Contract Book

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Biographies

Nela Mohan is a senior undergraduate student at Johns Hopkins University studying Biomedical Engineering and Electrical Engineering. Her focus is in signal processing with plans of working in surgical robotics.

Samantha Weed is a senior undergraduate student at Johns Hopkins University studying Biomedical Engineering. Her focus is in imaging and instrumentation with plans of working in patient data.

Alex Ozbolt is a senior undergraduate student at Johns Hopkins University studying ECE. His focus is in quantum photonics and nanomaterial fabrication.

Abstract and Mission Statement

This product is an automated bag-mask system that standardizes the pressure of compressions and frees the hands of EMTs and other clinicians throughout the duration of the bagging procedure. An electronic motorized system controls the continuous pumping of the mask while carefully monitoring the pressure being delivered. With this design, EMTs can more easily intubate their patients during transport and in field settings, ensuring that no matter where these patients are, they are getting adequate oxygenation.

Keeping your hands free so you and the patient can breathe.

Introduction/Pitch

In February of 2021, one of our founders contracted COVID. She unfortunately got very sick and her health went downhill very quickly. With a fever soaring above 103 °F, she struggled to stay awake. At that point, it became harder and harder to breathe. She had reached a condition where she needed medical transport and attention. An ambulance arrived quickly with two EMTs ready to perform emergency service.

In the event of a medical emergency such as this, patients may need to call an ambulance to get transported quickly to the hospital. However, EMTs also need to be able to transfer a possibly immobile patient from one location into the ambulance. In this situation, it is possible that the patient is also experiencing respiratory failure. Ideally, the patient would receive air through the bag mask procedure where a mask is fitted onto the patient's face and held secure by one EMT, while a second EMT compresses the bag, supplying oxygen. However, performing this procedure is currently not possible during transport.

In a typical emergency transport setting, two EMTs are stationed at the ends of a gurney to carry the patient to the emergency vehicle. This transport process prevents other EMTs from having the necessary space and time to properly perform the bag mask procedure, leaving patients without oxygen while being moved to the ambulance.

Additionally, the current bagging procedure calls for EMTs to manually squeeze the bag mask apparatus. This is normally done using a single hand, leading to quick fatigue and varying compression pressure. As a result, the patient is subject to non-standard oxygen saturation levels. Manual bagging also prevents EMTs from performing other tasks, requiring extra personnel that may not be available.

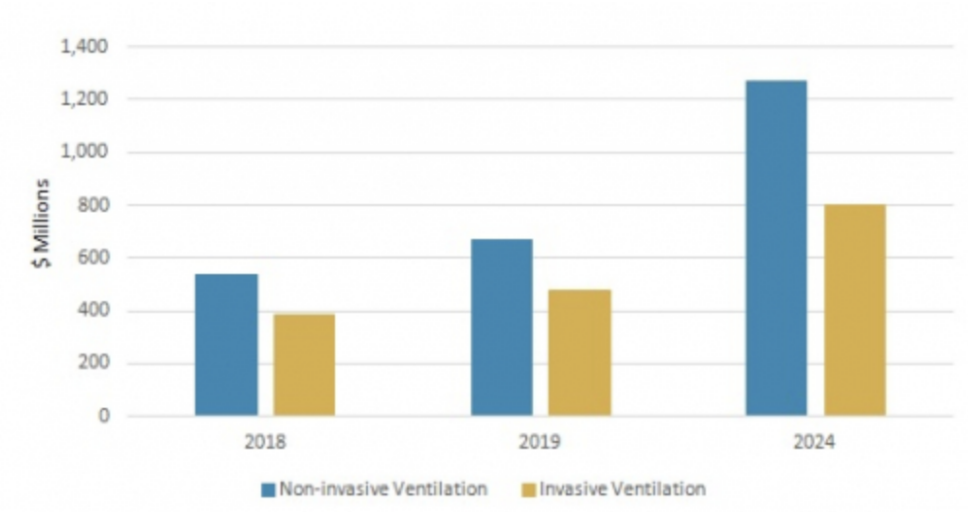
Our product automates this procedure, making it hands-free and consistent. This will allow EMTs to bag patients during transport, leave them free to perform other necessary tasks and standardize bag compressions.

