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QuickCough: An instrumentational proximal airway clearance technique (ACT) for select patients with Neuromuscular Disease (NMD)

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Team 3: Engineers for the Future (E4F)

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Abstract

Patients with neuromuscular disease (NMD) requiring tracheostomy and mechanical ventilation secondary to respiratory failure encounter increased difficulty in removing pulmonary secretions from the airways. To combat issues associated with current treatment modalities for insufficient cough efficacy (cost, poor mobility, discomfort, lack of evidence), we have developed an instrumentational proximal airway clearance technique (ACT) which augments a manual proximal ACT developed by a client with NMD. QuickCough is a 3D-printed PLA attachment to the tracheostomy apparatus which has demonstrated its ability to facilitate pressure changes necessary to increase patient's peak cough flow (PCF) by providing a stronger exsufflation for the patient. QuickCough meets client needs by providing a machine-washable, inexpensive method of facilitating secretion expulsion without the use of bulky equipment in-transit. This novel instrumentational augmentation of a manual ACT was designed using the engineering design process discussed in The University of Akron's biomedical engineering design course 4800:470. Future work ought to focus on development of an automated procedure to allow application of QuickCough in cases of global paralysis or insufficient home-care.

Description of the Project Problem

Patients who are no longer able to carry out normal respiration may require respiratory support with the use of a tracheostomy [1], which is a surgical procedure performed to bypass the upper airway and create access to apply ventilatory respiratory support [2]. A modified endotracheal tube is then inserted through the tracheostomy to maintain the airway indefinitely (*Figure 1a*). A small balloon at the distal end of the tracheostomy tube (TOT) is inflated with saline to maintain a sufficient seal and prevent aspiration (*Figure 1b*). Tracheostomy is accompanied by mechanical ventilation through the tracheostomy apparatus by an external pump,

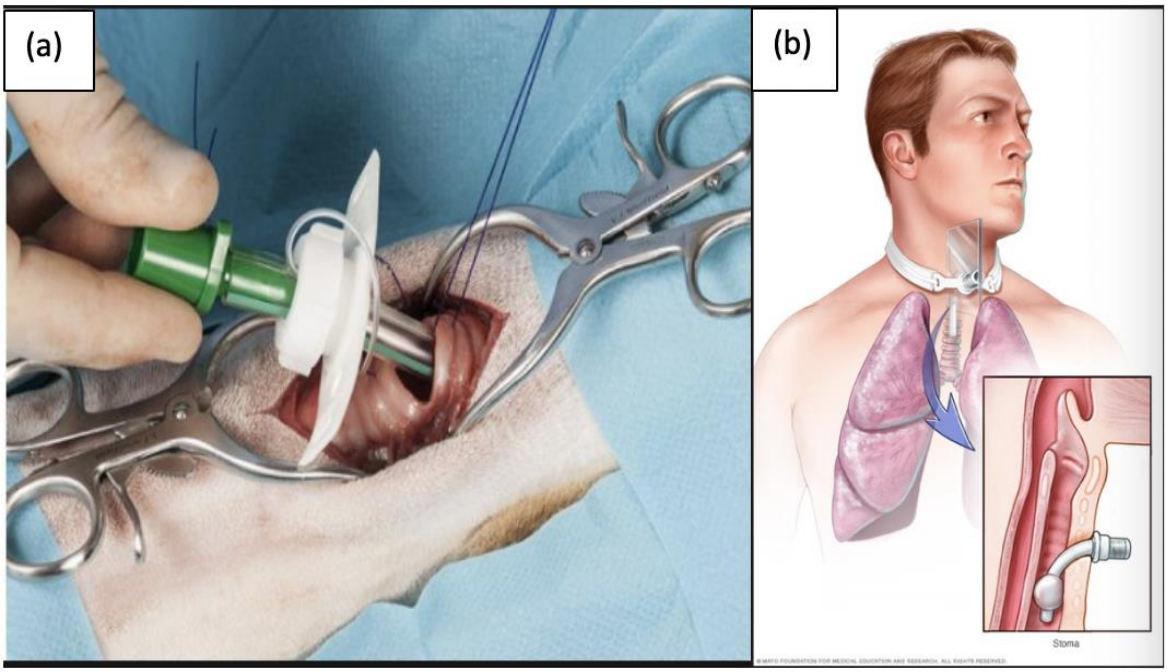

Figure 1. (a) Image of a tracheostomy tube being passed through the tracheostomy incision of canine model (https://ccforum.biomedcentral.com/articles/10.1186/cc4926). (b) Illustration of implanted tracheostomy tube, highlighting location of exterior port and presence of saline-inflated balloon distally (https://www.mayoclinic.org/tests-procedures/tracheostomy/about/pac-20384673).

which facilitates the respiratory cycle and maintains homeostatic gas exchange [3]. Illustrations of these devices are shown in Figure 2. Short-term utilization of tracheostomy for mechanical ventilation may be indicated in young or healthy patients who have undergone acute trauma, extensive surgery, or have a tortuous upper airway preventing traditional endotracheal intubation (see *Figure 2*) [4-6]. The most common indication for long-term mechanical ventilation is acute respiratory failure [7], which may be caused by infection, major adverse cardiovascular events, worsening of chronic respiratory disease, acute asthma, trauma, neuromuscular disease (NMD), or a combination of these [8, 9]. Tracheostomy is currently the best modality for long-term mechanical ventilation, as traditional endotracheal intubation poses a number of threats to the patient in long-term use [10, 11]. Despite the benefits of tracheostomy in long-term management of respiratory failure, there are several significant adverse events which may occur in patients with tracheostomy, which are reviewed in depth by Stauffer et al [11]. The scope of this project pertains to patients with acute respiratory failure secondary to neuromuscular disease, and the subsequent inability to expel secretions from the respiratory tract; therefore, please refer to the aforementioned review [11] for additional information.

