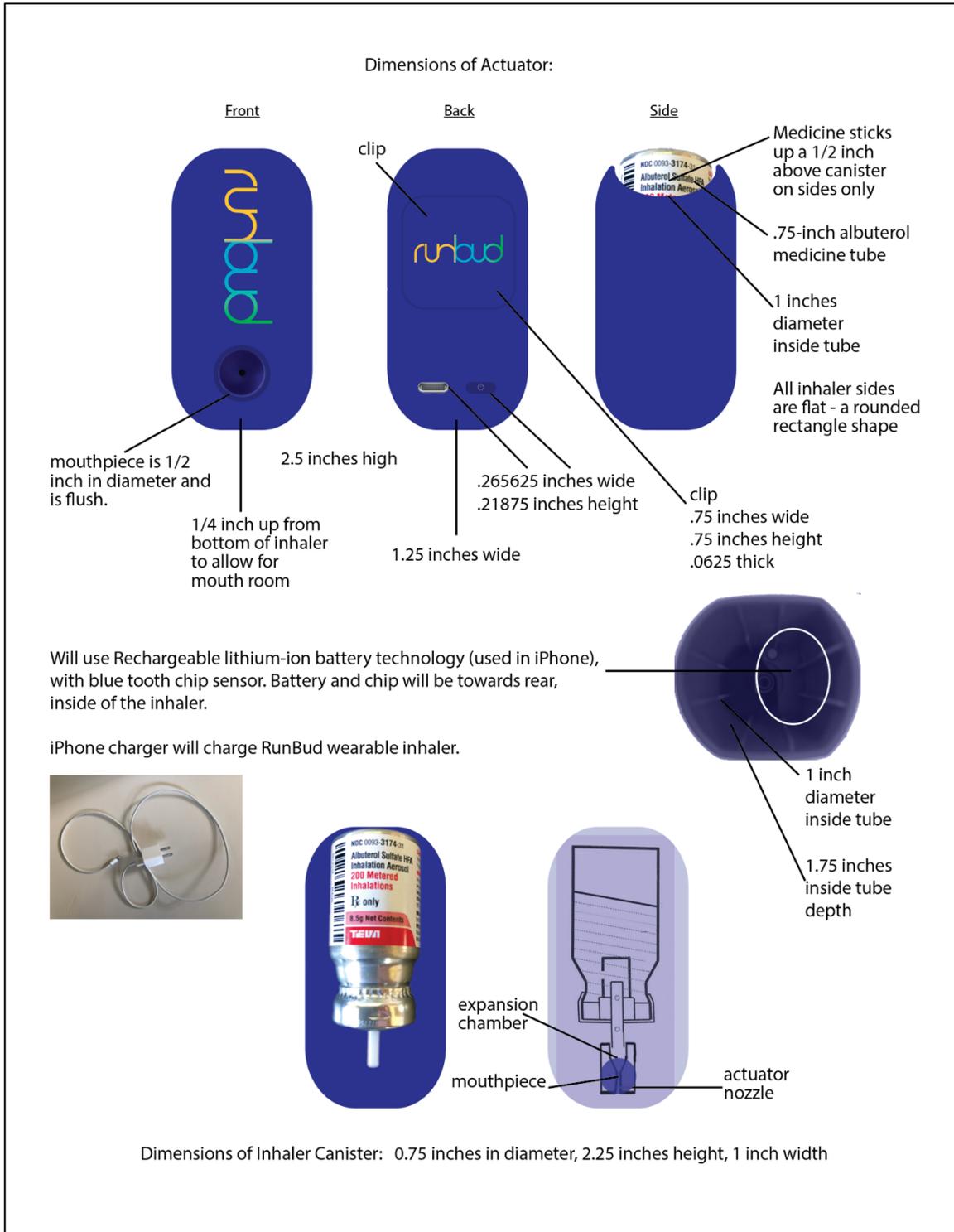
The Blue tooth technology will also keep track of how many inhalations are left in the MDI canister. **The problem I identified, is once the medicine is removed from the original canister, it will no longer contain a metering valve to keep track of how many doses are left.** The user will have to input that data into the settings section on their phone once a new MDI canister is placed into the RunBud actuator.

Why can't I add the metering valve to the RunBud actuator?
If I add the metering valve to the RunBud actuator, it will have to be a disposable actuator because there is no way to reset it manually. All inhalers currently are made to be disposed of.

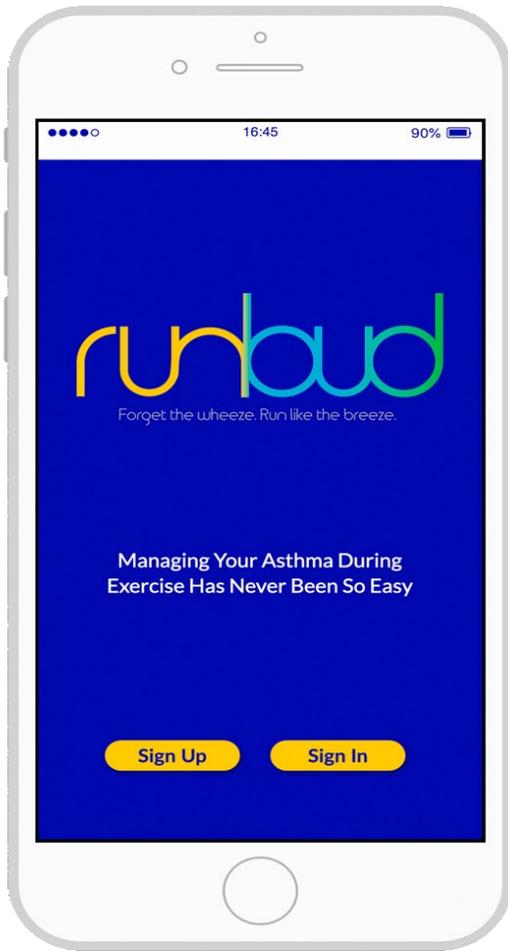
This will make the product become costly. It needs to be a one-time purchase.

Asthma inhaler features

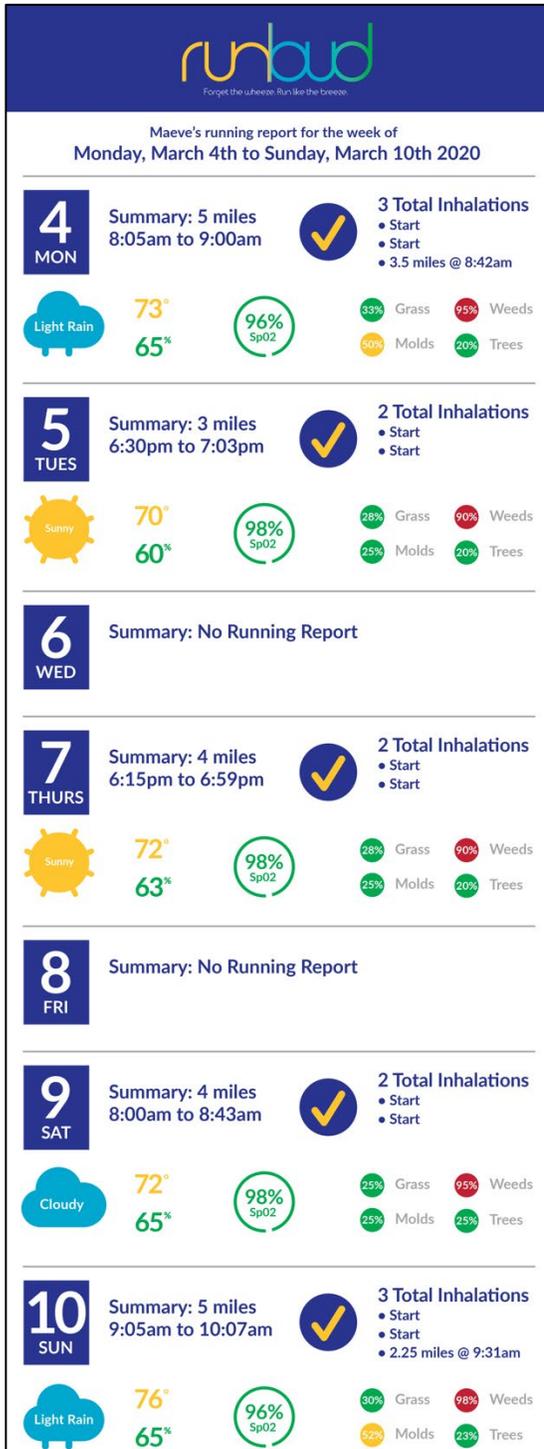
| Metered dose inhaler | Dry powder inhaler |
|---|---|
| Small and convenient to carry. | Small and convenient to carry. |
| Doesn't require a deep, fast, inhaled breath. | Requires a deep, fast, inhaled breath. |
| Accidentally breathing out a little isn't a problem. | Accidentally breathing out a little can blow away the medication. |
| Some inhalers require coordinating your breath with medication release. | Doesn't require coordinating your breath with medication release. |
| Can result in medication on the back of your throat and tongue. | Can result in medication on the back of your throat and tongue. |
| Some models don't show how many doses remain. | It's clear when the device is running out of medication. |
| Requires shaking and priming. | Single-dose models require loading capsules for each use. |
| Humidity doesn't affect medication. | High humidity can cause medication to clump. |
| Use of a cocking device generally isn't necessary. | May require dexterity to use a cocking device. |



Appendix I – Mobile and Watch Applications



Appendix J – Downloadable Report



Appendix K - Video Script and Storyboard



| | | | |
|------------------------|------------------------------------|--------------------|--------------|
| CLIENT: | University of Baltimore, Thesis | DATE: | 10-21-20 |
| TITLE: | <u>RunBud</u> | WRITTEN BY: | Kelly Fickus |
| SCRIPT VERSION: | Draft 2 | TRT: | |

| VIDEO | AUDIO |
|---|---|
| Describe visuals here. | Describe audio and SFX here. |
| 1. Maeve (back of her) running down a wooded trail (wide shot) Words on screen: A wearable fast-acting inhaler with Apple watch and mobile application | Fade in - Inspirational/Uplifting music |
| 2. <u>RunBud</u> product shot, front, side and back (medium shot) | Inspirational/Uplifting music |
| 3. Maeve unclipping <u>RunBud</u> wearable inhaler from clothing and using it (close-up shot) | Inspirational/Uplifting music |
| 4. (Close up shot) of Apple Watch on runner's wrist (mat in video-show check mark indicating inhaler taken) | Inspirational/Uplifting music |
| 5. Words on dark blue screen – Track your inhaler usage during your run | Inspirational/Uplifting music |
| 6. (Close up shots of clicking through screens) Inhaler map and notification screens | Inspirational/Uplifting music |
| 7. Words on dark blue screen – See your blood oxygen levels | Inspirational/Uplifting music |
| 8. (Close up shots of clicking through screens) Blood oxygen screens | Inspirational/Uplifting music |
| 9. Words on dark blue screen – Track your asthma symptoms after your run | Inspirational/Uplifting music |
| 10. (Close up shot) of Apple Watch on runner's wrist (mat in symptoms screen) | Inspirational/Uplifting music |
| 11. Words on dark blue screen – Keep track of your asthma triggers | Inspirational/Uplifting music |
| 12. (Close up shots of clicking through screens) Trigger screens | Inspirational/Uplifting music |
| 13. Words on dark blue screen – Usage details, along with the day's temperature, humidity level and my | Inspirational/Uplifting music |



| | |
|--|-------------------------------------|
| allergens will also be available as daily or weekly downloadable reports | |
| 14. (Close up shots) Best times to run screen and downloadable report | Inspirational/Uplifting music |
| 15. Dissolve into main RunBud mobile and watch app screens | Inspirational/Uplifting music |
| 16. Dissolve in Last screen – dark blue RunBud logo with tagline | Inspirational/Uplifting music fades |
| 17. Disclaimer | No music |