Customer Needs List

Need	Priority and Reasoning	How we address it
EMTs need their hands free	Highest: Care providers need to be able to perform other tasks in addition to ventilating the patient, especially if there are a limited number of EMTs available. This will also allow EMTs to intubate patients even when they are being transported.	After the initial positioning of our device, the EMT only needs to start the device. Then, they are free to perform other duties.
EMTs need the intubation equipment to be portable	High: Non-Invasive bag mask ventilation is typically used during transport or in field settings. This makes ease of use critical, as EMTs are typically not able to move the patient to the device and do not have time to struggle with carrying heavy equipment	Our device is lightweight and portable, adding negligible weight to the existing system. Care providers will be able to easily bring the device to the location of the patient and navigate the setup easily.
Bag compression pressure needs to be consistent	Mid: Ensuring a patient is getting the correct amount of oxygen is critical. If a patient has yet to be hooked up to an oxygen monitor or EMTs can not watch the patient's breathing closely, standardizing the compression pressure could prevent complications.	Since our device will be automated and mechanical, compressions will be uniform.

Market Research

Summary Figure: A
Global Market for Medical Ventilators, by Ventilation Type, 2018-2024
($ Millions)



Number Breakdown

- Global market for medical ventilators (includes both categories) is projected to grow from $1.1 billion in 2019 to $2.1 billion by 2024
- CAGR of 12.5% for the period of 2019-2024
- Ambu bags/bag mask ventilation are encompassed by Non-Invasive Ventilation
    - Within Non-Invasive Ventilation: Bag mask ventilation and nasal ventilation
- Global market for non-invasive ventilators is projected to grow from $670.6 million in 2019 to $1.3 billion by 2024
- CAGR of 13.6% for the period of 2019-2024

Market Dynamics

- Previous increase in the market was caused by COVID-19
- Now, pneumonia stemming from COVID-19 is contributing to a continued increase
- The effects of long COVID are also leading to complications post COVID-19 that require ventilation, also leading to a market increase
- Another source of these increasing projections includes the rise of air pollution and the anticipated effects this environmental change will cause
- The final factor leading to increased projections includes the rising geriatric population

- The American population of people over 65 is expected to double by 2050 (48 to 88 million). This older population statistically needs access to more non-invasive ventilation
- Life expectancy is also expected to increase, causing an increased anticipation of respiratory device demand

Competitive Analysis

Table 48
Global Market Shares of Medical Ventilators, by Manufacturer, 2019
(%)

Company	Market Share (%)
Medtronic plc	16.5
Getinge AB	13.0
Drägerwerk AG & Co. KGaA	11.3
ResMed	9.1
Philips	8.5
Smiths Medical, Inc.	8.2
GE Company	7.2
Fisher & Paykel Healthcare Ltd.	6.2
Others	20.0

General Ventilation

- Medtronic is the main competitor for general ventilation. Following COVID-19, they invested more into specifically the mechanical ventilation area. However, they are not directly competing with our automated bag mask ventilator.
- We have not found competitors that have addressed the problem of not having the personnel required to properly use bag mask ventilation in a way other than automating the bagging process
- Major med tech companies have focused more on invasive mechanical ventilation typically used by patients on long-term life support, so overall, we do not think our main competition involves these large companies

More Direct Competitors

- Smaller start-ups and student groups have attempted to automate bag mask ventilation
- These products have failed to be adopted because they have overlooked some of the needs we have identified
    - Many designs are large and not portable, making them difficult or impossible to use in an emergency care setting
    - Others have not aimed to be hands-free, instead focusing on oxygen standardization, failing to address a key problem

Patent Search

EP270706 Medical ventilation system with ventilation quality feedback unit
This patent describes a device that includes an ambu bag and integrated sensors. The sensors are placed in the airflow path to measure the flow of air. These sensors return a value for End Tidal CO2 to the user, allowing them to adjust compression speed and pressure if needed.

US20080236585A1 Indicating Device for a Ventilator
This device attaches to a bag mask ventilator. It measures the pressure drop and then turns this measurement into volume and flow rate. Care providers can input desired ranges for these values based on the patient's weight and the amount of oxygen they desire the patient to receive. The device will then alert EMTs if these measurements extend outside of the target range.