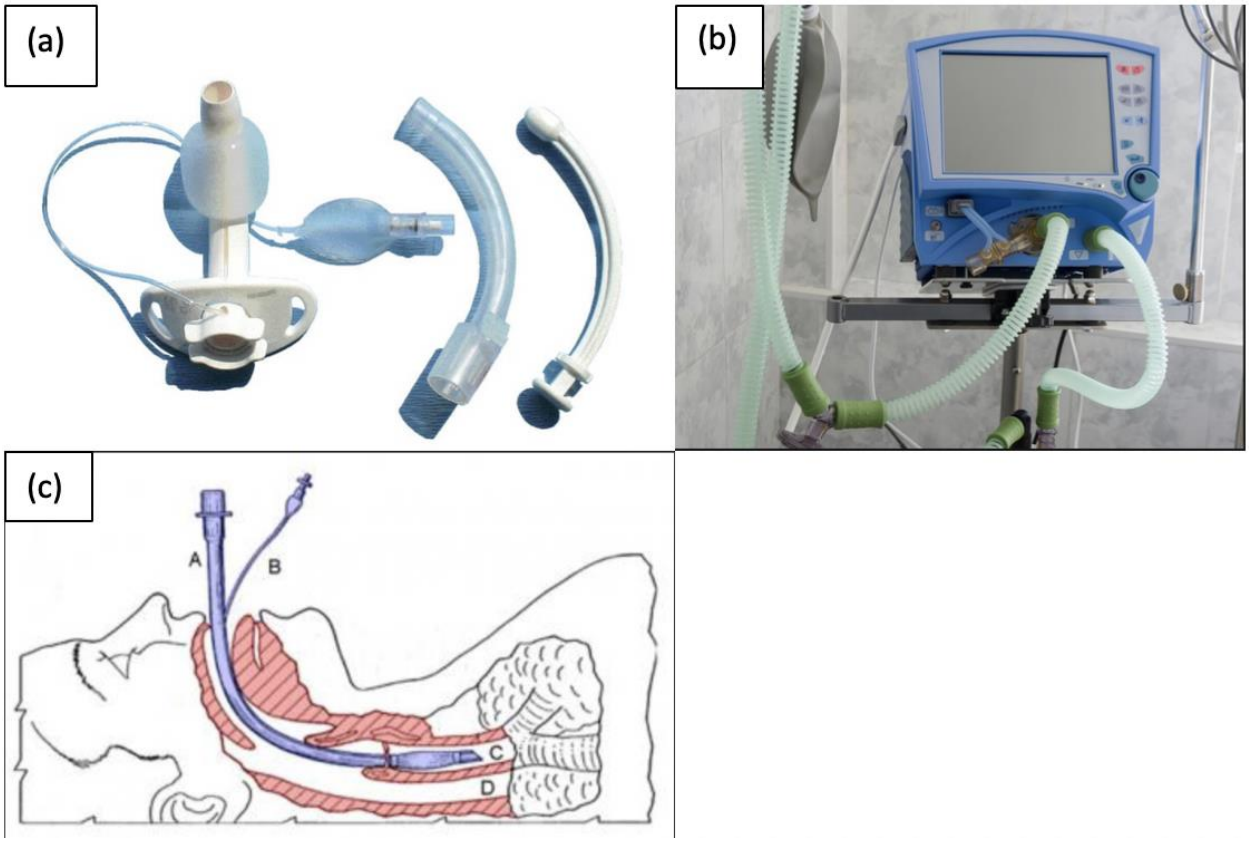

Figure 2. (a) Tracheostomy tube with components. Note the saline-inflated balloon at the distal end of the device, as well as two sleeve components for surgical placement (https://www.hopkinsmedicine.org/tracheostomy/about/types.html). (b) Mechanical ventilation machine. A device such as this is typically found in the home of mechanically-ventilated patients (https://www.sonashomehealth.com/medical-ventilator/). (c)

Traditional endotracheal intubation. Note the passage of the artificial airway through the vocal cords as opposed to a surgical incision through the anterior neck. In a tortuous airway, passing the endotracheal tube may be harmful or impossible (https://emedicine.medscape.com/article/109739-overview).

Patients with NMD are at increased risk of respiratory-related mortality due to diminishing gas exchange and inability to remove airway secretions [12]. Tussis, or coughing, is a mechanism by which airway secretions are expelled to prevent infection, acidosis, hypoxia, atelectasis, or obstruction [13]. In conjunction with progressive neuromuscular pathology, undergoing TOT placement presents anatomical and physiologic changes which may disturb or burden the cough cycle. In the setting of progressive neuromuscular disorder, patients may have weakened inspiratory and expiratory muscle groups preventing large-volume exsufflation required to expel pulmonary secretions [13-15]. Secretion burden is exacerbated by placement of a TOT, which causes excess tracheal secretion build-up in and around the TOT despite traditional preventative measures such as suction or humidification [16-20]. Complications related to secretion build-up include TOT blockage and life-threatening infection caused by retained microorganisms [16, 21-24].

Many techniques are available to augment the coughing mechanism for NMD patients who are mechanically ventilated through tracheostomy (NMDmvT), which are well-reviewed by Chatwin et al [25]. Briefly, assisted cough techniques (ACTs) may be designated into two categories. Proximal ACTs directly impact the patient's peak cough flow (PCF) by aiding in inspiratory or expiratory pressures. The scope of this project centralizes around adverse events associated with the use of a mechanical insufflation-exsufflation (MI-E) device, which aims to replicate the airflow seen in a normal cough by augmenting inspiration with positive-pressure, followed rapidly by negative-pressure to force the air out of the lungs. This modality is commonly indicated in NMDmvT patients, who have poor inspiratory and expiratory performance [25-27]. These devices are unable to provide mobile care given their size and are often limited to the confines of a home or hospital suite. Complications of this technique are uncommon but significant [28, 29], the most immediate concern being thoracic wall discomfort and anxiety with loss-of-control of the respiratory cycle [13]. Additionally, MI-E devices are costly, and may not be reimbursed or available in certain regions [25, 26].

Peripheral ACTs indirectly improve cough efficacy by loosening and mobilizing secretions from small airway structures into large airways, which allows for more clearance during cough cycles [30]. The two peripheral ACTs contested in the scope of this project are the use of a high frequency chest wall oscillation (HFCWO) vest, and development of a manual technique to loosen secretions. These items will be further described in the background section of this report. Instrumentation for peripheral ACTs are limited by high cost, routine need for subsequent use of a proximal ACT, and risk of respiratory arrest secondary to sudden mobilization of large-volume secretions into major airways [25, 31, 32]. Pitfalls of manual peripheral ACTs include insufficient evidence-based medicine directing their use in NMD and poor understanding of physiologic effects [25]. Particularly in moderate-to-severe NMD, a limitation of all present ACTs is the need for a caretaker to assist with or perform the technique.

In light of the current modalities and limitations of airway clearance in patients with NMD, a clear subset of NMDmvT patients are identified as underequipped for management of airway secretions. Many NMDmvT patients may still be attending school, even at the collegiate level, and require the resources to perform adequate airway clearance outside of their primary care center or home. Many of these patients use instrumentational or manual peripheral ACTs in conjunction with suctioning, but as previously discussed, is not as effective as techniques such as MI-E [25, 26, 33, 34]. Patients who note anxiety or discomfort with more invasive modalities

also ought to have a sufficient manual technique which provides them with the sense of control and security needed to maintain cooperativity and effectiveness of treatment. Throughout the course of this project, we aimed to develop a solution which addresses the main problems addressed throughout this section, as well as additional well-known concerns: cost, portability, ease-of-use, sterility, and production of adequate pressure waveform to generate effective airway clearance. The scope of this project centers around mild-to-moderate cases of NMD in which patients have some independence of respiratory-related muscle groups. Prognostically, NMD patient conditions will continue to progressively worsen and require more aggressive management of respiratory failure throughout disease development [35].

Background

The client for this project is a 22-year-old male with progressive NMD who, for the past 7 years, has required mechanical ventilation through his tracheostomy tube secondary to NMD-associated respiratory failure. Secondary to global neuromuscular decomposition, he depends on mobility through use of a motorized chair, as well as direct care with the help of a family caretaker. Despite his disabilities, the client is an active student at a nearby university, attending classes regularly and involved in extracurricular activities. He follows up for respiratory care at a nearby pediatric tertiary care center, where he has received his care since notable onset of NMD-related symptoms and respiratory insufficiency. The client's respiratory management over the past several years has been widely variable, and significant complications of his disease have included numerous admissions over the past several years related to secretion burden in the central airways. At home, he uses a currently marketed MI-E device for proximal airway clearance, as well as a HFCWO vest for peripheral support; however, the MI-E device is associated with thoracic wall discomfort and emotional stress and during use, forces his caretaker to disconnect his ventilation tube, and decreases his mobility while transitioning from home to school. Unfortunately, the utilization of multiple instrumentational techniques has not eliminated pneumonia-related admissions.