<https://youtu.be/ICLeGaVUUb4>

<https://www.companionmedical.com/why-inpen/>

RunBud Storyboard

1



2



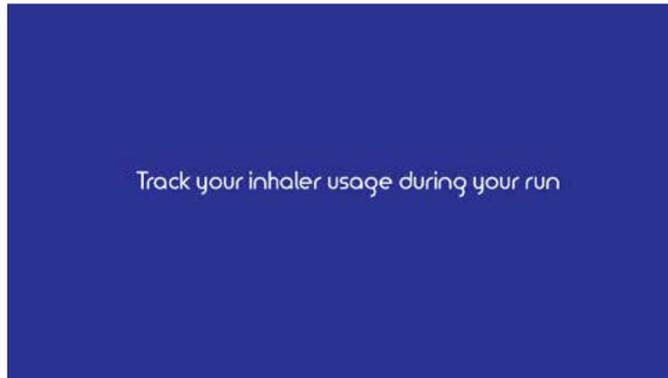
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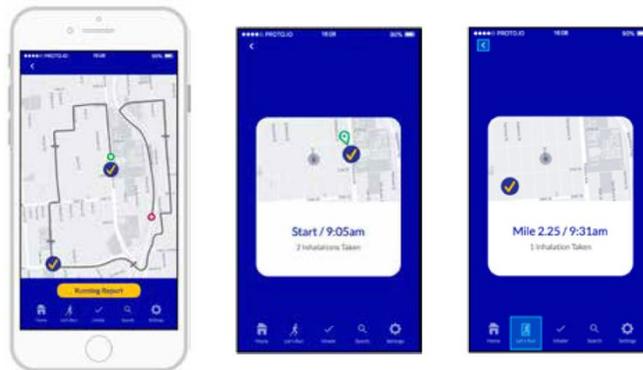
4



5



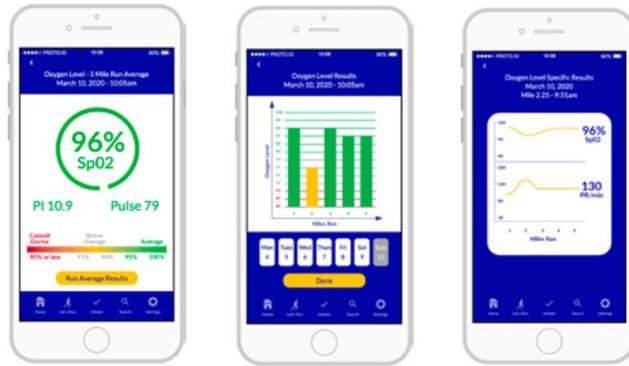
6



7



8



9



10



11



12



13

Usage details, along with the day's temperature, humidity level and my allergens will also be available as daily or weekly downloadable reports

14



15



16



17

INDICATIONS AND IMPORTANT SAFETY INFORMATION

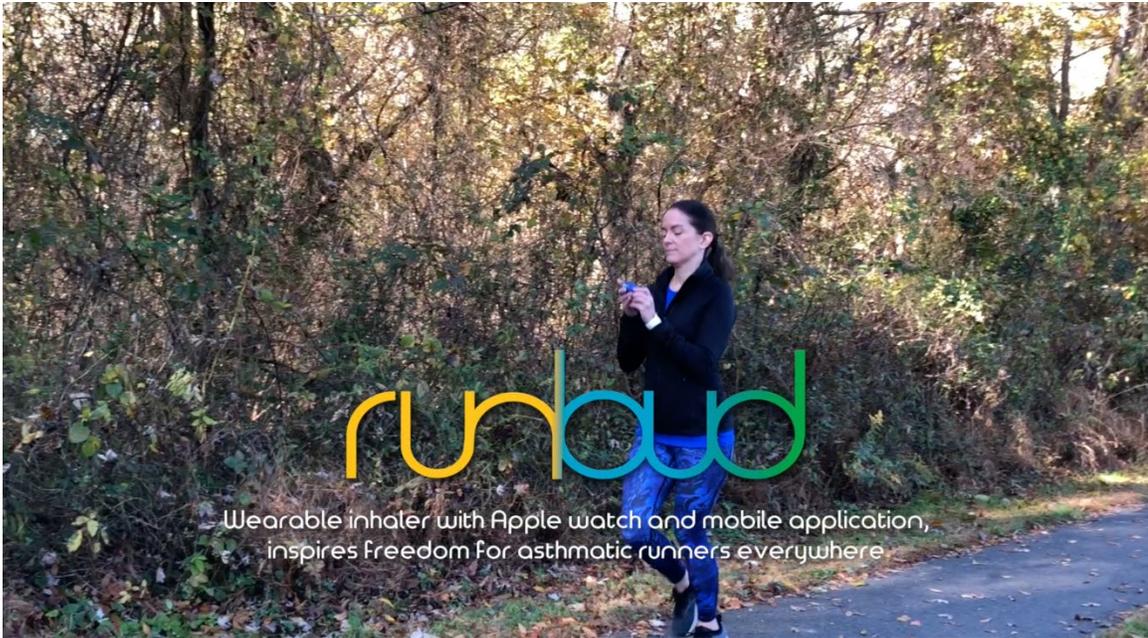
FreeStyle Libre and FreeStyle Libre 14 day Flash Glucose Monitoring systems are continuous glucose monitoring (CGM) devices indicated for replacing blood glucose testing and detecting trends and tracking patterns aiding in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments in persons (age 18 and older) with diabetes. The systems are intended for single patient use and require a prescription.

CONTRAINDICATIONS: Remove the sensor before MRI, CT scan, X-ray, or diathermy treatment.

WARNINGS/LIMITATIONS: Do not ignore symptoms that may be due to low or high blood glucose, hypoglycemic unawareness, or dehydration. Check sensor glucose readings with a blood glucose meter when Check Blood Glucose symbol appears, when symptoms do not match system readings, or when readings are suspected to be inaccurate. The systems do not have alarms unless the sensor is scanned, and the systems contain small parts that may be dangerous if swallowed. The systems are not approved for pregnant women, persons on dialysis, or critically-ill population. Sensor placement is not approved for sites other than the back of the arm and standard precautions for transmission of blood borne pathogens should be taken. The built-in blood glucose meter is not for use on dehydrated, hypotensive, in shock, hyperglycemic-hyperosmolar state, with or without ketosis, neonates, critically-ill patients, or for diagnosis or screening of diabetes. When using FreeStyle LibreLink app, access to a blood glucose monitoring system is required as the app does not provide one. Review all product information before use or contact Abbott Toll Free (855-632-8658) or visit www.freestylelibre.us for detailed indications for use and safety information.

