

# 2021-2022 UC Irvine Writing Award Winner For Best Public or Professional Writing Category

## *EzBreathe*

*Group Paper A*

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ENGR 190W  
Professor Hong  
18 October 2021

Editor:

Grading Categories:

1. Critical thinking & analysis:
2. Use of evidence/research:
3. Development & structure:
4. Language & style connections:

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## 1. **Introduction**

Twenty-five million Americans suffer from asthma, a disease of the lungs. This translates to 8% of all adults and 7% of all children in the United States [1]. The patients with mild-to-moderate asthma are at a higher risk of ER admission as a result of improper inhaler use and management. Studies on misuse of inhalers in hospitalized asthma patients demonstrate that up to 86% of patients are using them incorrectly [2]. For instance, 84% of inhaler users do not wait the minimum time of 30 seconds in between inhalations, causing them to not acquire the recommended dose of medicine [3]. Furthermore, 75% of inhaler users do not properly hold their breath after inhalation [4]. These mistakes can lead to an exacerbation of symptoms and potential hospitalization.

Most asthma patients are not managing their asthma symptoms and attacks. Doctors recommend asthma patients to record their symptoms in a notebook or “asthma diary” [5]. This may not be done by the patient since they can forget or are uneducated of the symptoms they should be looking for. Asthma is poorly controlled in over 50% of cases and the “promotion, uptake, and use of self-management among people with asthma, carers of children with asthma, and healthcare professionals remain low [6]”. In order for patients to understand their lung function, they have to go to the doctor's office for an assessment. They can also manage their lung health using at home devices like the peak flow meter, which can measure nitric oxide in exhaled breath. Nitric Oxide levels indicate the severity of inflammation in the lower airways [7]. However, these devices are expensive, hard to use, and the results are difficult to interpret.

The Coronavirus (COVID-19) pandemic has caused concern about its effects on asthma patients. According to the Center for Disease Control and Prevention (CDC), “ people with moderate-to-severe or uncontrolled asthma are more likely to be hospitalized from COVID-19”

[8]. Furthermore, COVID-19 in asthma patients can lead to “an asthma attack, pneumonia, or other serious lung disease” [9]. Extra caution is recommended for asthma patients to avoid contraction of COVID-19, along with ensuring they are controlling their asthma. Studies are still being conducted to determine the long term effects of COVID-19 on asthma patients. Now, more than ever, it is vital for people with asthma to manage their condition and be diligent with their treatment.

## **2. Proposal Statement**

The proposed EzBreathe inhaler attachment, along with the integrated smartphone app, is designed to help people manage their asthma more effectively. By integrating a spirometer and nitric oxide level measurements, patients will be able to assess their lung function and any indication of airway swelling on a regular basis using the corresponding user-friendly app. The app will also include features such as clear and concise results, tips for correct breathing techniques to properly inhale the prescribed amount of medicine, and reminders to help patients stay consistent with treatment and assessment. The Asthma Therapy Assessment Questionnaire (ATAQ) will also be integrated into the app to evaluate patients’ asthma control and management. Based on this, patients will be notified when they need more intense treatment and what areas of management they can improve on.

## **3. Work Product**

The EzBreathe inhaler attachment will incorporate a spirometer, an exhaled nitric oxide detector, and a bluetooth communication device that pairs with the smartphone app. It will be used to ensure the correct dose of medicine is administered, keep the patient consistent with treatments, and assess lung function and risk of asthma attacks. The EzBreathe is compatible with any traditional inhaler, but the prototype is modeled based on the measurements of a

standard albuterol inhaler. Fig. 1 below shows the EzBreathe attachment in brown over the gray and blue inhaler.



*Fig. 1: EzBreathe attachment (brown) with Inhaler (gray)*

EzBreathe will be available for over-the-counter purchase without a prescription. Patients will only need a prescription for their inhaler which will pair with the attachment. EzBreathe will fit over the standard albuterol inhaler prescribed to asthma patients, with an extra channel below where medicine is dispensed that the patient will blow into when performing lung assessments. The lung assessment chamber will be able to fold downward when not in use so that patients can properly inhale the medicine. There will be two buttons on the right side of the device to toggle between air collection and medicine deployment. The attachment will be made of polypropylene, a thermoplastic commonly used for the inhaler housing. It will weigh approximately 8 grams without the inhaler and 16 grams with the inhaler inserted. Fig. 2 and 3 below illustrate the structure of the EzBreathe attachment shown in brown over an inhaler shown in gray.