Approximately 1 year ago, the client developed a personalized manual technique that he uses frequently with great success. Briefly, the client removes the ventilation tubing from the lateral aspect of the tracheostomy hardware; he is able to maintain his airway for several minutes without direct ventilatory support. Following separation with the ventilation pump, the client seals the small opening on the tracheostomy apparatus with his thumb. Simultaneously, the caretaker connects a vacuum pump to the end of the tracheostomy port perpendicular to the anterior neck, which contains a small catheter that can advance into the central airways to suction out secretions. As the vacuum pump is inducing negative pressure in the airways, the client's thumb-seal allows this negative pressure to build up inside of the airways. The client has performed this technique enough times such that he is able to feel an increasing degree of suction imposed on the thumb sealing the ventilation port. The client releases the thumb-seal at a self-defined level of suction felt on his thumb, which forces a rapid elimination of the negative pressure gradient and seemingly augments a strong exsufflation as described in the problem description section of this report. As a result of this pressure change, secretions are believed to move proximally and eventually into the suctioning device, clearing the central airways after multiple cycles of the technique. He is able to perform this anywhere, provided he has the necessary assistance. The client claims he has had no pneumonia-related admissions since development of this technique. Despite the technique's success, the client and his caretaker are not satisfied with the need for assembly deconstruction prior to technique performance.

Design Requirements for Project Specification

There were fifteen design requirements that were used to develop QuickCough. These requirements and their descriptions can be seen in **Table 1** below.

Table 1: Design Requirements

Requirement	Purpose	Numerical Value
QuickCough cannot exceed the mean weight of provided ventilator attachments.	Ensures that the device will not weigh down the tracheostomy port and ventilator tubing.	Mean weight of ventilator attachment: 11.9 g
QuickCough must be no larger than the largest ventilator adaptor provided by the client.	Ensures that the device will not interfere with the tracheostomy port and ventilator tubing.	Dimensions of largest ventilator adaptor: 8.5 cm x 4 cm x 4.5 cm
QuickCough must provide an airtight seal when activated.	An airtight seal is essential to generating a negative pressure in the lungs to increase the efficacy of secretion expulsion. This was tested by submerging the device in water and blowing air through the device to see if any bubbles were generated.	In a bubble test, 0 bubbles must be generated
QuickCough cannot decrease the tidal volume of the patient.	The device is intended to be worn at all times and that would not be possible if it was impeding the flow of air to the client.	Patient's tidal volume should not be less than 207 ml per inspiration (Dexter, 2018)
QuickCough must be compatible with the tracheostomy port, ventilator tubing and ventilator attachments.	For the device to be used properly, it must live in line with the ventilator tubing, attachments and tracheostomy port, which is measured by the outer diameter (OD) and inner diameter (ID) of the tubing.	Outlet - OD 1.9 cm - ID 1.7 cm Intlet - OD 1.5 cm - ID 1.3 cm

QuickCough must be easily activated.	The device is intended to be used by a caregiver or the patient themselves so it must not require much force to compress the button. It requires 12.9 N to hit a keystroke (Dennerlein, 2009) so this amount of force or less is acceptable for the user to expend when using the device.	The force required to hit a keystroke: 12.9 N
QuickCough must be able to withstand a life cycle of 1 month.	A greater life cycle would require fewer replacements for the client. Every three days, the client expels secretions 100 times. So, in a 30-day month, the client will use the device about 1,000 times.	Number of compressions required to simulate one month of use and wear: 1000 compressions
QuickCough must be able to withstand a shelf life of 2 years.	A shelf life of 2 years allows for the device to be produced in bulk about once a year, instead of creating a new device each month.	Required shelf life: 2 years
QuickCough must generate a breathing waveform, as seen in other devices that occludes airway, when attached to a lung simulator.	This waveform ensures that a proper seal is generated and that the device will not hurt the patient	Visual inspection and analysis of data from testing with Ms. Volsko at Akron Children's Hospital
QuickCough must have a safety feature which prevents unintentional activation.	Safety is always the highest priority and a failsafe must always be included in a device.	N/A
QuickCough must be made of a material which can withstand high temperatures for cleaning within a dishwasher.	The device must be easily cleaned. The average maximum temperature a dishwasher reaches is 180 °F [36]	Washing machine maximum temperature: 180 °F
QuickCough must be made of a material which does not induce an immune response when in contact with the patient.	As this device will always be in contact with the patient, it is important that the material in the device does not irritate the user.	N/A

QuickCough must be made of a material which is disposable.	Ensures that the device is non-hazardous waste and can be disposed of in a trashcan.	N/A
QuickCough must be easily manufactured by 3D printing.	Ensures low cost and ease of building.	N/A
QuickCough must allow the user to feel how much pressure is being applied when it is activated.	Currently, the user is able to feel how much pressure is being generated on their thumb when they perform this technique. The client would like to keep this feature.	N/A

Test

The device underwent 27 test cases, categorized in **Table 2**. Each evaluation method had qualitative or quantitative criteria for success. The device passed each test case described in **Table 2** unless discussed below. The device failed 2 tests, had 6 acceptable failures (equivalent passes), and passed the remaining 19 tests. In depth descriptions and results of each test are found in the Appendix.

Acceptable Failures

The first acceptable failure is that the device is not entirely 3D printed. This is acceptable because the screws and tubing are easily acquired and assembled. Another acceptable failure is the size of the device, which does not exceed 2 centimeters past the criteria in any dimension. It is also acceptable that the silicone tubing failed in pushing the plunger back up in 5 seconds, as it was able to return to neutral position in 8 seconds. The device required more than 12.9 N to depress the plunger, but this result is an acceptable failure because the human factors test subjects were able to depress the plunger without undue burden and there was insufficient equipment to test this case. Similarly, the device acceptably failed shelf life and lifecycle testing due to inaccessibility of equipment.

Failures

The device failed the weight test case and is approximately 6 times the goal weight. The goal weight is the mean weight of provided ventilator equipment, 12 grams, while the device weighs approximately 70 grams. Another failure of the device is its inability to provide tactile or electronic pressure feedback. These items could be fixed in a second version of this product, but cannot be addressed at this time.

Table 2. Testing results (summarized into categories).

Test Category	Evaluations
Marketing and Manufacturing	The device comes with instructions or graphics on the device to ensure proper use, is not easily manufactured via 3D printing, is easy to replace, is easy to use, and is not difficult to train people to use
Measurement	The device is 1.4 times larger than the largest device attachment the customer provided us, is easy to transport, and weighs about 6 times more than the heaviest attachment.
Material Analysis	The device is biocompatible, is compatible with air, is compatible with water, can withstand machine washing in a dishwasher, is disposable after a certain period of use, does not contain any electrical components, and does not collect data.
Occluding the airway	The airway is instantaneously blocked when the user wishes to close the airway and there is a way to ensure that the device will never lock in the closed position. The silicone tubing takes 8 seconds to push the button back into a neutral position, more than 12.9 N is required to compress the button and plunger, and the user is not able to physically feel how much pressure is being applied. The device will create a pressure waveform, does not leak any air, does not restrict airflow, and is comfortable to use.
Fit with attachments	The device fits in line with the ventilation tube and with other ventilation tube adaptors
Wear on the device	We were unable to test if the device can withstand a 1 month of use or has a shelf life of 2 years.