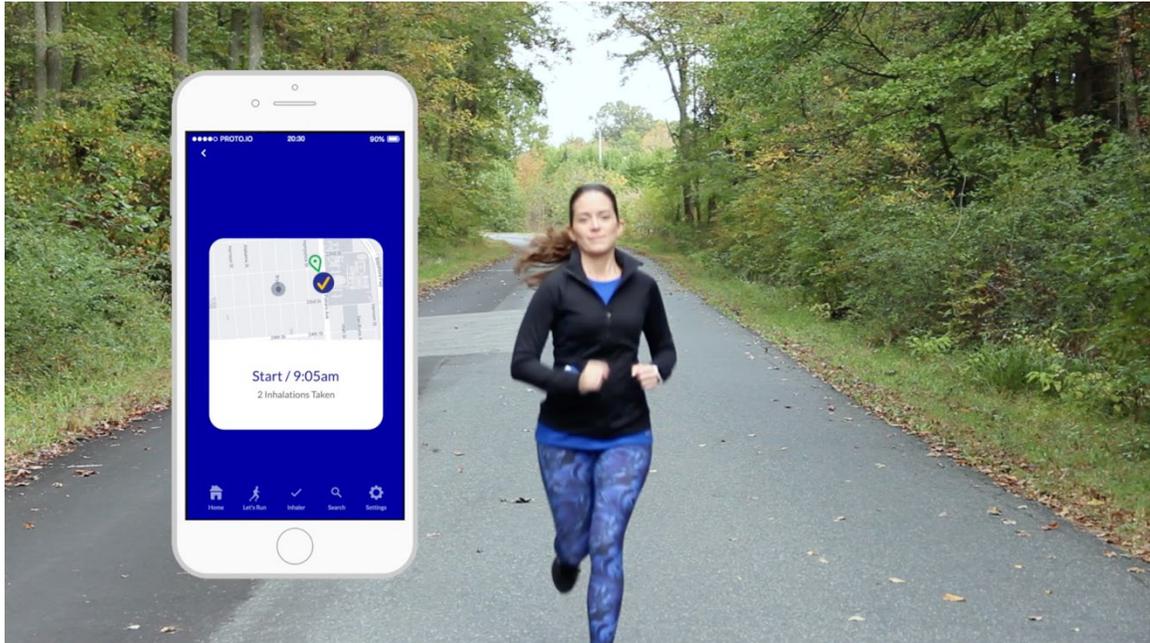
0:41 / 0:45

Appendix L – Final Informational Video

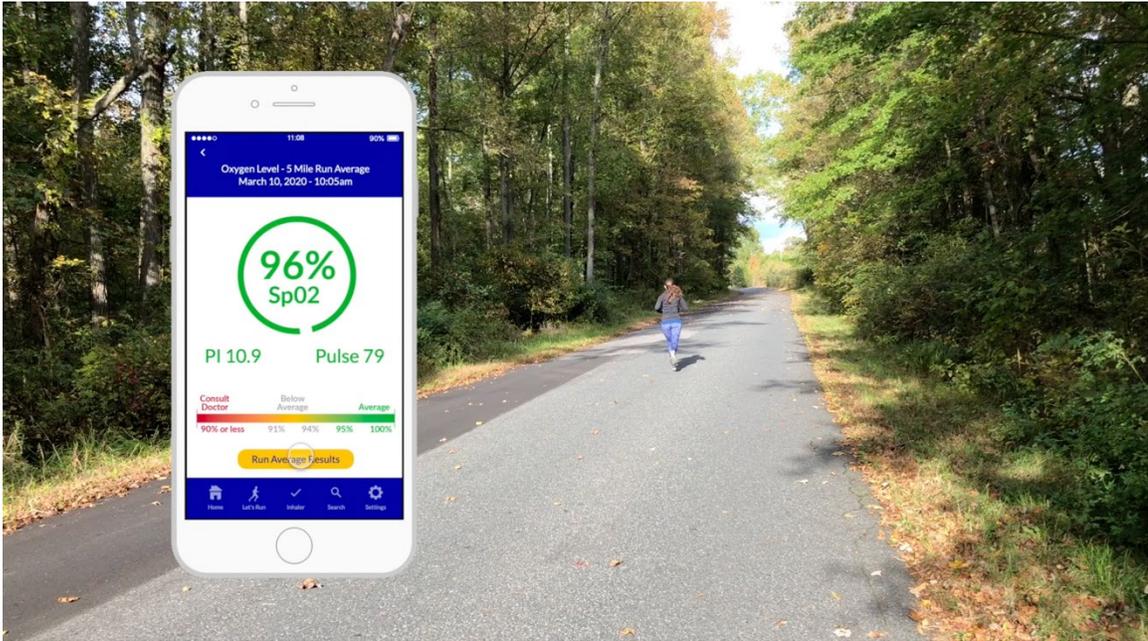


Track your inhaler usage during your run





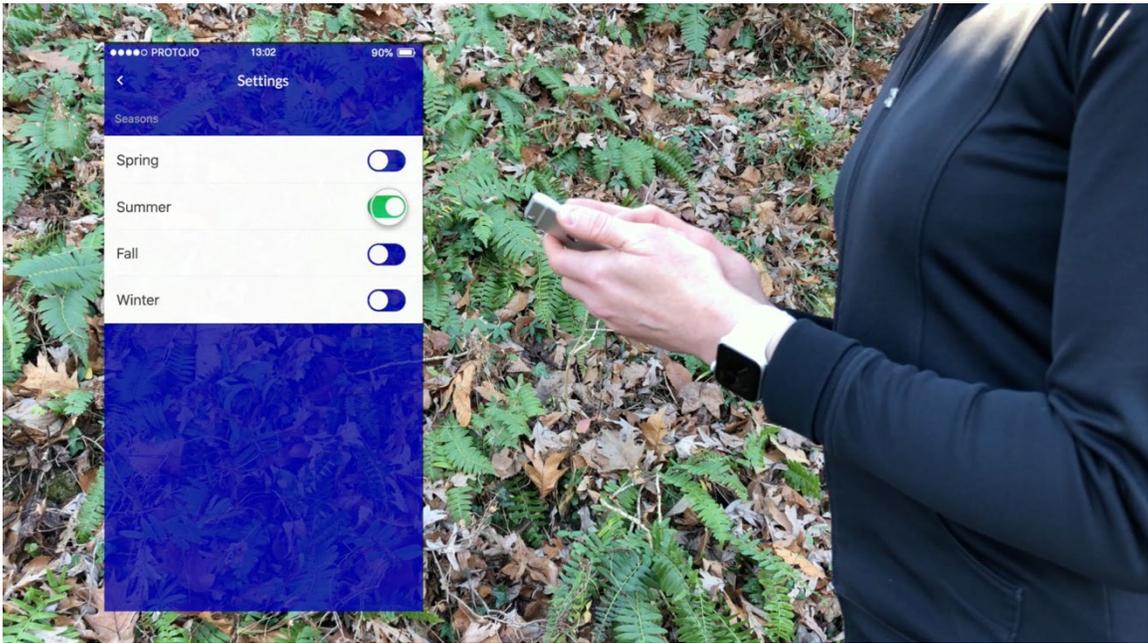
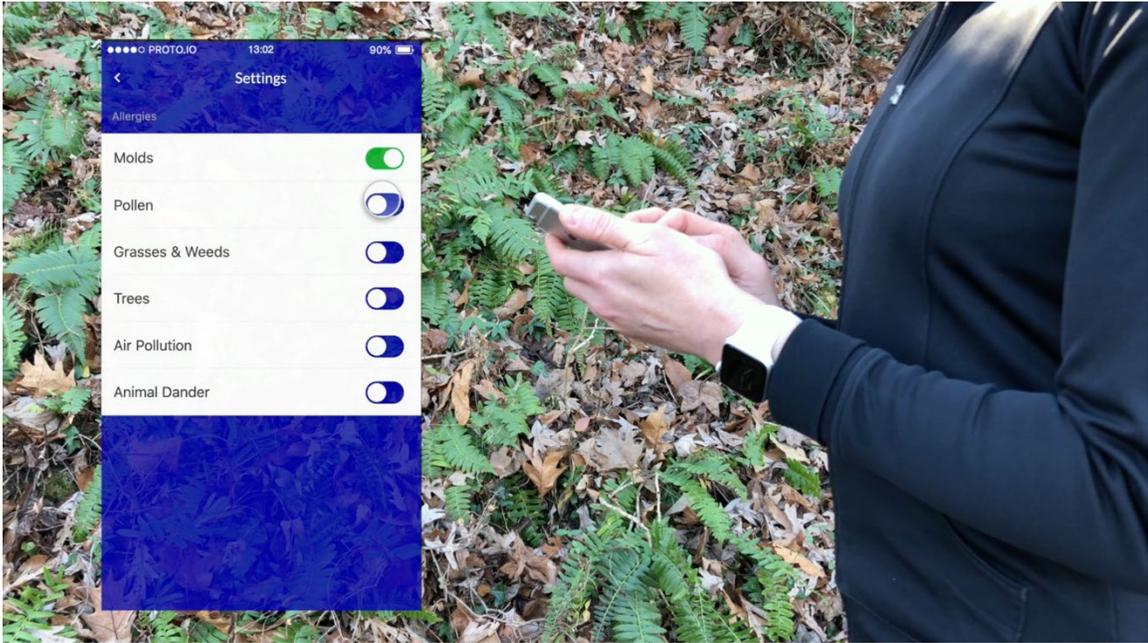
See your blood oxygen levels



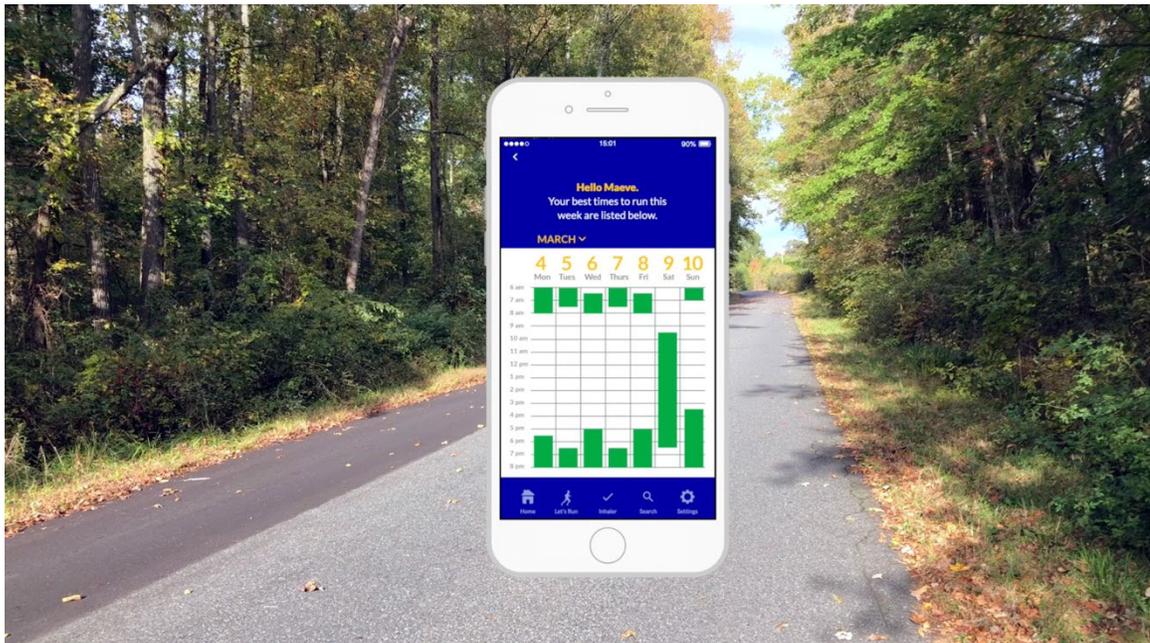
Track your asthma symptoms
after your run



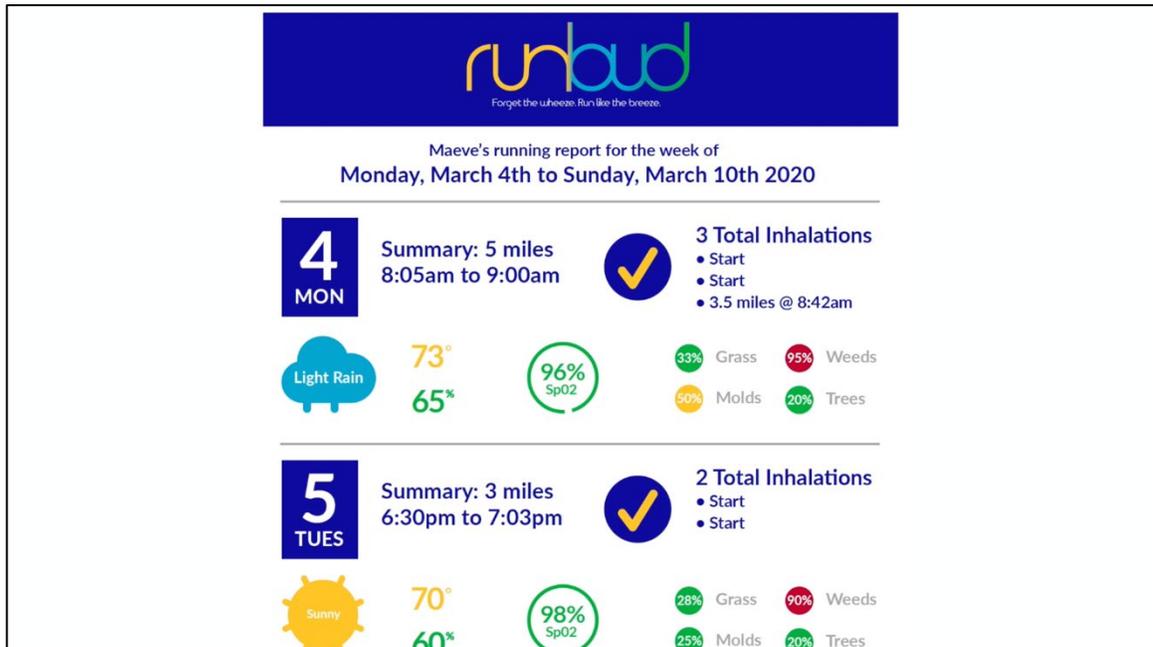
Keep track of your asthma triggers

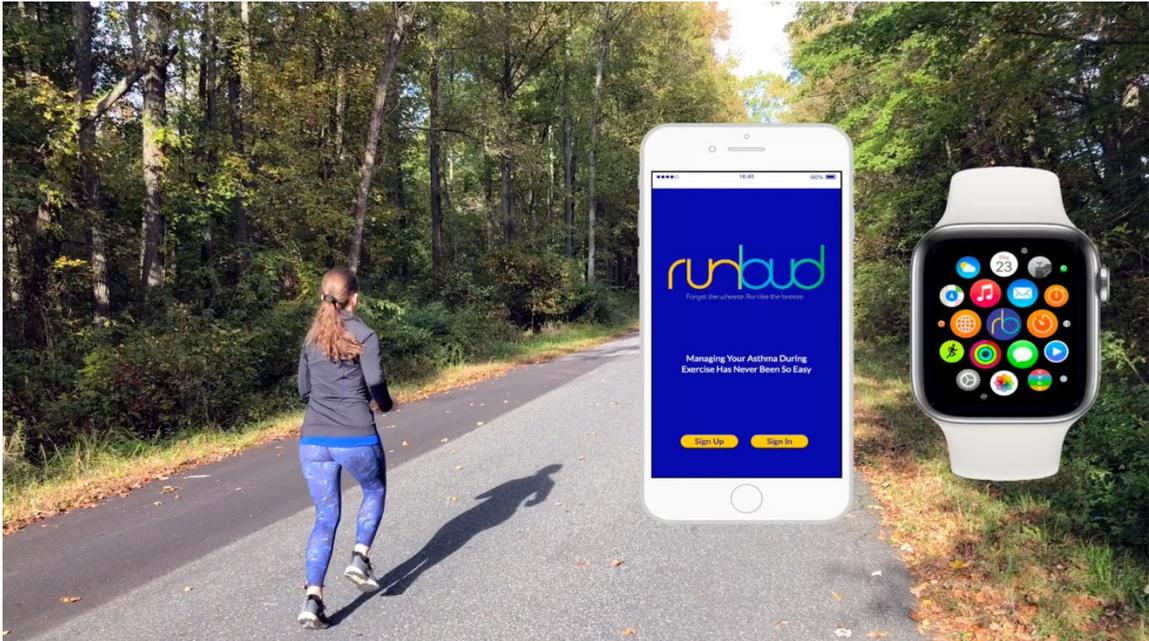


Get your weekly personalized run report
based on your triggers



Usage, temperature, humidity level and allergens are available as downloadable reports





Terms and Conditions

I agree not to hold the creator of the RunBud app responsible for any injuries or misfortune sustained while in the act of any physical activity.