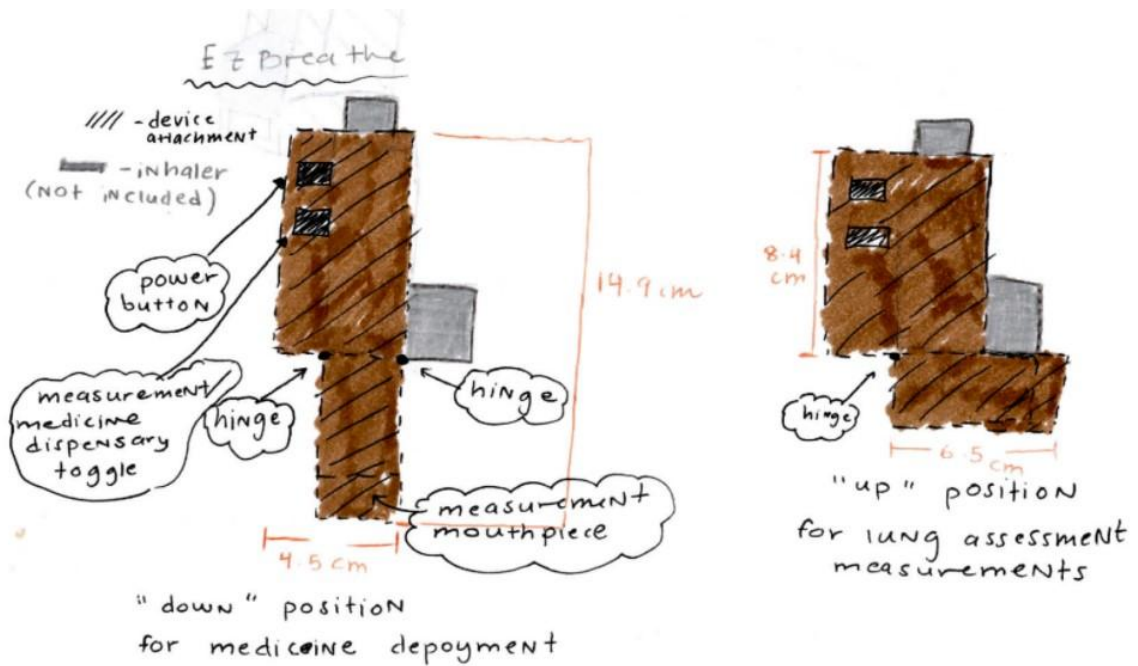


Fig. 2: Side View of EzBreathe (brown) and Inhaler (gray)

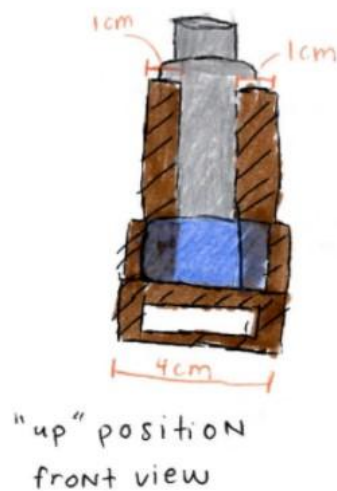
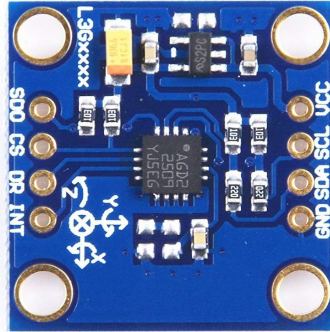


Fig. 3: Front View of EzBreathe (brown) and inhaler (gray and blue)

The physical components of the attachment include several sensors which detect how often it is being used as well as how much medication is being administered to the user. A digital

gyroscope, measuring 23 by 23 millimeters [10], will be incorporated into the attachment to detect the angle at which the inhaler is held, as shown in [10, Fig. 4] below.