Business Aspects

QuickCough's similarity with the component for Haylard's closed suction tracheostomy tube make it possible to run into patent laws for the design, which could pose an issue to sell this product commercially. However, if a patent lawyer was consulted with and the device was deemed fit for patentability the following plan would be implemented. QuickCough is specific for those who are able to have at-home care with a ventilator. The transition from the hospital to the home follows a strict protocol, with the fifth mentioning home equipment (HME) companies, "Provide HME company with a list of equipment and supplies" [37]. These HME companies would ultimately be the entities which would pay us. The goal would be to leverage a business to business approach, targeting the companies so we can reach the largest number of patients. QuickCough would be patented and the rights would be leased to the HME companies so that they will be the ones creating the physical product. Revenue would be made through the lease by per-unit sales royalties and twice a year the leasing contract would expire so that the royalties

can be adjusted for inflation and other economic variables. The profit will be maximized and overhead reduced since we eliminate the need for a distribution network by leasing the design. Additionally, marketing, advertising and promoting would be the responsibility of the lessee. After review of the initial business proposal outlined in a presentation on March 11th, 2019 and summarized in the paragraph above, the team has decided that no further updates/alterations are necessary.

Final Implementation

Our final design for the QuickCough mechanism is displayed in the expanded drawing below (*Figure* 3). The device consists of a lower housing (part 8), which is 3D printed, holds the silicone tubing (part 7) in place, and allows for ventilation tubing and other attachments to fit onto either end of the device. The upper housing (part 6) is also 3D printed and connects to the lower housing with four screws (parts 1). There is a slot through the middle of this upper housing, which allows for the plunger (part 5) to move vertically and compress the silicone tubing when a user depresses it. The cap (part 4) attaches to the plunger with a screw. This piece provides comfort for the user and ensures a firm grip on the device. The safety cage (parts 3) snugly fits around the neck of the plunger with the use of neodymium magnets (parts 2) to prevent the plunger from being compressed and closing the patient's airway prematurely or permanently. The safety cage must be on the device at all times and should be removed before use. Detailed drawings of each assembly can be found in the Section E of the Appendix.

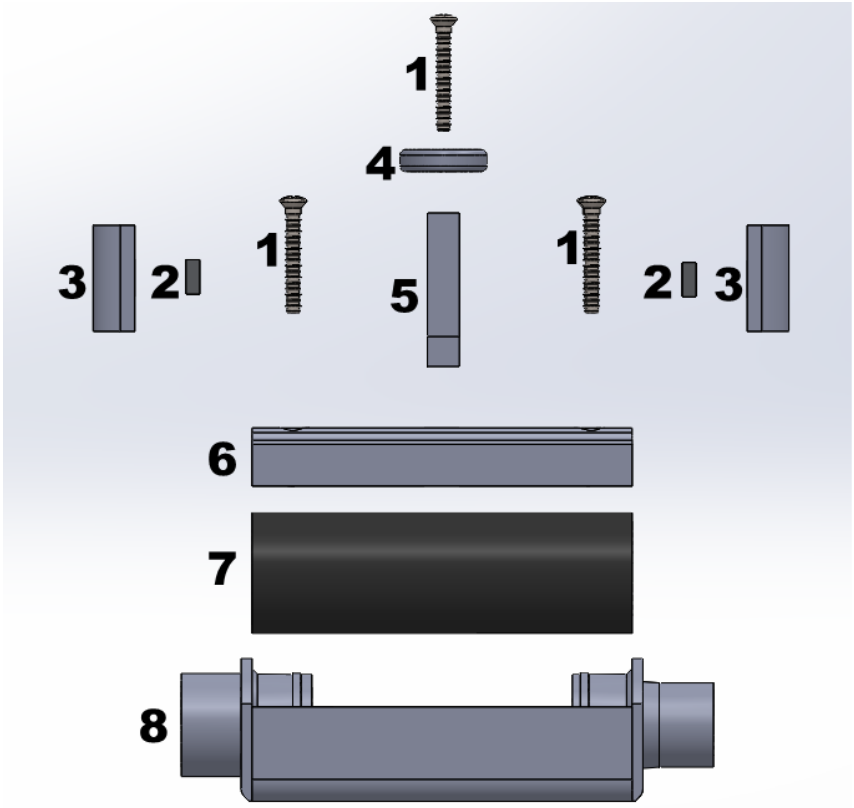

Figure 3. Exploded view of the device. 1 - Self-tapping screws. 2 - Neodymium magnets with adhesive. 3- Safety cage. 4 - Top cap for plunger. 5 - Plunger Body. 6 - Upper housing of main body assembly. 7 - Silicone tubing. 8 - Lower housing of main body assembly.

The device will remain attached to the patient's tracheostomy port at all times, except when it needs disconnected for regular cleaning and maintenance. When a user wants to use this device, they will remove the safety cage from the plunger and compress the device for no longer than 16 seconds. When an appropriate level of negative pressure is achieved (this is to be determined by the client and their comfort level), the user will release the button and air from the ventilator will be reintroduced to the client's lungs. After use, the safety cage must be reattached to the neck of the plunger.

A description of airflow through the device can be found in the below block diagram (*Figure 4*). Air will begin at the ventilator and travel through the input of the device. If the client does not wish to expel secretions from their lungs, the safety guard will remain on the device, which will prevent the button and plunger from being compressed. The air will continue its journey through the silicone tubing (located in the housing), leave the device through the outlet, and eventually travel into the user's lungs. Air can then be exhaled from the lungs by traveling in the opposite direction out of the device and back towards the ventilator. If the user wishes to expel secretions from the lungs, the user will remove the safety guard and compress the newly-freed button. This button will depress the plunger and pinch the silicone tubing, creating a seal. At the same time, one end of the tracheostomy port will be hooked up to a pump, which is constantly running and trying to pull secretions from the lungs. The combination of this pump (which is removing air from the lungs) and the seal within the device (which prevents air from entering the lungs) creates a negative pressure in the lungs. This negative pressure is used to draw mucous in the lungs towards the bronchial tubes and eventually sucked out by the pump, simulating a cough. When an appropriate level of negative pressure is created (as defined by the patient), the button can be released so that air will re-enter the lungs. This process can then be repeated to expel more secretions, or the safety guard can be replaced and allow the user to breathe normally until the next time secretions must be expelled.

Deliverables

Year-long deliverables to both the professor and to the client are outlined in our Memorandum of Understanding (MOU). Deliverables to the advisor include the design history file, the NABC (Need, Approach, Benefits, and Competition) project sheet, project specifications, the initial drawings, meeting minutes, design verification document, test plan, decision matrix, video demonstration, and an executive summary. To the client, we will deliver intellectual property rights, the final prototype, Solidworks files and images, project specifications, and the design verification document.

Scope of Work Excluded

At the beginning of the semester, we established with the client that deliverables will consist of a complete design file and working prototype. The intention behind these items is that these documents will contain sufficient information for the client to manufacture these parts on their own. Over the course of the year, our scope expanded slightly to include instructions for how to use the device, but this is a very minor addition to the project.