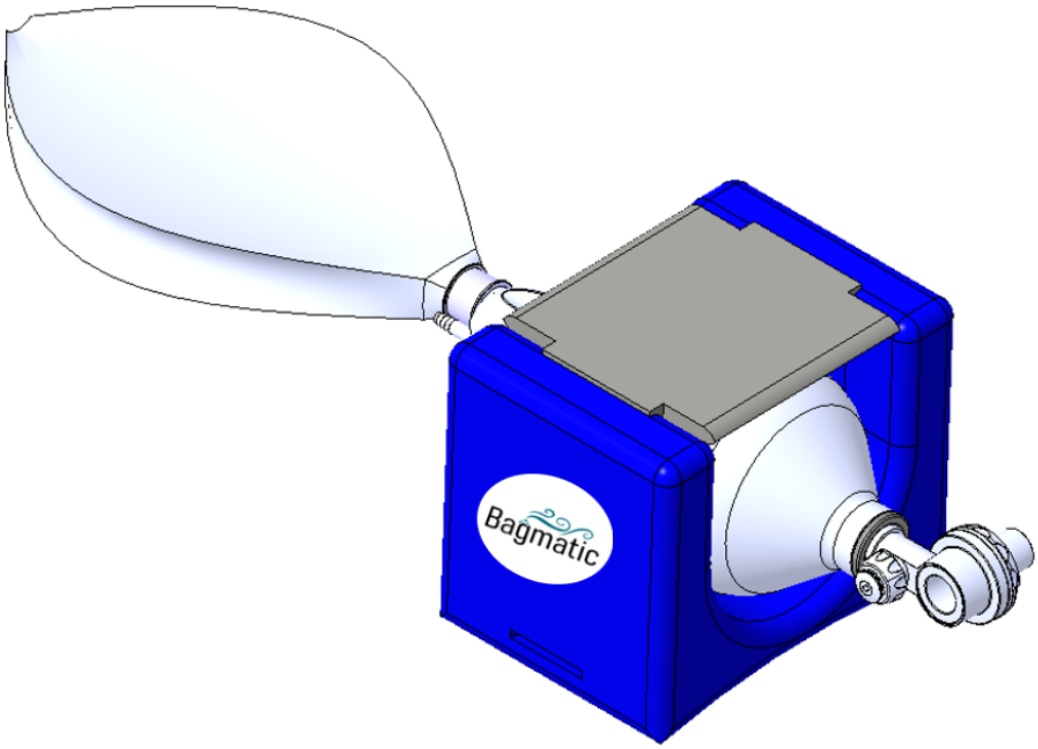
US9675770B2 CPR volume exchanger valve system with safety feature and methods
This patent describes a method to regulate the airflow during respiratory assistance. This product engages sensors to measure volume and airflow, thus monitoring the amount of oxygen a patient is receiving. It also contains a valve that can open and shut after receiving feedback from the flow system to further regulate oxygen saturation.

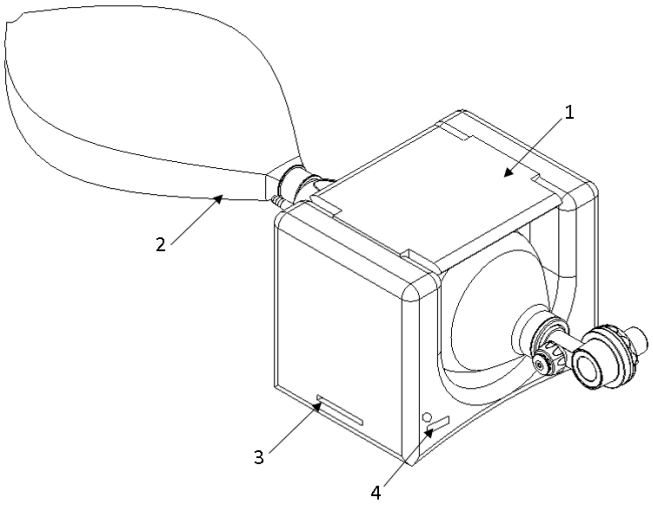
US20190366029 Pressure Safety Device for Bag Valve Mask
The described device attaches to the bag mask ventilation system and acts as a safety device. The product measures airflow and then impedes further flow when the optimum number is reached. Additionally, the device provides tactile feedback to the care provider in order to help with training. This device aims to provide patients with the ideal oxygen saturation while assisting EMTs with their training.

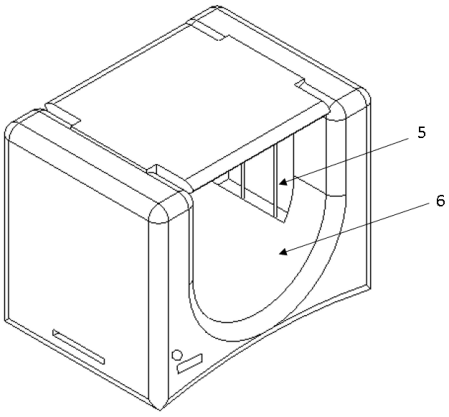
Product Specifications

A bag-valve mask is placed inside the polypropylene housing of the device. The system is strapped to the patient's chest and the mask is fixed onto the patient's mouth and nose (as would be done in the traditional bagging procedure). With the press of the start button, the system begins automatically compressing the bag-valve mask. A microprocessor chip interfaces with the DC stepper motor controller to open and close the PP housing. These compressions provide oxygen to the patient and dispel carbon dioxide. One light on the system indicates the power level of the system's battery. This light turns on at a power level of 20% to indicate the battery will need to be replaced soon. The second light on the system, along with a distinct beeping noise, indicates a significant change in pressure detected using an electronic sensor. This may occur when a complication arises in the patient's airway or lungs that may indicate the need for further medical attention. With the press of the emergency release button, the power to the system is cut off and the bagging process halts.