*[10, Fig. 4]: Digital Gyroscope Chip*

There will be a miniature spirometer contained within the attachment to measure forced expiratory volume (FEV1), which is the amount of air exhaled in 1 second, and peak expiratory flow (PEF), or the total amount of air exhaled from the lungs, as well as integrated technology from the COSMED Vivatmo me, a handheld device that measures exhaled nitric oxide levels [11]. FEV1 can be used to determine the level of blockage in a patient's airways and PEF can assess overall lung fitness [12]. [13, Fig. 5] below shows a miniature spirometer, measuring 170 by 60 by 26 millimeters. The components of the spirometer will be built into the back panel of the EzBreathe attachment, along with the gyroscope chip and the COSMED Vivatmo me parts. EzBreathe will send collected data to the app via bluetooth that the patient and their medical provider will be able to access.



*[13, Fig. 5]: Micro Medical MicroPlus Spirometer*

The integrated app showcases live results and their interpretations, helpful guides, alerts for when patients' results are abnormal, and tips on how to properly use the inhaler. It will serve as an instructional tool and medical log for each patient. It will be pre-programmed with written and auditory instructions on how to properly hold and operate the inhaler, as well as how to breathe in the medicine. For example, cues will appear on the smartphone screen to demonstrate inhaler use, as shown in Fig. 6 below. The app will graph the number of treatments, nitric oxide levels, and PEF over a period of time. The app will also have a section explaining the patient's specific treatment routine and dose of medicine. The user will also be able to activate "Child Mode" on the app, which will have a simpler interface and hidden personal data. This information will be input into the app by the user or the user's medical provider.

The patient will also be able to fill out the Asthma Therapy Assessment Questionnaire (ATAQ) on the app. The ATAQ is a self-administered questionnaire used mainly to "measure a person's self-reported severity of asthma symptoms, and medication compliance barriers." The ATAQ assigns an asthma control score ranging from 0 to 4, where 0 indicates no issues and 4 indicates major issues with asthma control. It can also identify areas of a treatment plan that need improvement [14]. Based on frequency of treatment, lung performance, and ATAQ responses,



the app will recommend beneficial treatment plan changes based on an algorithm. Fig. 6 also includes two sample questions from the ATAQ.



*Fig. 6: App Instructions for Inhaler Use, Patient Daily Report, and sample ATAQ*

#### **4. Target Customer**

The EzBreathe inhaler attachment is intended for those who are prescribed an inhaler for an asthma or lung condition. In the United States, 25 million people suffer from asthma each year; 5 million of those being children under the age of 18 [1]. Each year, 60 million prescriptions of inhalers are administered to people each year [15]. Less than 30% of those who receive a prescription are getting a written asthma after-care plan [16]. With no new advancements to the treatment of asthma, these numbers will continue to increase. The EzBreathe inhaler attachment could help millions manage their asthma better as well as prevent thousands of hospitalizations. Since asthma affects each age group, it is crucial to create a user-friendly phone application with everyone in mind.

The EzBreathe system is curated for both independent use and shared use. The parents of young children with asthma can pair their phone to their child's attachment and assure themselves that they are using their inhaler correctly. The attachment also has the option to sync with two devices, making it easier for a parent or senior caretaker to see the live results. The EzBreathe attachment along with its app makes it easy for anyone to better manage their asthma, regardless of age.

#### **5. Competition**

A modern-day metered dose inhaler (MDI) stands as one of EzBreathe's baseline competitors, as it became "the first device to effectively deliver medicine to the lungs" [17]. This device created a major breakthrough back in the 1950's, and has since paved the way for the development of more advanced asthma technologies.

Over the years, the MDI's reliance on inhaler training from healthcare professionals for the patient's "correct actuation and inhalation coordination," has been one factor that has

outweighed the advantages of the convenient medication delivery method that was first introduced for the MDI inhaler concept [18]. This has led to the worldwide demand for digital asthma treating solutions, due to “the increasing penetration of Internet of Things (IoT) in the healthcare and medical devices sector” [19]. Therefore, the EzBreathe device with its application is introduced as an innovative solution to meet this demand and incorporate lacking functionalities that the traditional inhaler cannot achieve on its own. This is achieved by designing the EzBreathe app to educate patients on the proper use of their inhalers, provide more extensive health data such as the FEV1, PEF and nitric oxide measurements and allowing for patients to take control of their journey alongside the physicians and caregivers. These and many more features, provide ideal components that surpass the benefits from the traditional inhalers, while introducing new and effective methods of asthma treatment management.