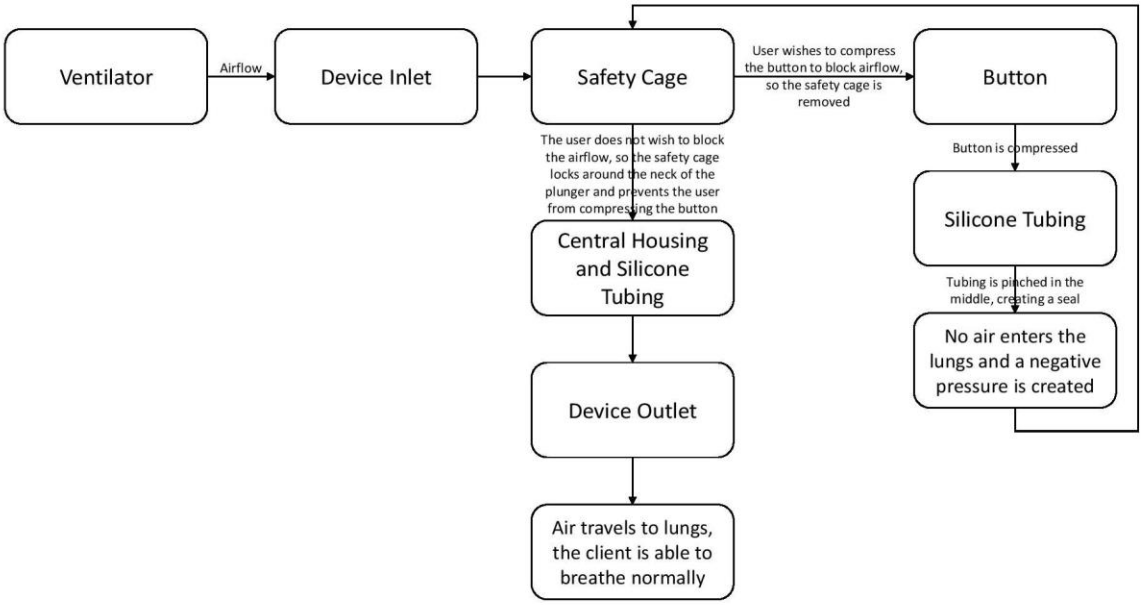

Figure 4. Block diagram of airflow through the QuickCough device. Air starts at the ventilator, travels into the input of the device, and will travel through the device to the lungs if the safety guard is in act or will stop if the button is compressed and the silicone tubing is sealed.

Performance Test Results

From our testing at Akron Children's Hospital with our mentor, Ms. Terry Volsko, we found that the QuickCough device was able to generate a viable waveform on the lung simulator that was sufficient to seal the airway shut and create a negative pressure in the user's lungs. Furthermore, upon releasing of the plunger to allow air to enter the lungs again, the plunger quickly returned to a neutral position to restore airflow back to the levels that it was at before occlusion (*Figure 5*). While these two results were anticipated before testing, it was not expected that the device would weigh almost 6 times greater than the average attachment. Previous estimates for the weight of the device had only included the 3D printed plastic housing. When we discovered that the housing itself could not create a sufficient seal, the silicone tubing, two-part housing that is attached with a total of five screws, and the safety cage were added to the design. Each component is required to carry out the complete functions of the device while still remaining safe for the client. As expanded upon in Section XIII Future Work, the weight of the device could be reduced in future versions of the device.

Another customer requirement that we failed to meet was creating a way for the user to verify that the device created an airtight seal. The current technique that the client uses for this process allows for the user to feel the pressure that is generated in the lungs on their thumb. While it is not explicitly necessary for the function of the device, by assessing the pressure generated in the lungs the user is able to verify that the device is functioning normally, and that maximum mucous secretion is achieved.

It was also expected that the entire device would be 3D-printed in order to allow quick and cheap manufacturing for the user with minimum processing. With the addition of screws and silicone tubing, the device is no longer entirely 3D printed. Greater than 80% of the device is 3D printed but requires post-processing of the device and some fine maneuvering is required to clear out all of the extra plastic material. The addition of the silicone tubing ensures that an airtight

seal is created every time but attaching the tubing into the housing is neither quick nor easy - it takes both timing and the right touch in order to securely attach the tubing within the lower housing. The addition of self-tapping screws into the device takes a little bit more time to assemble the completed device but ensures that the upper and lower housings are securely attached and reduces the likelihood that the silicone tubing will disconnect from the inner ports of the housing.

All other test cases succeeded, including the compatibility of the device with the patient and environment, the creation of an airtight seal, and the ability of the device to connect to the ventilation tubing and other attachments.

Future design considerations to alleviate the issues cited above include decreasing the overall weight of the device by removing excess material. Additionally, instead of splitting the housing into two parts horizontally, the device could be split vertically. A vertical split would allow for easier 3D printing as the top cap would no longer be printed in two parts and it would become easier to attach the tubing within the housing.

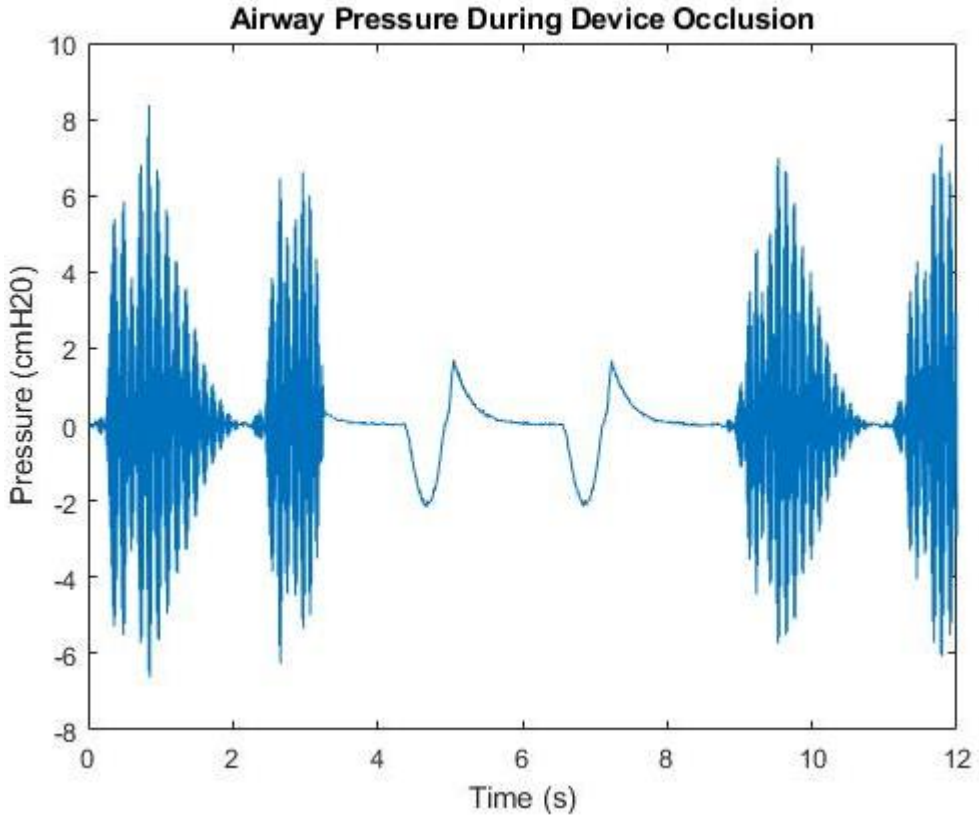

Figure 5. Airway pressure during the occlusion of two breath cycles. Notably, from seconds 4-8 a waveform is maintained during occlusion, similar to analogous devices.