Privacy Policy

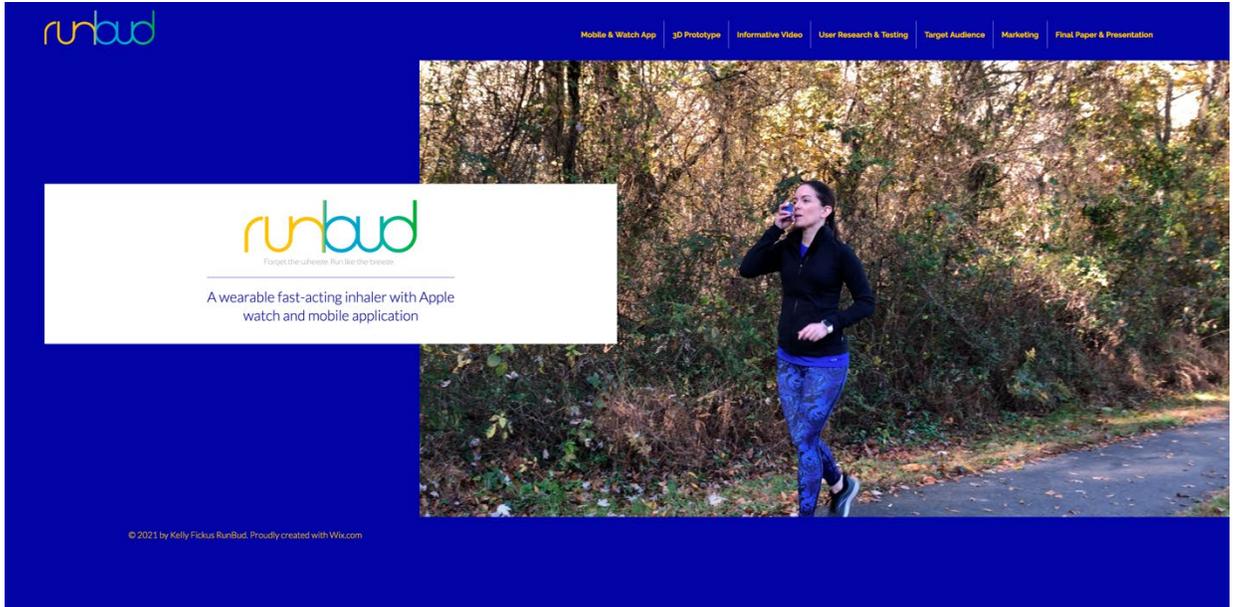
Privacy Policy Last updated: September 13, 2020.

RunBud operates RunBud watch and mobile app. We are informing you of our policies regarding the collection, use and disclosure of personal information we receive from users of the app. We use your personal information only for providing and improving the app. By using the app, you agree to the collection and use of information in accordance with this policy.

Third Party Apps

Apps such as weather.com and mapmyrun.com feed information into RunBud to provide the most up-to-date information on a daily basis.

Appendix M – RunBud Project Website



Appendix N - IRB Research Certificate– February 2020

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)
COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Kelly Fickus (ID: 8872745)
- **Institution Affiliation:** University of Baltimore (ID: 4239)
- **Institution Email:** kelly.fickus@ubalt.edu
- **Institution Unit:** Liberal Arts - Integrated Design
- **Phone:** 410.837.6058

- **Curriculum Group:** Human Subjects Research (HSR)
- **Course Learner Group:** Revised Common Rule
- **Stage:** Stage 1 - Basic course

- **Record ID:** 35187653
- **Completion Date:** 29-Feb-2020
- **Expiration Date:** 28-Feb-2023
- **Minimum Passing:** 80
- **Reported Score*:** 86

| REQUIRED AND ELECTIVE MODULES ONLY | DATE COMPLETED | SCORE |
|---|----------------|------------|
| Overview of the Final Rule Revisions (ID: 17909) | 29-Feb-2020 | 5/5 (100%) |
| New and Revised Definitions (ID: 17910) | 29-Feb-2020 | 5/5 (100%) |
| Informed Consent – Changes and Additions to Consent Processes (ID: 17911) | 29-Feb-2020 | 4/5 (80%) |
| Informed Consent – Changes to the Documentation of Consent (ID: 17912) | 29-Feb-2020 | 4/5 (80%) |
| Understanding Broad Consent (ID: 17913) | 29-Feb-2020 | 4/5 (80%) |
| Secondary Research with Identifiable Information and Biospecimens (ID: 17914) | 29-Feb-2020 | 4/5 (80%) |
| Effect of Revised Common Rule on Research Roles (ID: 17915) | 29-Feb-2020 | 5/5 (100%) |
| Updates to Exemption Categories (ID: 17916) | 29-Feb-2020 | 4/4 (100%) |
| Limited IRB Review (ID: 17917) | 29-Feb-2020 | 4/5 (80%) |
| Updates to Expedited Review Procedures (ID: 17918) | 29-Feb-2020 | 3/5 (60%) |

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: www.citiprogram.org/verify/7k1d107e0a-609d-410a-b3e1-68e0744e3c94-35187653

Collaborative Institutional Training Initiative (CITI Program)
 Email: support@citiprogram.org
 Phone: 888-529-5929
 Web: <https://www.citiprogram.org>

Appendix O – Preliminary Product Survey Consent Form – March 2020

Whom to Contact about this study:
Principal Investigator: Kelly Fickus
Department: Student Research for Thesis
Telephone number: 443.977.8857

CONSENT FORM FOR PARTICIPATION IN RESEARCH ACTIVITIES

RunBud - A wearable fast-acting inhaler with Apple watch and mobile application

INTRODUCTION/PURPOSE:

I am being asked to participate in a research study. The purpose of this study is to view the preliminary user testing video and take a short survey. The feedback I provide will guide the student, Kelly Fickus to make the right optimizations, based on real data & real feedback. I am being asked to volunteer because I am an asthmatic runner who is age 18 and over. My involvement in this study will begin when I agree to participate and will continue until I review the video and submit the survey questions. About 10 to 15 persons will be invited to participate.

PROCEDURES:

As a participant in this study, I will be asked to view the preliminary user testing video and take a short survey. I will be able to participate in the study on my own device from any location. The video and survey questions are embedded on <https://kellyfickus.wixsite.com/runbud> website that will be email to a small handful of known asthmatic runners and posted on the Sharman Ultra coaching team social media site. My participation in this study will last for approximately 15 minutes. No personal identifying information will be written with responses to the questions.

RISKS AND BENEFITS:

My participation in this study does not involve any significant risks and I have been informed that my participation in this research will not benefit me personally, but the project is important because a wearable fast-acting inhaler combined with a sports watch and environmental tracking technology will simplify the lives of physically active asthmatic adults. The wearable product will make engaging in sports activities easier by: (1) providing a fast-acting inhaler that is easy to inhale on the move, (2) being less cumbersome, (3) tracking simple sports-related tasks such as calorie burn, distance and time, (4) tracks inhaler usage including the exact mileage point(s) the user administers the inhaler and (5) tracks daily environmental irritants such as pollen count, humidity level and temperature. The product and mobile application cannot cure asthma, but it will benefit many adults and athletes with the disease.

CONFIDENTIALITY:

Any information learned and collected from this study in which I might be identified will remain confidential and will be disclosed ONLY if I give permission. All information collected in this study will be stored in a locked file cabinet in a locked room. Only the investigator and members of the research team will have access to these records. If information learned from this study is published, I will not be identified by name. By signing this form, however, I allow the research study investigator to make my records available to the University of Baltimore Institutional Review Board (IRB) and regulatory agencies as required to do so by law.

Consenting to participate in this research also indicates my agreement that all information collected from me individually may be used by current and future researchers in such a fashion that my personal identity will be protected. Such use will include sharing anonymous information with other researchers for checking the accuracy of study findings and for future approved research that has the potential for improving human knowledge.

SPONSOR OF THE RESEARCH:

This research study is for a master's thesis, MFA Integrated Design.

COMPENSATION/COSTS:

My participation in this study will involve no cost to me.

CONTACTS AND QUESTIONS:

The principal investigator, Kelly Fickus, 443.977.8857, kelly.fickus@ubalt.edu has offered to and has answered any and all questions regarding my participation in this research study. If I have any further questions, I can contact Megan Rhee, faculty advisor at 410.837.6062 or mrhee@ubalt.edu.

For questions about rights as a participant in this research study, contact the UB IRB Coordinator: 410-837-4057, irb@ubalt.edu.

VOLUNTARY PARTICIPATION

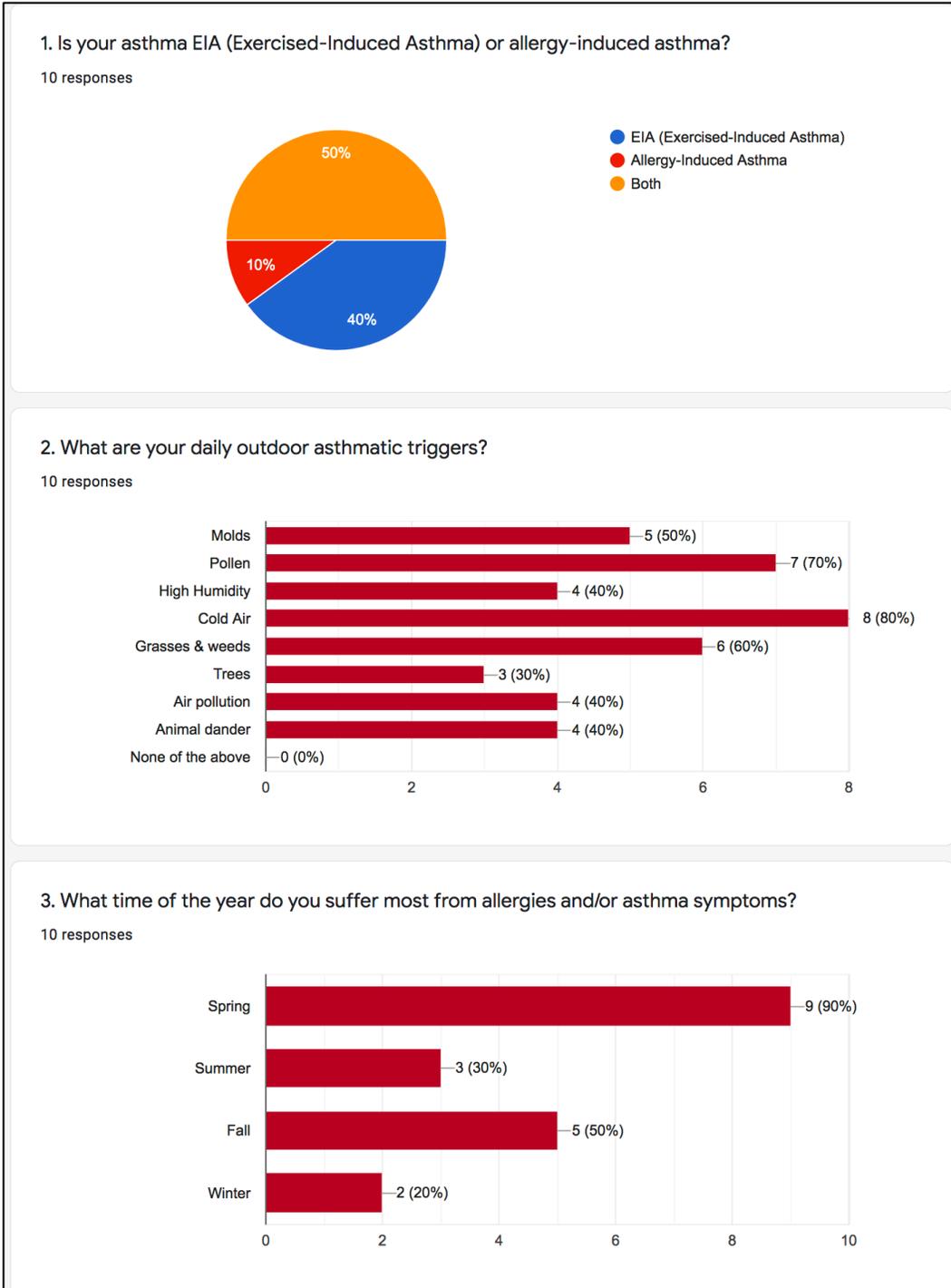
I have been informed that my participation in this research study is voluntary and that I am free to withdraw or discontinue participation at any time.

I will be given a copy of this consent form to keep.