Aside from MDI's, the closest competitor to the EzBreathe is Cognita Lab's CapMedic device, seen in [21, Fig. 7] below. The CapMedic, approved by the Food and Drug Administration (FDA), is a reusable and rechargeable cap that guides patients with asthma, chronic obstructive pulmonary disease and other respiratory disorders, on how to properly use their inhalers to ensure a full dose of medication [20]. The cap emits visual, audio and haptic signals, accompanied by a smartphone app for further instruction. It also comes equipped with an at-home spirometer to measure FEV1 and a peak flow meter to test PEF, both of which will have their results displayed on the corresponding app.



*[21, Fig. 7]: CapMedic attachments & smartphone application*

The EzBreathe device, similar to the CapMedic, will be designed to measure both PEF and FEV1, as they are the two most common lung function tests in the diagnosis and monitoring of respiratory conditions, along with also incorporating exhaled nitric oxide testing. An inconvenience the CapMedic introduces however, is requiring an additional attachment for performing the peak flow test. Since CapMedic's primary device is not capable of conducting all measurements needed for a full lung assessment when being simply attached to the inhaler, the user would have to carry around an extra component for performing the PEF test, risking the misplacement or potential loss of the secondary attachment.

While it is important to account for another mouthpiece that can test the lungs without the need of medication, such as when performing forceful exhalations, an all-in-one device would be much more effective. Therefore, EzBreathe will conveniently incorporate a non-detachable mouthpiece to be used when measuring not only the peak expiratory flow, but the nitric oxide tests as well, both of which require exhalation, without the need to switch off between components. This way, the data and trends of lung function will not be affected by the lack of testing from the patient, as it will all be accessible for them to perform as required. To also ensure that the process of taking the medication is not affected by the secondary mouthpiece, the

EzBreathe application will instruct users to place the mouthpiece in the “down” position, as shown previously in Fig. 1, to allow them to comfortably and effectively take their medication.

With the EzBreathe, unlike for CapMedic, asthma patients will also not be required to receive a prescription, making it much more accessible to the public. While an inhaler, its medication and the dosage require a prescription from a licensed physician to treat specific needs, the EzBreathe is simply an attachment that does not come with any form of medication, and is therefore safe to buy over-the-counter. This will in turn, save asthma patients from a costly doctor’s visit that might be made exclusively to obtain an EzBreathe prescription.

Another improvement EzBreathe will apply is the Asthma Therapy Assessment Questionnaire (ATAQ) on the smartphone app, for patients to take during the course of their treatment. With integrated text boxes, users can go into detail with explaining any abnormal symptoms they may experience in combination with rating their asthma control from 0-4. Not only does this allow EzBreathe to qualitatively document the patient’s state of health, but it also eliminates the need for patients to recall exactly how they felt 3 or 4 months prior to their visit with their healthcare providers.

In terms of the selling price, the CapMedic’s device requires recurring payments of \$49 for every 6 months for 2 years. However, users must also pay a \$30 sign-up fee when registering their device on the application, creating a total price of roughly \$226 for two years of usage. Considering that multiple or recurring payments may be inconvenient for the user to keep track of, the EzBreathe makes it simple by only requiring a one-time purchase of \$280, which covers any application fees. Although the EzBreathe is available at a higher cost, returning users will only need to pay \$70 for repairing or replacing their device, making it a much more affordable option in the long run. It also incorporates many more advanced components, such as a

gyroscope, which aids the asthma patient like never before. A breakdown of the costs is provided in [21, Tab. 1] below.