Product Architecture/Schematics







The ventilation bag [2] is placed inside of the Portable Oxygenation System. The compression platform [1] of the system pushes down on the bag expelling air into the patient, similar to manual bagging. The device can be optionally strapped onto the patient using the anchoring slots [3]. Indicators for consistent pressure and battery level [4] are located on the front of the device for easy visibility. The belt-driven elevator mechanism [5] used to raise and lower the compression platform [1]. This system is controlled via an integrated microprocessor and its associated electronic components [6]. These include the DC stepper motor and its controller, the pressure sensor, and the rechargeable battery.

Regulatory Information

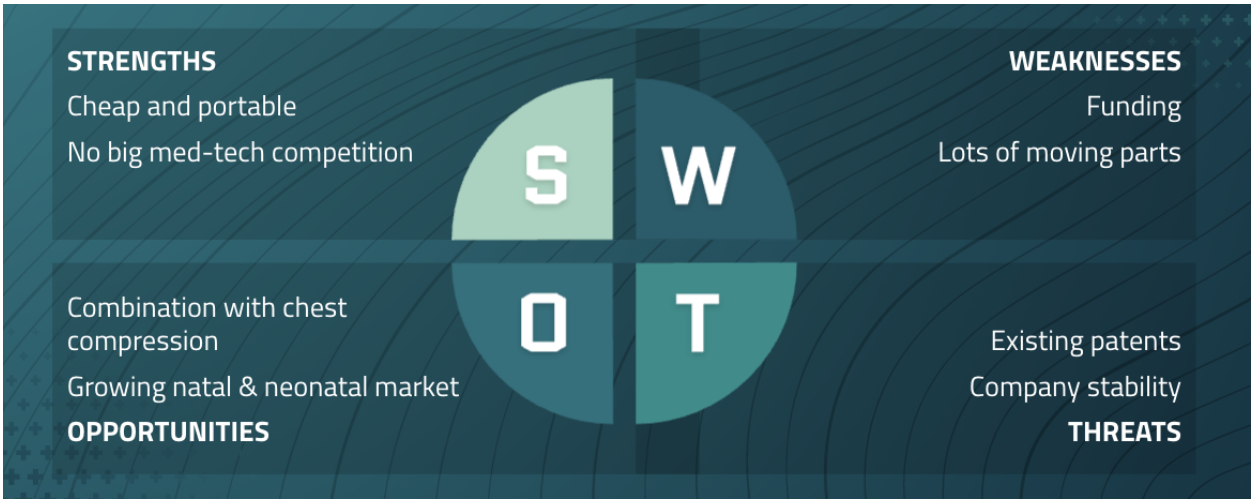
The Bagmatic® Portable Oxygenation System is intended for the purpose of sustaining life through oxygen delivery to incapacitated patients. For this reason, it needs to go through the FDA approval process as a Class III medical device. Our system will need to go through the premarket approval review system, during which the safety and effectiveness will be evaluated. The main risks of the POS lie in its oxygen delivery capabilities. Scientific proof will need to be supplied to show that the motor-driven system functions at a consistent rate without fail. Additionally, we will need to show that our pressure-sensing system accurately measures airway capacity and only sets off the alarm in the case of actual blockage. On a positive note, any potential mechanical and electrical risks are mitigated by secure casing and isolation of pinch points and live wires. We do not need to take any steps for the approval of the bag-valve-mask device itself because we are selling the compressor system separately from the masks. This lets us avoid other hazards such as risk of disease transmission and air purity.

Business Plan

We plan to take a business-to-business approach when selling our product. Hospitals will purchase this device for use by their EMTs performing medical transports to the hospital and by clinicians within the hospital transferring patients to different locations. The plan is to leverage our existing connections and start our launch at the Johns Hopkins hospital. Being a large research and teaching hospital, we anticipate Johns Hopkins being open to adopting new technology, especially a device that can help trainees and less seasoned care providers perform well. Once we have found success at Johns Hopkins, we will use this credibility to expand to other hospitals.