Progress

While the goal of the team was to implement each and every specification, some specifications were not reasonable to impose on the product. For example, upon development of the initial prototype, it was discovered that an entirely 3D printed mechanism would not be

suitable for use as intended. Upon the next iteration, a silicone tube was introduced to the design to accomplish a relatively easy activation, airtight seal and minimal impedance of airflow. Another specification that was not implemented was that QuickCough be no larger than the largest ventilator adaptor provided by the client (8.5 cm x 4 cm x 4.5 cm). This specification was not implemented because the device simply cannot be decreased in volume due to the design. In future iterations of the QuickCough, the team could consider ways to shrink the size of the device. A third specification that was not implemented was that when the user activated the device by pressing the button, they would be able to feel by touch or visual aid how much pressure is being exerted on the lungs. This aspect was brought up by the client during the design development and due to time constraints it was not feasible to implement in the current design. However, further iterations of QuickCough could potentially satisfy this specification. The last two specifications that were not implemented into the design were regarding the wear on the device. The life cycle specification was unable to be implemented due to the lack of availability of highly accelerated life testing equipment, while the shelf life specification could not be implemented due to time constraints for testing.

Individual Contributions

Russell was the primary contact with our mentor, Ms. Terry Volsko at Akron Children's Hospital. He completed substantial background and market research for the device and created the work distribution sheet. He coordinated test plans and developed a basic understanding of the testing model to evaluate QuickCough's performance once data had been collected.

Mariah helped with the data collection with Ms. Volsko at Akron Children's for the device, interpreted the data gathered from the testing machines, helped with designing the prototypes through iterations, developed and maintained the Gantt chart for the entire product development cycle, developed the decision matrix selecting a prototype, created the bill of materials of the device, and worked with an advisor to create with a safety feature for the device.

Sydney met with the customer for the initial meeting in order to develop the customer requirements document, assisted in designing the newest iteration of the device, completed our market analysis, documented and organized a majority of the DHF, created the specification document, ordered the silicone tubing, and organized and maintained the team google drive.

Madison served as the primary contact point with the client, created the design verification document, recorded meeting minutes during all team meetings, developed the MOU and received sign-off from the client, created the block diagram of how the device's function, assisted with testing at Akron Children's, and met with the client several times.

Sean did the majority of the CAD drawings for the device throughout all iterations. He was the primary contact with Steve Paterson for 3D printing the device, investigated manufactured valves to improve the device design, met with Dr. Willits to come up with the silicone tubing addition, and ordered the magnets and tubing for the device.

Financial Considerations

Overall, Cough-Start costs about $36 to manufacture (**Table A**), includeing the cost of the 3D print, self-tapping screws, magnets, and tubing. Looking at the other devices mentioned above, Cough-Start is actually the second cheapest (**Table B**). However, the majority of the price for Cough-Start comes from the price of the magnets. Nonetheless, the time required to make the

device has the majority of the time spent in the 3D printing process. The actual assembly of the device is relatively quick. This is the case because the idea for the device is that it would be possible for the end-user to manufacturer so the price for manufacturing would not be an issue allowing the product to stay cheaper.

Table A. Pricing for the different components of the device. Prices listed here are the pricing needed to make exactly one of the device.

Part	Amount required	Price per part	Total Cost of Parts
Overall 3D print cost in Raptor PLA	0.15 lb	$32.99/lb	$4.95
No. 4 self-tapping screws	5	$9.65/50 screws	$0.97
Silicone tubing	2.5 in	$5.60/24 in	$0.58
Magnets	4	$7.26/magnet	$29.04

Table B. Condensed product comparison table between the QuickCough device, mechanical insufflation-exsufflation (MI-E), Bag-Valve Mask (BVM), and Intermittent Positive Pressure Breathing (IPPB) used in proximal cough assistance. Popular producers are listed in the Company column. Four important customer needs are used for the comparison, including: the manual nature of the device, comfort during use, cost, and portability.

Product	Company	Manual	Comfortable	Expensive	Portable
Quick-Cough	—	YES	YES	NO	YES
MI-E	Respironics, Hill-Rom, Phillips, Emerson	NO	NO	YES	NO
BVM	Medline Industries, Ambu, Moore–Medical, MCR Medical	YES	NO	NO	YES
IPPB	Axcent Medical, Air Liquide Healthcare, InterSurgical, Hill-Rom	NO	NO	YES	NO

Summary Feasibility Discussion

The need identified at the beginning of the effort was to convert the client's technique for increased efficiency of secretion expulsion into a physical product which could live in line with his ventilator tubing and port. The technique that was used by the client consisted of him detaching himself from the ventilator and covering the ventilator port with his thumb while the suctioning assembly was in use. The QuickCough device replicates the thumb of the client by

completely sealing airflow into the tracheostomy port and generating a negative pressure within the lungs. Additionally, QuickCough can be attached to the ventilator port, tubing and specific attachments (humidifier, inhaler, etc.). This alone proves that the need identified at the beginning of the effort was satisfied. However, it is important to note that certain design specifications were unable to be met and therefore requires further iterations of QuickCough to be developed.

Currently, QuickCough is considered a prototype for a variety of reasons. The first being that QuickCough demonstrates multiple functional aspects of the design instead of just one (therefore differentiating it from a proof-of-concept model) [38]. A second reason is that additional testing must be completed to ensure that there are no errors present in the design so that final product construction can be competed [38]. Also, certain product specifications were unmet and are important to satisfy in order for QuickCough to enter the market and be put on patients.

Future Work

This device has room for development in future iterations, particularly in cases of mass production and increased budget. One customer requirement left unfilled was the request for the device to "allow the user to know how much pressure is being applied when it is activated." The current method of achieving this action is the inclusion of an open hole in the device. The patient or caregiver can place their thumb over this hole to feel the pressure change. Because the team wanted a continuous, closed, and quasi-permanent pathway from the ventilator to the patient, the device has no open hole. However, in a high tech, high budget iteration, a pressure sensor and user interface could also achieve this result. While expensive, the addition of the pressure sensor could introduce a momentous safety feature: the ability to detect and alert others if the patient is no longer receiving ventilation. This feature would be critical for patients who suffer from neuromuscular disorders, who may helpless to correct an airway blockage. A pressure sensor and user interface with an accompanying alarm feature would help give caregivers more time to correct blockages, saving patient lives. Further, this feature would help caregivers optimize pressure differences in the secretion expulsion process while maintaining patient comfort and cleanliness.

This device could also be improved by making it smaller and, with the addition of a pressure sensor, could improve the patient's comfort as the device is always connected to the ventilation tubing and resting near the patient's neck and head. Future work should also go into researching a better closure solution for the safety cage. Currently, magnets were used to close the safety cage. These magnets were costly, accounting for 85% of the product cost, which was acceptable with the current device, as this safety feature was critical to the success of the device. However, the closure mechanism can be optimized for cost. Finally, future work could include decreasing the amount of force that is required to close the airway. While we did not find an exact value for the force required to compress the button, it seems to be larger than our goal of 12.9 N.

Discussion, Conclusions, Lessons Learned, and Recommendations

The device has gone through several major design revisions from when it was first drafted. Initially the device started out as a component similar to what was already a part of the

entire suctioning assembly. However, with time, many issues were found that needed to be solved. These issues were all essentially solved by introducing a silicone tube. However, to accommodate for the tube, the device had to become larger and became less like the part already present on the assembly. By using this version, it was possible to gather test data to show that the device was capable of producing the necessary seal. However, the device was not without issues. The device did not have an intrinsic safety precaution built into the main body assembly, so a safety cage had to be developed, detached from the rest of the device. This addition increased the overall bulk of the entire device. It would be recommended for future iterations of the device to avoid having this extra bulk on the top and to instead find a way to incorporate it into the the design of the main body.