SIGNATURE FOR CONSENT

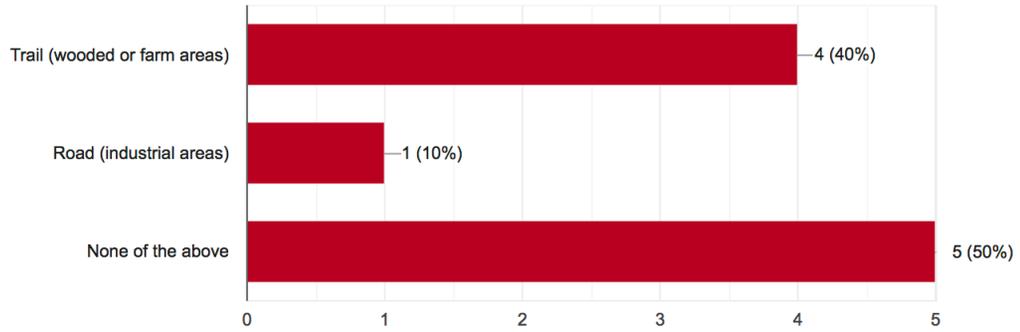
The above-named investigator has answered my questions and I agree to be a research participant in this study. By accepting this consent form, I am acknowledging that I am at least 18 years of age. Please click the button below to accept.

Appendix P – Preliminary Product Survey Questions/Responses March 2020



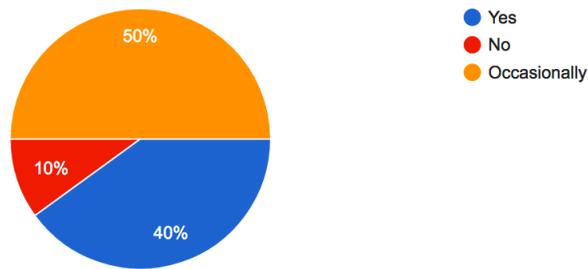
4. What environment have you avoided on your run to help prevent asthma symptoms?

10 responses



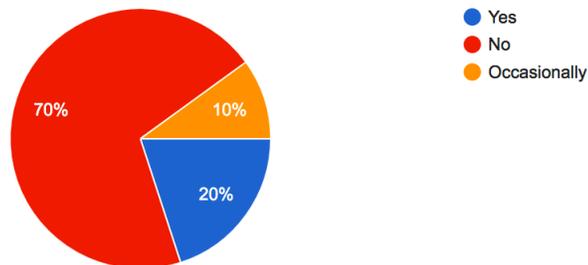
5. Are your asthma symptoms different if you're exposed to humid, hot air versus cold, dry air?

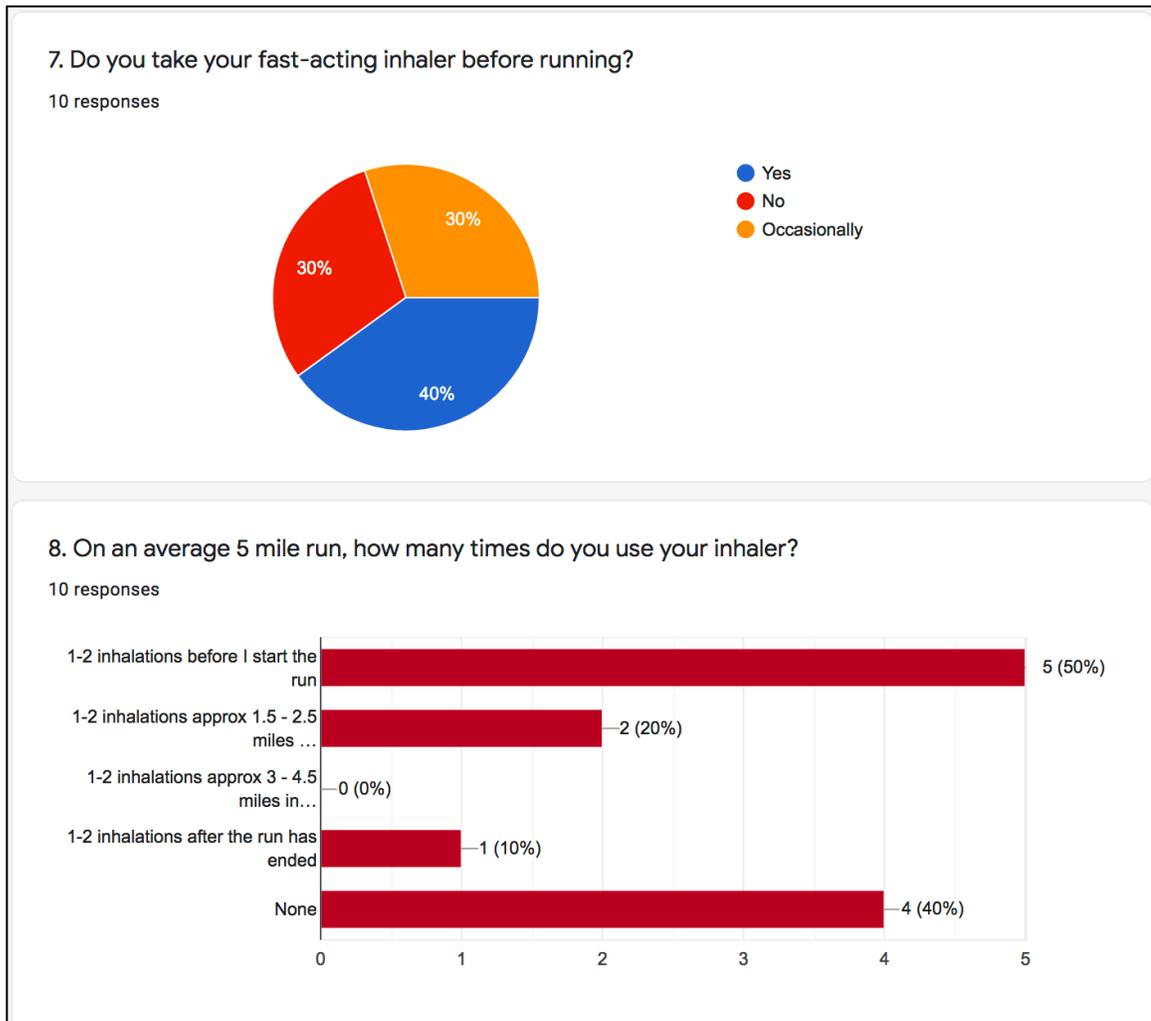
10 responses

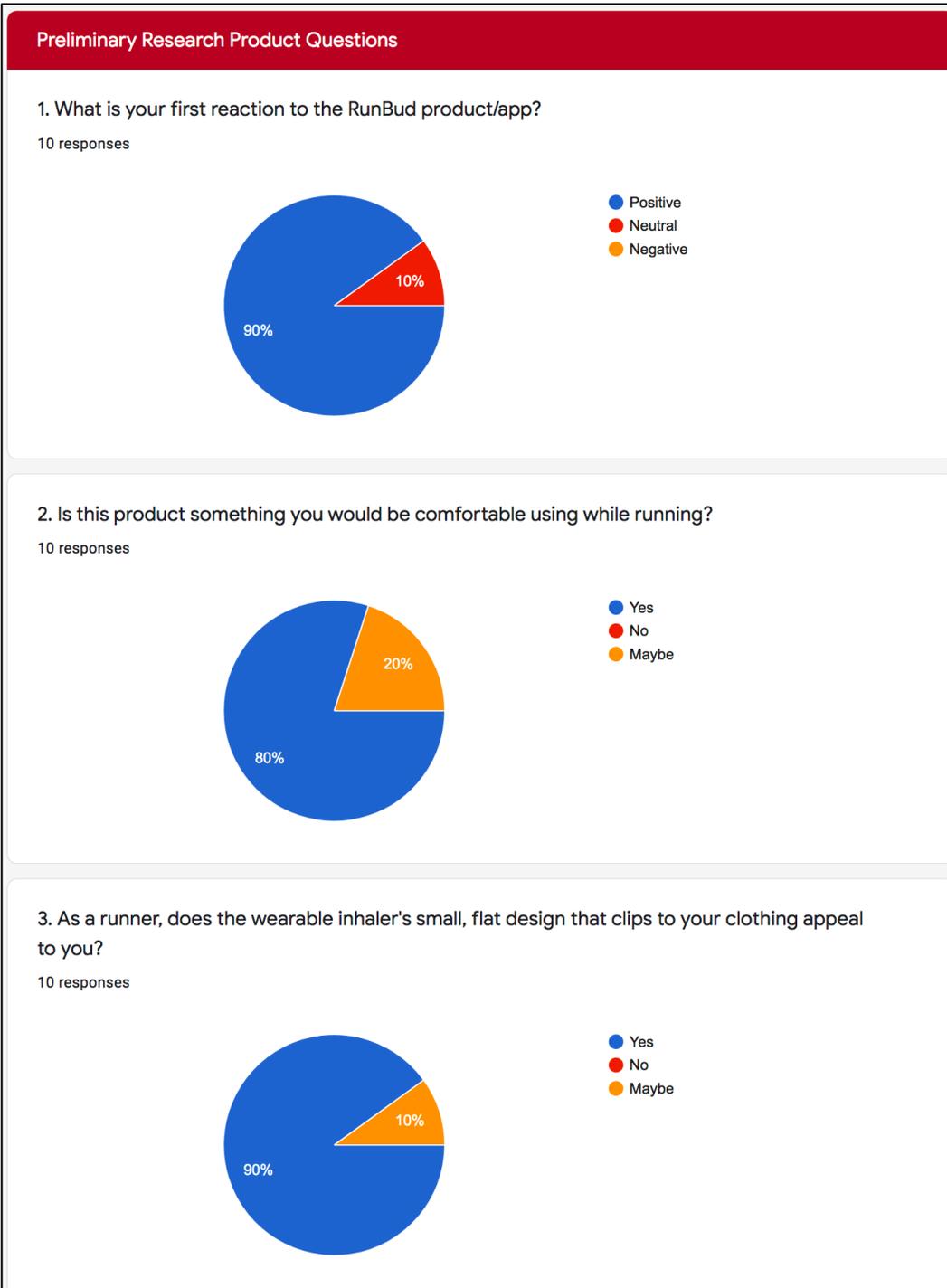


6. Is your asthma only triggered when running?

10 responses

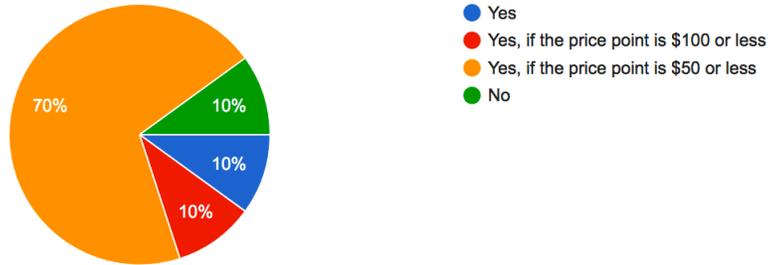






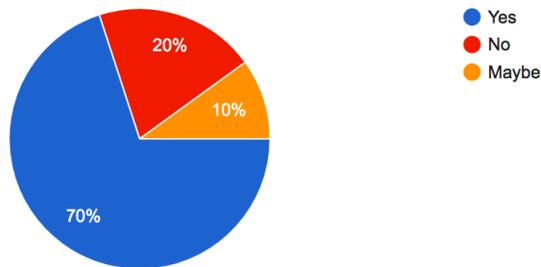
4. Would you spend money on purchasing the wearable inhaler and app?

10 responses



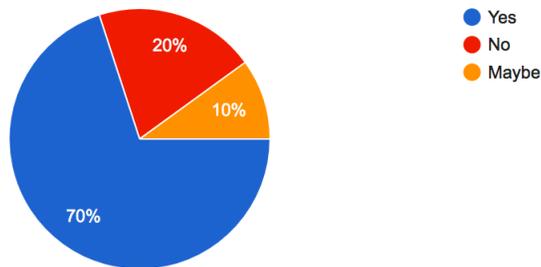
5. Would the breathing pace section of the app be useful when you run to keep your breathing on track?