Our product consists of the automated housing while hospitals will supply their own bags. The single manufacturing price of our design was $35. However, by utilizing different printing techniques and making other adjustments, we anticipate lowering this to a bulk manufacturing price of $6.50. Considering this price, the cost of other emergency medical products, and what hospitals are typically able to pay for equipment, we set our product at a price point of $26, resulting in a 400% return.

Since there are no major competitors automating the bagging process, we intend to capture a large section of the market. Rather competing with other similar products, we will be aiming to replace the current manual bagging procedure. Once we are able to prove the advantages of our device through testing and use at Johns Hopkins, further market penetration should be straightforward.



Financial Plan

Expenses	Cost
Operations - Office space - Equipment - Personal: Engineers	$500,000
Research & Development - Verification & validation testing - Clinical trials	$300,000
Regulatory - FDA application process - Personnel: regulatory compliance lawyer	$50,000
IP Development - Patent applications - Personnel: patent attorney	$20,000
Business Development - Pilot production - Marketing - Personnel: Sales	$150,000
Total Expenses	$1,020,000

Market Entry Strategy

Due to our product being a business-to-business transaction, we will start with the businesses that we already have relationships with, mainly the Johns Hopkins Hospital and then move to the Baltimore EMS system. With our pilot wave of production, we would like to first infiltrate the local market of hospitals. After gaining both media attention and lasting partnerships, we will expand our reach across the United States with more regular production cycles. We anticipate the need for our product to increase as more long term complications of COVID-19 arise in the United States as well as having an increasing geriatric population.

Other markets we hope to go into are emergency ventilation of military application and international

hospitals with lower personnel resources. In both of these cases, our product is compelling due to the limited interaction and manpower needed to use it. Military field medicine must be effective with little resources, interaction, and weight, making this the perfect product. Military grants and partnerships will lead to a high source of revenue. Also, effects of the COVID-19 pandemic will likely last longer in underdeveloped countries, with limited resources, increasing the time of that market space.

Project Schedule

2022

Within 2022, we would like to complete the application process for patenting the Portable Oxygenation System with a patent attorney to help guide us through the process. During the next year, we would also like to increase funding through small business grants, small business loans, pitching to accelerators and incubators, and increasing our investors. Finally, we would like to completely finalize our designs for our V0 product in order to go into testing with an accurate representation of our final product.

2023

With our V0 product finalized, we will go into verification and validation testing through the beginning of the year and make any changes if they are necessary. We will also write for IRB approval at the beginning of the year, to ensure enough time for the process before testing. When the safety of our product is verified, we will start with clinical trials, which will likely last the remainder of the year.

2024

In 2024, with the conclusion of our clinical testing, we will go into the FDA approval process. After we receive approval, we will start with the pilot production wave of our Portable Oxygenation System. This is also when a sales representative will be hired. We will start market entry at the Johns Hopkins Hospital along with Baltimore EMS due to our standing partnership and connections.

Future Work

Increased Sensing: Although our product can check if the bag is being correctly compressed or not, it does not yet have the ability to monitor the oxygen intake of the patient. Additional advancements will be made in the future to test the quantity of oxygen that the patient is receiving in order to have some feedback based on the state of the patient to the device.

Neonatal Application: Because of the sensitivity of neonatal patients, oxygenation bagging can be very dangerous and inconsistent. We plan to break into this needspace by creating a portable oxygenation device specifically for neonatal use.

Chest compression integrated system: Another common emergency procedure for resuscitation is the chest compression portion of CPR. While this procedure has been automated and is marketed as portable, the current products require an oxygen tank to be carried with the deceive and the patient still needs to be manually bagged. Due to this, we plan to combine automated bagging and check compressions to create a portable emergency CPR system.

Summary

The bag mask procedure is used to give patients sufficient oxygen during emergency situations and during transportation to the hospital or to different locations within the hospital. The standard procedure typically requires two EMTs, one to stabilize the head and keep the mask in place and the other to manually compress the bag to provide oxygen and expel carbon dioxide. While this process is critical to ensuring the correct respiratory function for critical patients, during medical transports, there is no way to properly bag a patient. EMTs must carry the patient to the ambulance, so their hands are not available to bag the patient. Additionally, even once in the ambulance, bag compression can vary and drop when an EMTs hand tires, leading to an inconsistent influx of oxygen.
This is where our product comes in. By automating oxygenation bagging, EMTs can perform the procedure hands-free and the compression of the bag can be standardized. This allows patients receiving medical transport, who desperately need air, to get the necessary care. Our product also prevents complications that could arise from incorrect levels of oxygen saturation by keeping compression pressure consistent. With our bag mask automation, we keep your hands free so you and your patient can breathe.

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