One of the biggest lessons from this project was the importance of deadlines and how, even with impending deadlines, design iterations can still be created. If we were to do this project again or create a second version of the QuickCough device, we would work to complete brainstorming by October, have an initial prototype before winter break, and begin creating iterations of the prototype and testing as soon as classes began again in January.

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Appendices

A. Design Verification Matrix

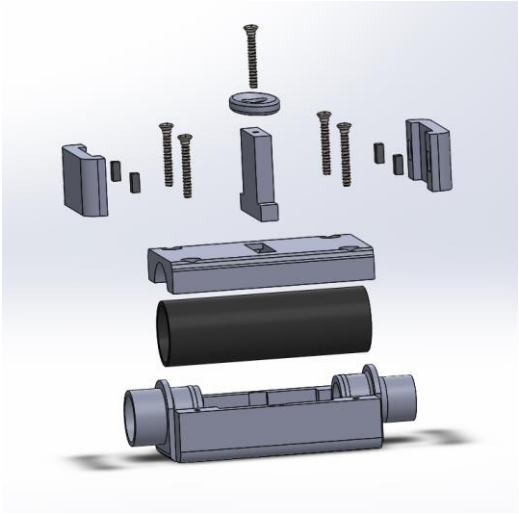
Test Case ID	Test Case	Description	Actual Output	Pass/Fail
1	device comes with instructions or graphics on the device to ensure proper use	Instructions are provided with the device	Graphical instruction document	Pass
2	device is easily manufactured via 3D printing	the device is 3D printed	The device is not entirely 3D printed (as tubing and screws are present) and needs to be processed by an expert	Acceptable Failure
3	the device is easy to replace	The device takes less than 24 hours to 3D print and costs less than $30 to replace	The device takes approximately 24 hours to print and costs approximately $26 to print	Pass
4	it is easy to use and not difficult to train people to use	It takes a new user less than 60 seconds to comprehend how the device works and how it should be used	2 human factors tests proved healthcare providers could understand in 60 seconds or less	Pass
Measurement				
5	device is small	Device is no larger than the largest attachment that our client provided us with: 8.5 cm x 4 cm x 4.5 cm	The device has a length of 9.79 cm, width of 4.10 cm, and height of 5.26 cm	Acceptable Failure
6	device is easy to transport	the device can easily fit within a coat pocket (10 cm x 8 cm)	The device fits within a coat pocket that is 10 cm x 8 cm	Pass
7	device is light	device weighs less than 11.91217 g (the mean weight of provided ventilator equipment - tracheostomy port & ventilator attachments)	Device weighs approximately 70 grams	Fail
Material Analysis				
8	device is biocompatible	Raptor, silicone, and the screws do not cause irritation to skin	All are biocompatible (Sydney has research articles)	Pass

9	device is compatible with air	the casing and tubing remains completely intact and functional when it comes into contact with air	the device maintains full functionality when exposed to air	Pass
10	device is compatible with water	the casing and tubing remains completely intact and functional when it comes into contact with water	the device maintains full functionality when exposed to water	Pass
11	device can withstand machine washing in a dishwasher	the casing and tubing remains completely intact and functional after going through a dishwasher cycle. The device will be seperated in the dishwasher, top rack, with dishwashing detergent	Device maintains functionality after dishwashing	Pass
12	device is disposable after a certain period of use	The device is non-hazardous waste and can be disposed in a trash can	Non hazardous waste	Pass
13	there are no electrical components to this device	there are no electrical components on the device	no electrical components are in the device	Pass
14	data is not collected from this device	data is not collected from this device	no data collected by device	Pass
Occluding the airway				
15	airway is instantaneously blocked when the user wishes to close the airway	It should take < 1 second for a complete seal to be reached after activating the device. From the time the button was compressed to the time that the airflow became stable again, occluded flow waveform formed is < 1 second difference	The device is able to block airflow in 0.1 seconds	Pass
16	device will create a pressure waveform	When attached to the artificial lungs, a smaller pressure waveform is created with the occluded airway than when the device is open and the airway is not occluded. The pressure waveform is similar to that found for similar devices	The device is able to mimic a pressure waveform seen in Figure 1, "Airway Pressure During Device Occlusion."	Pass
17	there is a way to ensure that the device will never lock in the closed position	The device will never be in a locked position unless a person is actively and intentionally pushing on it	Safety cage prevents lock in closed position when not in use	Pass

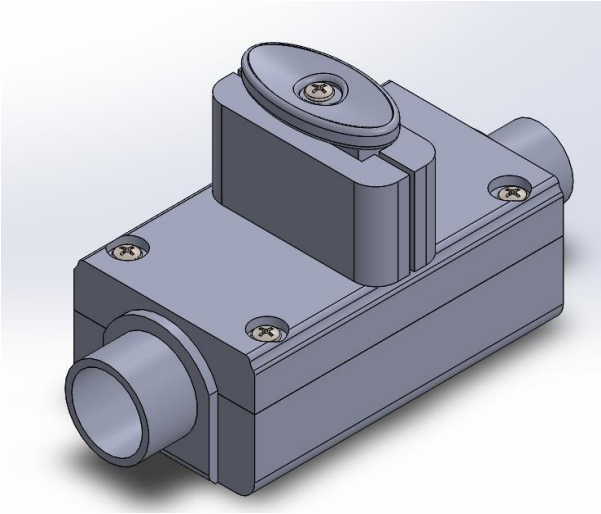
18	silicone is strong enough to push button back up	when compressed and released, it will take the button less than 5 seconds to completely return to resting position	Device took 8 seconds to return to neutral position	Acceptable failure
19	not much force is needed to press down on the button	the amount of force required to compress the button should be less than 12.9 N (the force required to press a key on a computer keyboard)	Equipment for testing unavailable. Anecdotal human factors testing indicated the device required slightly too much force to close, but did not provide undue burden	Acceptable failure
20	to press down on the button, there is a thumb indent for the comfort of the user	a thumb indent is present to ensure comfort for the user when they press down on it	a thumb indent is present	Pass
21	user must be able to feel how much pressure is being applied when the button is pressed down	when the user compresses the button, they are able to feel by touch or visual aid how much pressure is being exerted on the lungs	No tactile or electronic pressure feedback	Fail
22	the device does not leak any air	The device is place with one end underwater and a tube attached to the end sticking out to the water. When air is blown into the device and the button is compressed, no bubbles are generated	No bubbles are generated, which means that no air passes through the device	Pass
23	air flow is not restricted through the device	the breath that passes through the device is not constricted by the device. The non-occluded breaths from our measurements match normal breath patterns that one would expect from a child with a neuromuscular disorder	Airflow is maintained when device is inactive. This is validated during the first and last 3 breath cycles in Figure 1 of the Final Report, "Airflow Pressure During Device Occlusion."	Pass
Fit with attachments				
24	the device fits in line with the ventilation tube	The device connects snuggly with the ventilation tubing and will not easily disconnect so that the user can keep the device in line with the ventilation tubing all day	The device fits in line with the tracheostomy tubing	Pass
25	device will fit with other ventilation tube adaptors	The device will fit in line with the ventilation system and attachments can fit on either side of the device Are there standards for this?	The device attaches to other tracheostomy attachments on the smaller port only	Pass