	Cap Medic	Ez Breathe
<b>Selling Price (Attachment + Application Fee)</b>	\$49 every 6 months, for 24 months = \$196	All inclusive fee of \$280
<b>Sign Up Fee</b>	\$30	0
<b>Total (for 2 years):</b>	<b>\$226</b>	<b>\$280</b>

*[21, Tab. 1]: CapMedic and EzBreathe cost comparison*

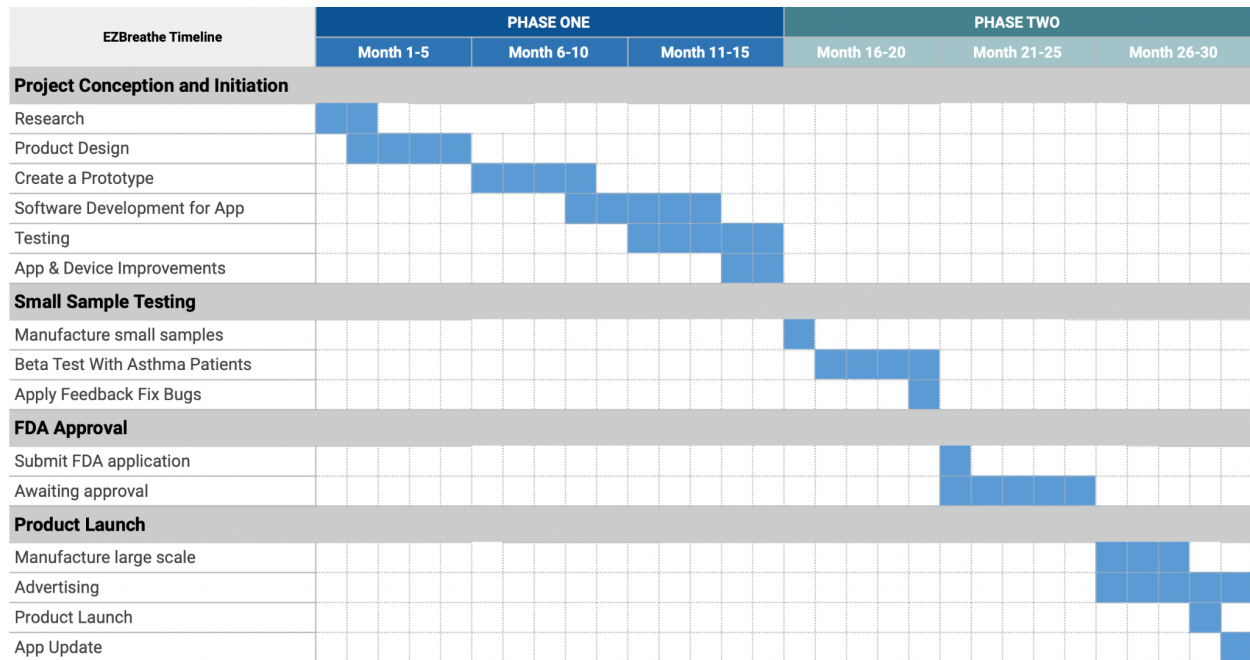
Overall, EzBreathe presents many improvements above the traditional metered dose inhalers and the CapMedic, by being an all-in-one design featuring FEV1, PEF and nitric oxide testing, ATAQ monitoring and an increased accessibility for purchasing. Therefore, Ez Breathe's functionalities make it unique in combating any barriers against successful asthma testing, management and inhaler usage.

## 6. Method of Approach

### 6.1. Schedule

The timeline from product conception to product launch is approximately 2 years and 6 months. Since the EzBreathe inhaler attachment classifies as a Class II medical device, it requires the approval from the FDA. Below in Tab. 2, the timeline is split into two phases. Phase one focuses on the preparation for the FDA application. This phase is 15 months long to assure that the product is well researched, designed, and tested. In phase two, the product will be given to a small batch of 200 asthma patients for beta testing. The patients will test the attachment for four months, followed by a month of applying their feedback to the app and device. In month 16, the FDA application will be submitted. The response could take up to 6 months to receive. Once

the product is approved, it will be manufactured in large quantities for four months. During these months, advertising for the product will begin. The product will be launched in month 25. The following month will be focused on the first app update to fix any bugs reported from the user.