10 responses



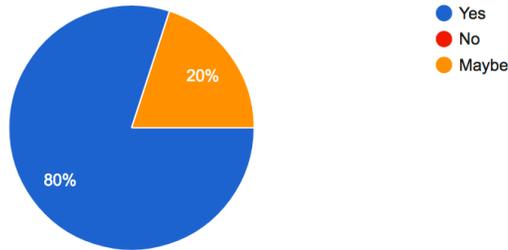
6. Would you use the blood oxygen level section?

10 responses



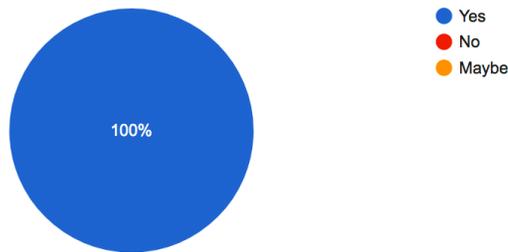
7. Under the "inhaler taken" section, your exact times and total inhalations during that run are logged. Would this be useful to you as an asthmatic runner?

10 responses



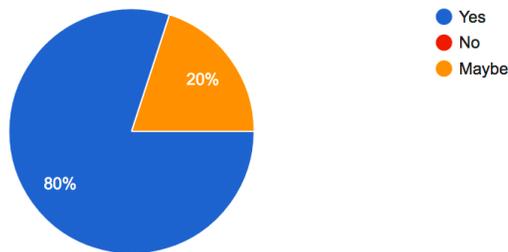
8. Under the "environmental report" section, you receive a personalized report based off the temperature, humidity level, and your active allergies on a particular run. Would you find this information helpful?

10 responses



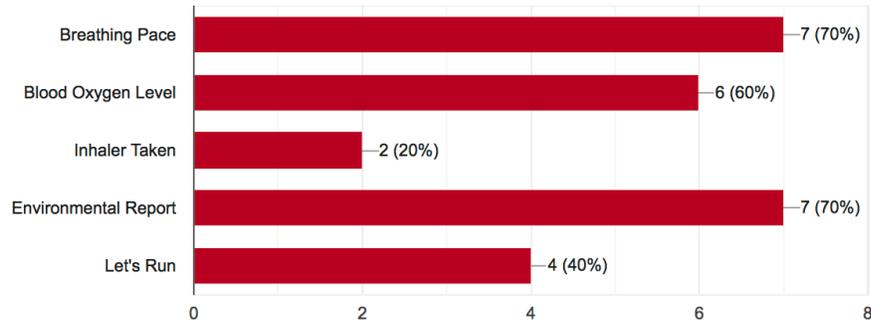
9. Based off of your daily schedule, the "Let's Run Section" provides the best times to run for the week. Would this information be useful to you daily/weekly basis?

10 responses



10. Which "section(s)" do you think would be the most beneficial to you as an asthmatic runner?

10 responses



Additional Comments?

1. Additional comments about the product and/or your asthma and running?

7 responses

None

5 miles is way longer than my ability at the moment and more often than not I take my inhaler with me but I don't have to use it. I also do not have an Apple watch so if it is only an Apple based product I would not use. But if it was for Garmin it is something I may consider.

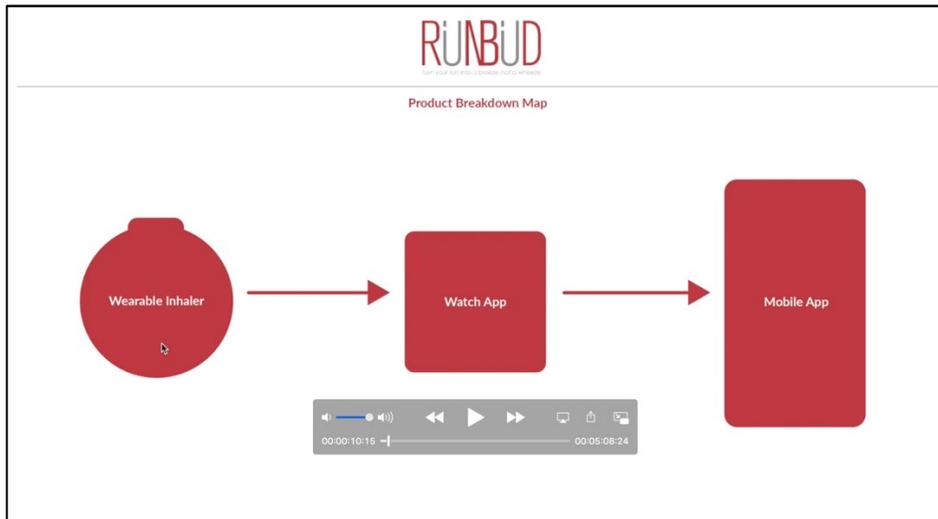
I like the inhaler taken section because I like to keep track of my inhalations so I do not over take my medications. This would help me to try and figure out a better running plan for myself if I can see that I am overusing my inhaler.

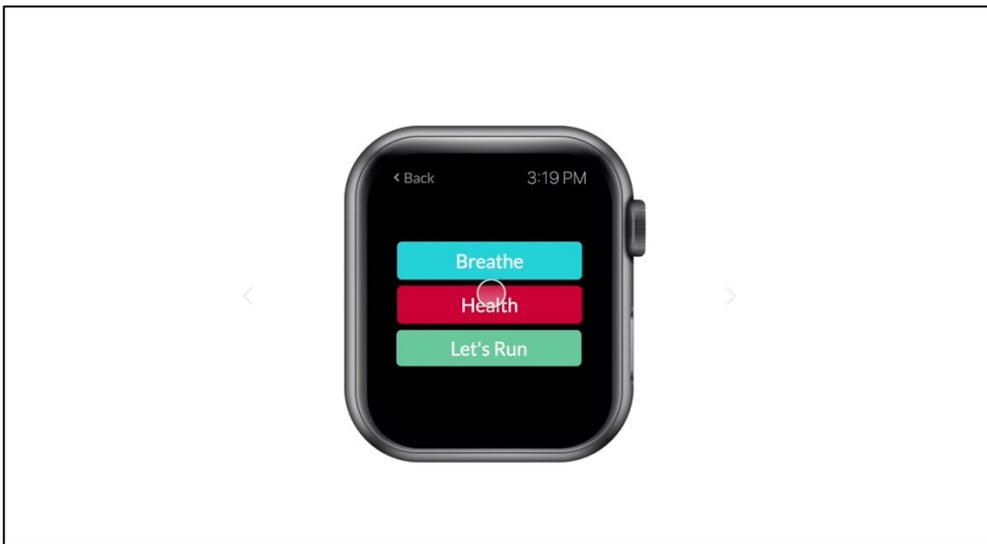
As an asthmatic, this product would definitely benefit me by providing real time data to prevent any health emergencies.

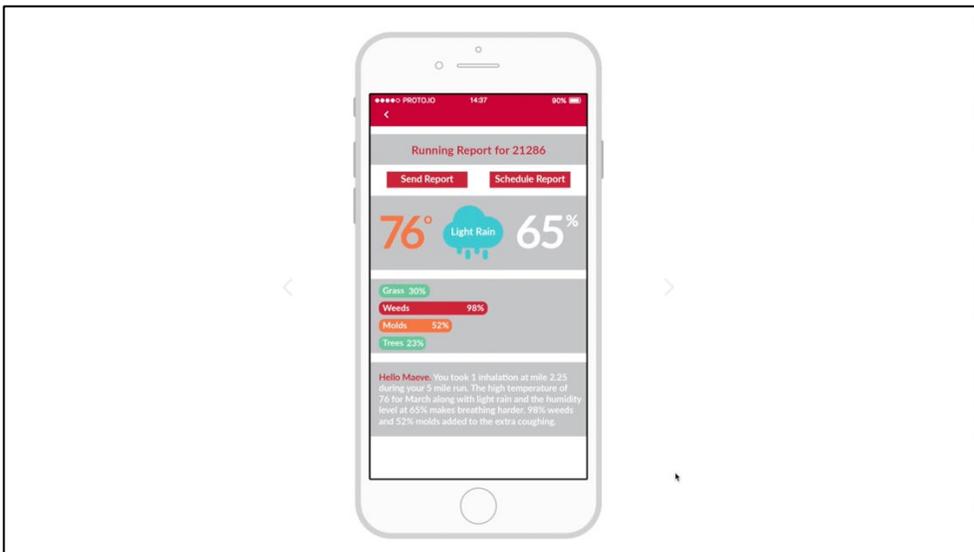
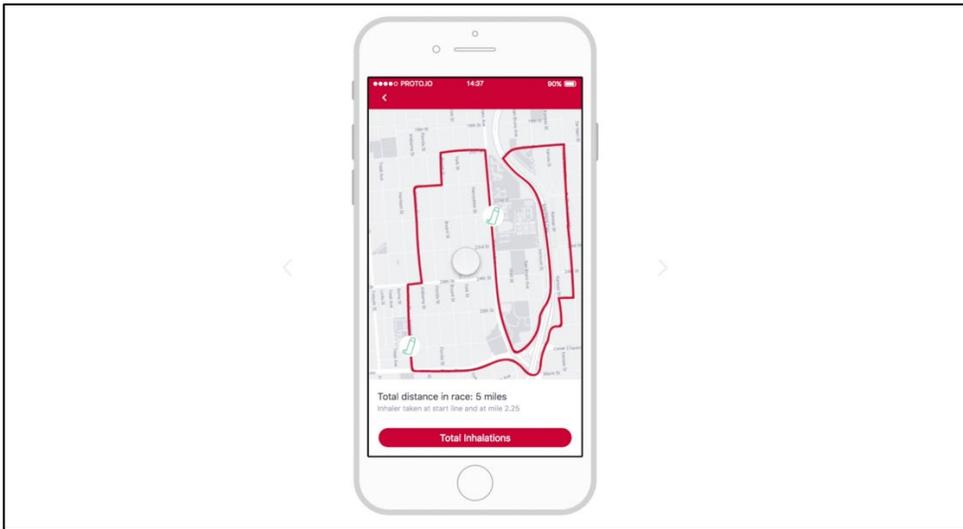
One of the biggest issues is panic once you realize you're in some trouble with breathing. Knowing the oxygen level is extremely useful to know how to react. I think that alone could have saved me a number of times from making my situation worse.