Wear on the device				
26	device can withstand a life cycle of 1 month before needing to be replaced	The device will perform at the same level as it had before testing after a simulated month's use of wear (1000 compressions)		Acceptable Failure
27	shelf life of the device is 2 years	The device, when left unused, will still work at full capacity after two years	Equipment for highly accelerated life testing unavailable.	Acceptable Failure

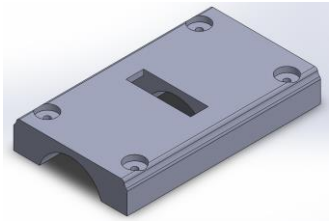
B. SolidWorks Figures



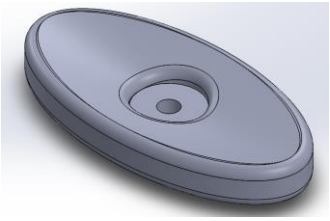
Exploded view of device with all component



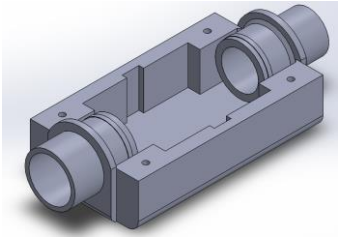
Assembled view of device



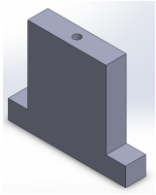
Top part of housing assembly



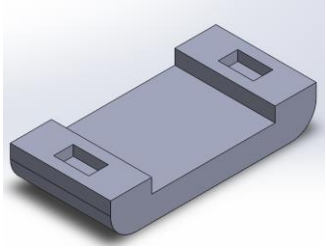
Top cap of plunger component



Bottom part of housing assembly



Plunger component



One half of the safety cage

C. Graphical Instruction

QUICKCOUGH

Cough assist permanently inline with ventilator for use at home and on the go.

ADVISORIES

Do not detach patient ventilator. Ensure safety cage removal before use and replacement upon completion. For sanitation, dishwash at highest temperature setting with antibacterial detergent. Sanitize at every tracheostomy port change, every 3-4 days. Replace device every 2-3 weeks. Shelf life: 2 years.

DIRECTIONS

1. Maintain device in neutral position inline with ventilator (**Figure 1**)
2. Insert suctioning equipment into patient tracheostomy port
3. Depress plunger to block airflow completely Maintain force no longer than 15 seconds (**Figure 2**).
4. Suction secretions
5. Elevate plunger to neutral position.
6. Remove suctioning equipment.

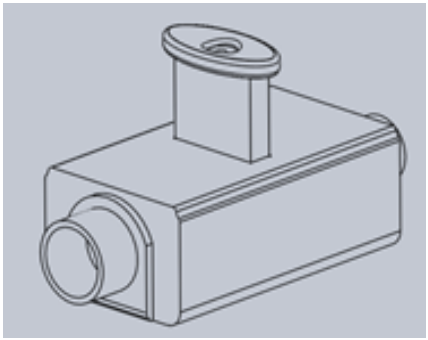


Figure 1. Neutral position

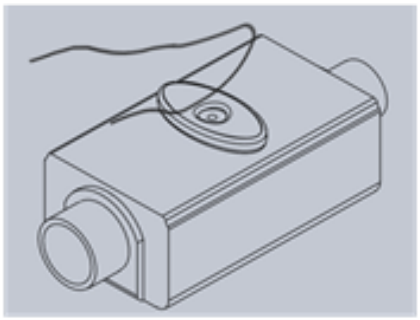


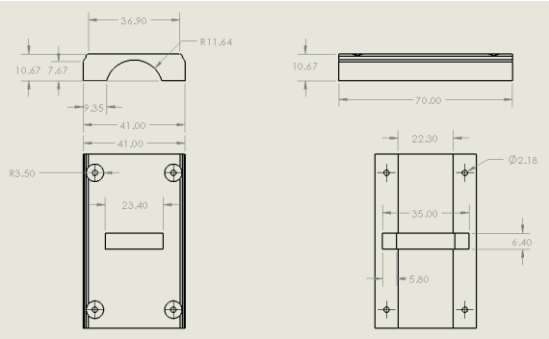
Figure 2. Activated position

D. MATLAB data extraction code

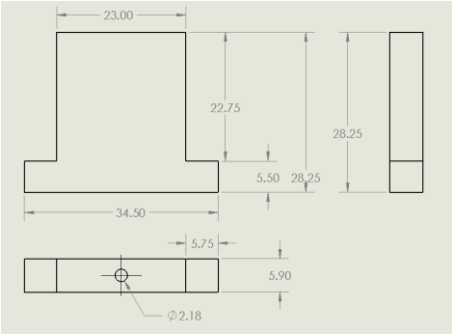
```
A=importdata('data2.rwa');
Time_import=A.data(:,1);
T_start=find(Time_import==74);
T_end=find(Time_import==85);
Time=Time_import(T_start:T_end,:);
Time_shift=linspace(0,12,length(Time));
AirwayPressure=A.data(T_start:T_end,2);
plot(Time_shift,AirwayPressure)
title('Airway Pressure During Device Occlusion')
xlabel('Time (s)')
ylabel('Pressure (cmH20)')
```

E. Drawings of the Individual 3D printed parts

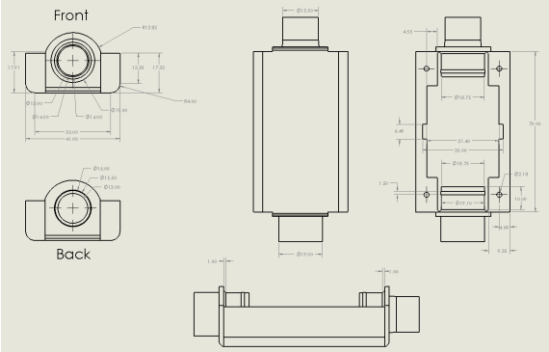
All dimensions shown are in millimeters



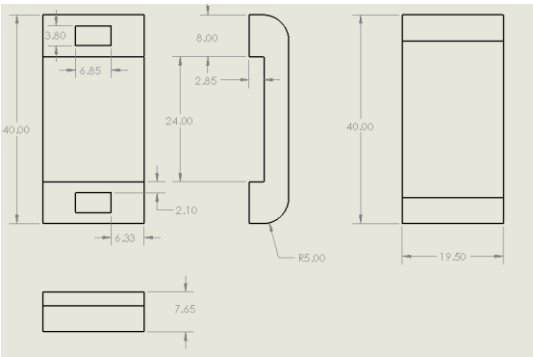
Top part of main assembly



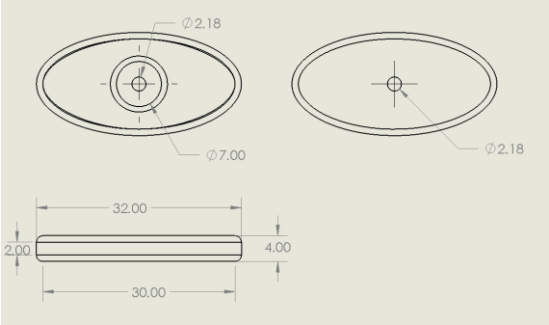
Bottom part of plunger component



Bottom part of main assembly



Safety Cage



Top part of plunger component