Tab. 2: EzBreathe Production Timeline

## 6.2. Cost

The selling price for the EzBreathe is \$280, which includes the attachment and the phone application. If the EzBreathe attachment needs to be repaired or replaced, an additional fee of \$70 can be paid. To develop an application with medium complexity it costs \$100,000 [22]. The EzBreathe attachment is considered a Class II medical device, in comparison to the CapMedic device. To develop a Class II cleared medical device, the cost is approximately \$30 million [23]. This includes the development, engineering, and FDA approval. About \$24 million is needed for FDA approval and activities, leaving about 20% of the \$30 million for manufacturing, labor, and engineering [24]. Two biomedical engineers along with two mechanical engineers will be needed through the production until large scale manufacturing ends. With a yearly salary of \$68,000 for

about 2 years, this accounts for 2.11% of the \$30 million. The cost of the physical components of the EzBreathe can be seen below [25-28, Tab.3], which totals the cost to about \$100 per attachment.

Component	Cost	References
3D printed plastic attachment	\$11	[25]
Digital Gyroscope	\$38	[26]
Spirometer Sensors	\$35	[27]
Circuits and Wires for Connectivity and Sensors	\$10	[28]
Circuitry for Audio	\$6	[28]
<b>Total Cost</b>	<b>\$100</b>	

*[25-28, Tab. 3]: Cost to manufacture EzBreathe*

## 7. **Risk Management**

The leakage of medical information can be one of the top risks associated with the use of EzBreathe’s smartphone application. Given that medical records act as a main source for providing personalized health information to providers, the leakage of health information can put patients at risk of being misdiagnosed or receiving the wrong treatment. Therefore, this significant privacy concern must be considered to accurately and effectively treat a patient.

To combat this issue, EzBreathe will integrate a two-factor authentication with each log in attempt. Doing this will ultimately strengthen access security by requiring two methods of verifying one’s identity. This would mean that aside from logging in with their username and password, users will also be required to approve authentication requests on their smartphone, making it a fast and easy way to “protect against phishing, social engineering and password brute-force attacks”[29]. For further protection, the application will also incorporate encrypted health information to block access from unauthorized users, while complying with the Health



Insurance Portability Act (HIPPA). According to CDC, HIPPA's privacy rule requires one to implement ways for "protecting sensitive patient health information from being disclosed without [their] consent or knowledge" [30]. Therefore, by implementing a combination of the two-factor authentication with encryption of medical data, the application will ensure an individual's health information is "properly protected while allowing the flow of health information needed to provide high quality health care" [30]. As a result, asthma patients will also be at ease when tracking their lung health, and will rely on EzBreathe to keep their critical medical information safeguarded.

Safety concerns regarding the product's longevity may also arise, due to Asthma being one of the most common chronic (lifelong) health conditions. This, for example, may include health risks associated with a lack of accurate readings and quality results over a long period of time. To put into perspective, most inhalers expire one year after being issued, because it is based on when the medication is most effective. As a result, patients are required to request a new inhaler and updated medication yearly by a doctor or pharmacist [31]. Since the EzBreathe itself is not supplied with any form of medication, it is expected to last up to an estimated time frame of 2-3 years when kept in good condition. Nonetheless, the lifespan of any medical device also "depends on a number of factors, including frequency of use, maintenance and servicing, and the way in which it's used" [32]. For the user's convenience however, the EzBreathe application will send several reminders to the user notifying them of a necessary replacement, along with a replacement or repair voucher that reduces the cost of the device to only \$70. Therefore, by having access to an over-the-counter device within a safe time frame and at a discounted price, the EzBreathe will reduce the risk of patients using the device for longer than the recommended time, leading to possible inaccurate test readings.

## **8. Conclusion**

Eight percent of all adults and seven percent of all children in the United States suffer from asthma [1]. Of those individuals, 86% use their inhaler incorrectly [2]. Inhaler misuse can lead to improper treatment, which can heighten normally manageable asthma symptoms. Misuse normally shows up in the form of improper breath holding and taking puffs too close together. Along with inhaler misuse, many asthma sufferers struggle with asthma management. Inconsistencies in treatment and lack of adherence to treatment plans outside of the doctor's office prevent patients from properly controlling their asthma. All of these factors point towards a need for straightforward, accessible asthma management and treatment.

The EzBreathe inhaler attachment allows patients to monitor their lung health, plan treatments, and administer medicine correctly. By providing clear visual and verbal instructions, EzBreathe minimizes patient error during self-treatment. Furthermore, PEF, FV1, nitric oxide, and ATAQ tests included in the app hold patients accountable and promote adherence to treatment.

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