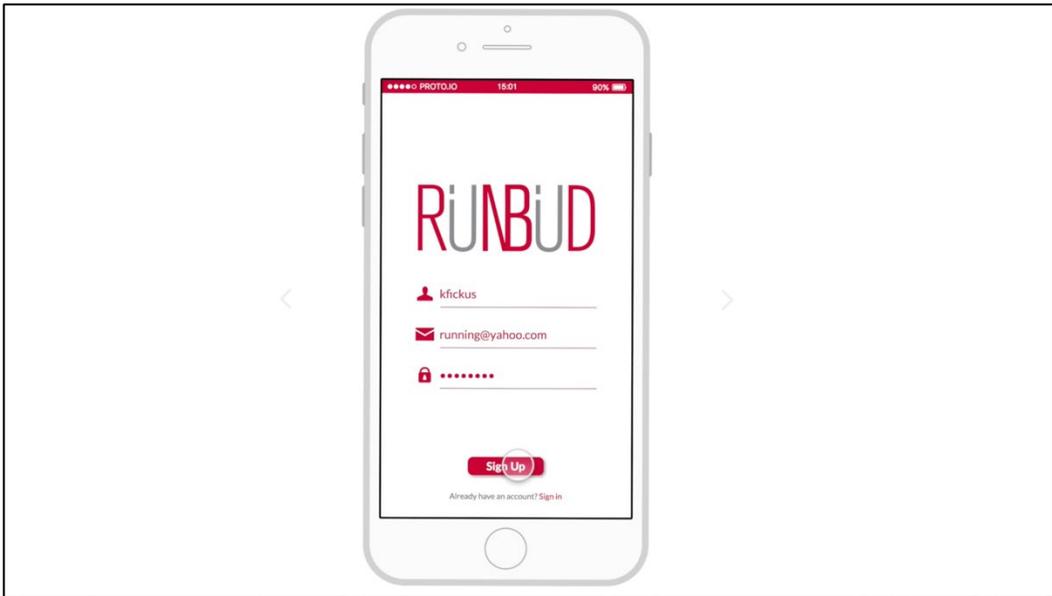
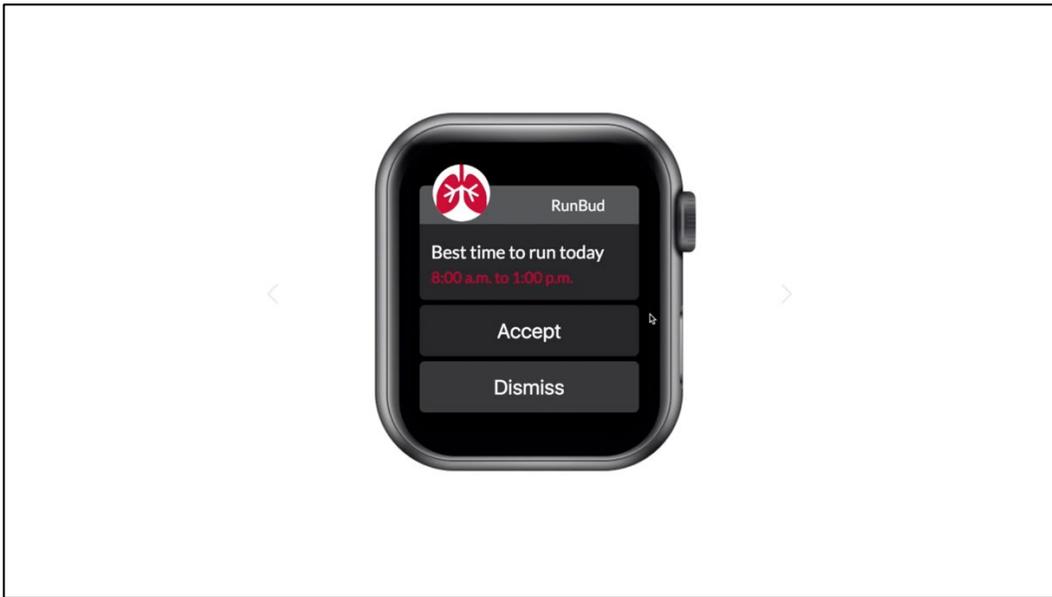
Very Interested

Appendix Q - Preliminary Product Survey Testing Video March 2020









Appendix R – Secondary Product Survey Consent Form July 2020

Whom to Contact about this study:
Principal Investigator: Kelly Fickus
Department: Student Research for Thesis
Telephone number: 443.977.8857

CONSENT FORM FOR PARTICIPATION IN RESEARCH ACTIVITIES

RunBud - A wearable fast-acting inhaler with Apple watch and mobile application

INTRODUCTION/PURPOSE:

I am being asked to participate in a research study. The purpose of this study is to interact with the mobile and watch app and answer research questions. I will be observed by Kelly Fickus and asked questions through Zoom. The feedback I provide will guide the student, Kelly Fickus to make the right optimizations, based on real data & real feedback. I am being asked to volunteer because I am an asthmatic runner (a few non-asthmatics will be tested for usability only) who is age 18 and over. My involvement in this study will begin when I agree to participate and will continue until I complete the mobile and watch app testing and answer the research questions. About 10 persons will be invited to participate.

PROCEDURES:

As a participant in this study, I will be asked to interact with the mobile and watch app and answer research questions via Zoom. I will be able to participate in the study on my own device from any location. The mobile and watch app and research questions are embedded on <https://kellyfickus.wixsite.com/runbud2> website that will be email to a small handful of known asthmatic runners (a few non-asthmatics will be tested for usability only). My participation in this study will last for approximately 30 minutes. No personal identifying information will be written with responses to the questions.

RISKS AND BENEFITS:

My participation in this study does not involve any significant risks and I have been informed that my participation in this research will not benefit me personally, but the project is important because a wearable fast-acting inhaler combined with a sports watch and environmental tracking technology will simplify the lives of physically active asthmatic adults. The wearable product will make engaging in sports activities easier by: (1) providing a fast-acting inhaler that is easy to inhale on the move, (2) being less cumbersome, (3) tracking simple sports-related tasks such as calorie burn, distance and time, (4) tracks inhaler usage including the exact mileage point(s) the user administers the inhaler and (5) tracks daily environmental irritants such as pollen count, humidity level and temperature. The product and mobile application cannot cure asthma, but it will benefit many adults and athletes with the disease.

CONFIDENTIALITY:

Any information learned and collected from this study in which I might be identified will remain confidential and will be disclosed ONLY if I give permission. All information collected in this study will be stored in a locked file cabinet in a locked room. Only the investigator and members of the research team will have access to these records. If information learned from this study is published, I will not be identified by name. By signing this form, however, I allow the research study investigator to make my records available to the University of Baltimore Institutional Review Board (IRB) and regulatory agencies as required to do so by law.

Consenting to participate in this research also indicates my agreement that all information collected from me individually may be used by current and future researchers in such a fashion that my personal identity will be protected. Such use will include sharing anonymous information with other researchers for checking the accuracy of study findings and for future approved research that has the potential for improving human knowledge.

SPONSOR OF THE RESEARCH:

This research study is for a master's thesis, MFA Integrated Design.

COMPENSATION/COSTS:

My participation in this study will involve no cost to me.

CONTACTS AND QUESTIONS:

The principal investigator, Kelly Fickus, 443.977.8857, kelly.fickus@ubalt.edu has offered to and has answered any and all questions regarding my participation in this research study. If I have any further questions, I can contact Megan Rhee, faculty advisor at 410.837.6062 or mhee@ubalt.edu.

For questions about rights as a participant in this research study, contact the UB IRB Coordinator: 410-837-4057, irb@ubalt.edu.

VOLUNTARY PARTICIPATION

I have been informed that my participation in this research study is voluntary and that I am free to withdraw or discontinue participation at any time.

I will be given a copy of this consent form to keep.

SIGNATURE FOR CONSENT

The above-named investigator has answered my questions and I agree to be a research participant in this study. By clicking the accept button below, I am acknowledging that I am at least 18 years of age.

Appendix S – Secondary Product Survey Questions and Responses July/August 2020

RunBud User Testing #2 Questions

A. Screening Questions

1. First name
2. Age
3. Occupation
4. Severity of asthma (mild, moderate, severe)
5. Do you take asthma medication daily (other than fast-acting inhaler)

B. RunBud functionality, usability questions (Recorded through Zoom)

1. Sign up
2. What are you thinking as you view the homepage? Does the language make sense?
3. If you were looking for your profile information, where would you expect to find it?
4. To build your asthmatic runner profile – asthma triggers, metered doses and running availability are needed. Go through each section and measure how easy or difficult it is to navigate.
5. How would you navigate the warm up and cool down sections? How easy or difficult was it to navigate?
6. If you were looking for your running availability, where would you expect to find it?
7. What are your thoughts on the language used under the Breathe section?
8. How would you navigate the inhaler taken section? Is it obvious to you to click on Rx icons for inhaler information?
9. If you were looking to report your asthma symptoms, where would you expect to find it?
10. How would you navigate the pulse oximeter section? How easy or difficult was it to navigate?

11. What are your thoughts on the overall design and layout?

C. Asthmatic User Questions (Zoom face to face interview)

1. How would you describe your overall experience with the product?
2. What features/sections of the app do you think would be the most usable to you as an asthmatic runner?
3. What features/sections of the app do you think you would use the least?
4. What, if anything, surprised you about the experience?
5. What, if anything, caused you frustration?
6. Overall, is this product valuable to you, as an asthmatic runner?

D. Any other comments to add about running with asthma?

RunBud User Testing Report – Round 2

Overall Summary

Testing conducted between August 4, 2020 to August 28, 2020

Ten participants – Six Asthmatic Runners and Four Non-Asthmatic Runners

Testing included mobile and watch app usability testing and 3D wearable inhaler review

All testing was recorded through ZOOM

Who I Tested With

I tested with six Asthmatic runners and four Non-Asthmatic runners. Ages ranging from 32 to 72 years old. Nine Caucasian females and one Latino male was tested. All participants took the usability testing on either a desktop or lap top computer.

Individual Asthmatic Runner Participant Write-Ups**Participant 1 – August 4, 2020****First name: Doug****Age: 44****Occupation: Investigator****Severity of asthma: moderate****Do you take asthma medication daily other than fast-acting inhaler? Yes,
Symbicort****Tasks:** *A list of tasks is listed at the end of this report***Usability Problems (What was observed):**

Unclear of what pulse oximeter means

Unclear to click on yellow graph bar for more detailed pulse oximeter information

Unclear of Rx icon on map (suggested a map legend or key)

Positive Feedback:Features most usable: Inhaler taken section –
map, inhaler usage tracking

Wearable inhaler conceals medication and looks less medical

Design is clean and simple to understand.

“Great, new technology for asthmatics to track symptoms and inhaler usage.”

Overall, valuable product that he would use.

Negative Feedback:

Would not use the pulse oximeter section.

Participant 2 – August 9, 2020**First name: Brynn****Age: 32****Occupation: Director of Marketing****Severity of asthma: mild****Do you take asthma medication daily other than fast-acting inhaler? No****Tasks:** *A list of tasks is listed at the end of this report***Usability Problems:**

No issues on mobile app

Watch – pulse oximeter – missing back button and watch always needs to go back to home screen – not RB icon

Positive Feedback:

Features most usable: Warm-up, Cool Down and Inhaler Taken sections.

Design is clean, easy to read, easy to use, sleek, on brand and not clunky.

Overall, valuable product that she would use.

Negative Feedback:

Running calendar – would not use time of day to set up running schedule – prefers an open day

Participant 3 – August 11, 2020

First name: Heather

Age: 36

Occupation: Teacher

Severity of asthma: between mild/moderate

Do you take asthma medication daily other than fast-acting inhaler? Yes, Advair 500mg

Tasks: *A list of tasks is listed at the end of this report*

Usability Problems:

Understands pulse oximeter, but feels name is too medical for app

Unclear of Rx icon on map (maybe add a label next to icon)

Unclear to click on yellow graph bar for more detailed pulse oximeter information

Unsure where to click in warm-up section

Positive Feedback:

Features most usable: Inhaler Taken section-would use it to log inhaler usage even without running.

Loves wearable inhaler design

Loves environmental report snap shot

Design is clean, simple, design is staggered well and loves the logo and colors. Very easy to understand.

Overall, valuable product that she would use.

Negative Feedback:

Would use the pulse oximeter section the least. Warm-up section was confusing.

Participant 4 – August 21, 2020

First name: Liza

Age: 48

Occupation: Running Coach

Severity of asthma: mild

Do you take asthma medication daily other than fast-acting inhaler? No

Tasks: *A list of tasks is listed at the end of this report*

Usability Problems:

Unclear of what pulse oximeter means

Unclear of SpO2 under pulse oximeter – maybe just leave it the average (96%)

Unclear of Rx icon – looks like Px – unsure to click on it

Unclear why track symptoms are the third button under breathe – thinks it would flow better to be second under pulse oximeter

Watch – pulse oximeter – missing back button and watch always needs to go back to home screen – not RB icon

Positive Feedback:

Features most usable: Let's Run section – likes best times of the day to run

Design is simple and easy to use, loves the colors. "I am not tech savvy and it was easy for me to understand."

Overall, valuable product that she would use.

Negative Feedback:

Would use the pulse oximeter section the least

Let's Run section – would make text bigger for older eyes

Participant 5 – August 26, 2020

First name: Maureen

Age: 62

Occupation: Government Operations

Severity of asthma: moderate

Do you take asthma medication daily other than fast-acting inhaler? Yes, Trilogy

Tasks: *A list of tasks is listed at the end of this report*

Usability Problems:

Unclear of what pulse oximeter means

Watch – pulse oximeter – missing back button and watch always needs to go back to home screen – not RB icon

Positive Feedback:

Features most usable: Let's Run section – likes best times of the day to run and reminders on text message, track symptoms section, environmental report

Design everything works together well (ex: weather, tracking, etc.) Very good idea and user friendly. Easy to use track symptoms section.

Overall, valuable product that she would use.

Negative Feedback:

Would use warm-up section the least. Found it confusing that the Let's Run section didn't start up the run. Confusing to start the run was in the warm up section.

Watch app keeps going back to RB icon – doesn't stay in app

Participant 6 – August 28, 2020

First name: Jane

Age: 72

Occupation: Retired

Severity of asthma: mild

Do you take asthma medication daily other than fast-acting inhaler? Yes, Flovent HFA

Tasks: *A list of tasks is listed at the end of this report*

Usability Problems:

Unclear of what pulse oximeter means

Unclear of Inhaler Taken meaning - change language

Unclear on + and – on metered doses section

Watch – pulse oximeter – missing back button and watch always needs to go back to home screen – not RB icon

Positive Feedback:

Features most usable: Cool down, Let's Run and Inhaler Taken

Design is simple and easy to navigate. Overall experience excellent for not being tech savvy. "I love how the technology and science work in this app, for example, tracking my inhaler usage."

Overall, valuable product that she would use.

Negative Feedback:

Would use warm-up section the least.

Need more visible homepage button in mobile app

Individual Non-Asthmatic Runner Participant Write-Ups**Participant 1 – August 10, 2020**

First name: Michelle

Age: 46

Occupation: Copy Writer / Editor

Tasks: *A list of tasks is listed at the end of this report*

Usability Problems:

Unclear of what pulse oximeter means

Unclear that Inhaler icon at the bottom of the app page was not to get to the inhaler taken section

Unclear of Rx icon – not seeing map as interactive (maybe use language overlay on map)

Watch – pulse oximeter – missing back button and watch always needs to go back to home screen – not RB icon

Need more back buttons

Positive Feedback:

Features most usable: Pulse Oximetry and Inhaler Taken sections

Design is clean, color is soothing, easy to use
Overall, valuable product that she would use.

Negative Feedback:

More back buttons

Participant 2 – August 16, 2020

First name: Samantha

Age: 41

Occupation: Project Manager

Tasks: *A list of tasks is listed at the end of this report*

Usability Problems:

Need cool down reminder – Let's keep moving (walking) reminder

Inhaler Taken button confusing – change button to Inhaler Report

Unclear - Report asthma symptoms section- create a dashboard – look at FitBit to see trends to manage running

Confusion – would add disclaimers of where this information is coming from- “Based on weather.com...”

Unclear – need more distinct variation in Track Symptoms when clicking on buttons – more gray

Unclear – Let's Run – change name – Let's Run Now or When to Run

Watch – pulse oximeter – missing back button and watch always needs to go back to home screen – not RB icon

Positive Feedback:

Features most usable: Like future enhancement – Pulse Oximeter section

Design is easy to understand and likes the colors

Overall, valuable product that she would use even with not having asthma.

Negative Feedback:

Run calendar – make look more like a calendar

Add more options to the temperature section- Hot & Dry, Warm/Hot, Cool/Cold,

Humid, Moderate or Dry

Participant 3 – August 16, 2020**First name: Carly****Age: 34****Occupation: Marketing****Tasks:** *A list of tasks is listed at the end of this report***Usability Problems:**

Unclear of what pulse oximeter means

Unclear of Rx icon – not seeing map as interactive (maybe use language overlay on map)

Unclear – Share medical report- reword to Export Full Report

Unclear – report asthma symptoms- unsure to associate with a past run

Unclear – report asthma symptoms- add the date on screen, done needs to be its own separate button

Unclear Pulse oximeter section- graph yellow bar not seeing as interactive – maybe add

Rx icon to bar – look at graph reporting

Unclear – on watch – Let's Run – makes me think I am launching into a run right away

Watch – pulse oximeter – missing back button and watch always needs to go back to home screen – not RB icon

Positive Feedback:

Features most usable: Inhaler Taken section, Reporting aspect beneficial

Design is clear, legible, easy to use, clear buttons, easy to click

Overall, valuable product that she would use even with not having asthma.

Negative Feedback:

Run calendar – make look more like a calendar

Watch- track symptoms and pulse oximeter has no benefit on the watch

Not sure track symptoms were run specific

Design – red on blue – revisit may be an issue

Small learning curve with using product – a short one minute walk through would be helpful

Participant 4 – August 23, 2020**First name: Jessica****Age: 43****Occupation: Accountant****Tasks:** *A list of tasks is listed at the end of this report***Usability Problems:**

Unclear Rx icon – equate to a pharmacy location on map

Unclear – want a button to just start running

Positive Feedback:

Features most usable: Pulse oximeter section

Design is simple and easy to use

Overall, valuable product that she would use even with not having asthma.

Watch – easy to use and modern

Negative Feedback:

Small learning curve with using product – a short one minute walk through would be helpful

Solutions

1. Mobile - Rework Rx icon and make more interactive looking
2. Mobile - Rename pulse oximeter to blood oxygen level
3. Mobile - Share medical report- reword to Export Full Report
4. Mobile - Report asthma symptoms- add the date on screen, done needs to be its own separate button
5. Mobile - Pulse oximeter section- graph yellow bar not seeing as interactive
6. Mobile - Want a straight-forward button to just start running
7. Mobile - Let's Run – change name – Let's Run Now or When to Run (changed to Run Schedule)
8. Mobile - Confusion – would add disclaimers of where this information is coming from- “Based on weather.com...”
9. Watch - need more distinct variation in Track Symptoms when clicking on buttons – darker gray (made darker)

10. Mobile/Watch - Need cool down reminder – Let's keep moving (walking) reminder
11. Mobile/Watch - Inhaler Taken button confusing – change button to Inhaler Report (changed to usage)
12. Watch – pulse oximeter – missing back button
13. Watch always needs to go back to home screen – not RB Icon
14. Watch – Let's Run – makes me think I am launching into a run right away (Changed to Let's start running screen when accept is hit) Apps

Tasks

RunBud functionality, usability questions (Recorded through Zoom)

1. Sign up
2. What are you thinking as you view the homepage? Does the language make sense?
3. If you were looking for your profile information, where would you expect to find it?
4. To build your asthmatic runner profile – asthma triggers, metered doses and running availability are needed. Go through each section and measure how easy or difficult it is to navigate.
5. How would you navigate the warm up and cool down sections? How easy or difficult was it to navigate?
6. If you were looking for your running availability, where would you expect to find it?
7. What are your thoughts on the language used under the Breathe section?
8. How would you navigate the inhaler taken section? Is it obvious to you to click on Rx icons for inhaler information?
9. If you were looking to report your asthma symptoms, where would you expect to find it?
10. How would you navigate the pulse oximeter section? How easy or difficult was it to navigate?
11. How would you navigate the Let's Run Section?
12. What are your thoughts on the overall design and layout?

Appendix T – Secondary Asthma Product Testing Website – July/August 2020



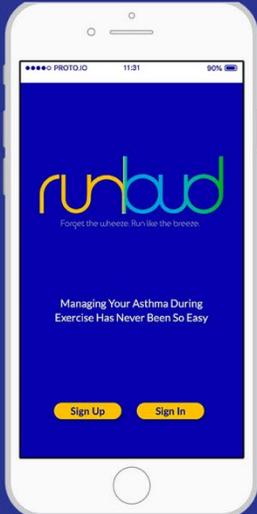
A wearable fast-acting inhaler with Apple watch and mobile application

Welcome to my MFA Integrated Design Thesis Project!

To summarize, the wearable fast-acting inhaler talks to both the Apple watch and mobile app. The wearable inhaler only tracks inhaler usage and sends usage information to the watch and/or mobile device.

The mobile and watch app and research questions are only open to asthmatic runners (a few non-asthmatics will be tested for usability only) who are age 18 and over.

I intend to have my participants interact with the mobile and watch app and answer research questions via Zoom. Your feedback will guide me to make the right optimizations, based on real data & real feedback. Please click mobile and watch links below to interact with the apps.



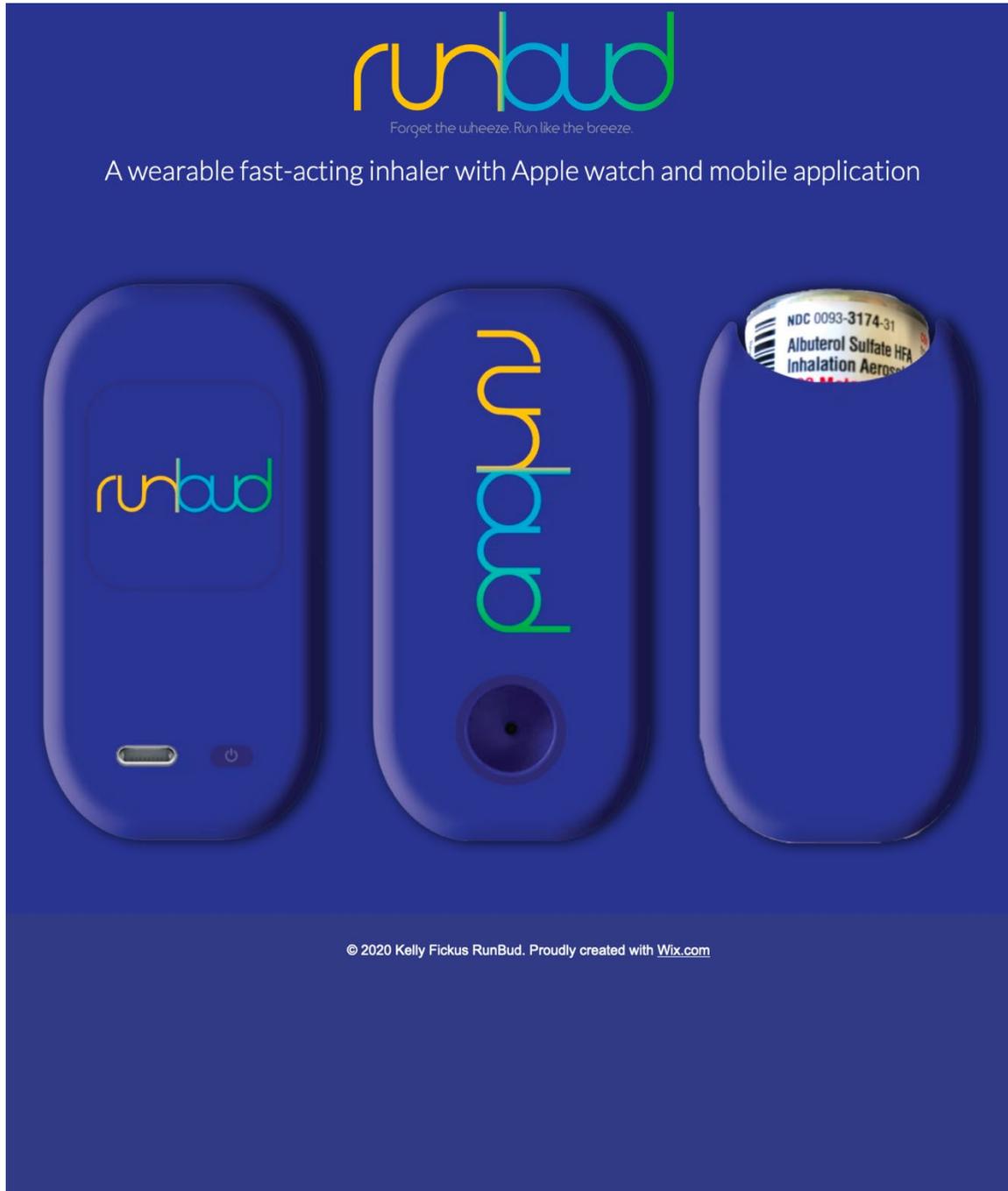
Mobile App



Watch App

Thank you to all who participated in the user testing for my RunBud wearable inhaler with watch and mobile app. Please take a look at the wearable inhaler prototype.

[View Prototype](#)



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