Design Optimization of Emergency-Use Ventilator to Improve Assembly Time

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Abstract

Ventis Medical seeks to improve emergency ventilation and patient care by reducing expertise and training barriers that are currently present with its low-cost emergency ventilator, the VM-2000. To improve the usability and efficiency of the VM-2000, this project used Fusion 360 to design a 3D-printed manifold and tubing clamp, integrated a wired button to enable more convenient administration of ventilation, and determined a more suitable tubing length. Emergency responders were first surveyed to inform design choices. Multiple manifold and clamp prototypes were then fabricated, and an optimal, shorter tubing length was determined after researching standards of care. Students at the University of Virginia (*n*=15) were recruited to assemble the original VM-2000 and the VM-2000 modified with the finalized prototypes, button integration, and tubing length. Participants were timed and asked to evaluate the usability and efficiency of the original and modified devices after performing each assembly. A reduction in average assembly time was achieved with the modified device. Participants perceived the modified assembly to be more user-friendly and efficient than the original. With statistical testing, it was concluded that the device modifications succeeded in optimizing the assembly process. Further developments on this project would work toward improving the ease of ventilation administration for both patients and caregivers, reducing training barriers in ventilation, and increasing the versatility of ventilators.

Keywords: ventilation, design optimization, tubing organization

Introduction

With the COVID-19 pandemic causing influxes of patients to overwhelm hospitals around the world, many facilities found themselves underprepared in terms of equipment and staffing. One such resource shortage that proved detrimental was the shortage of mechanical ventilators and trained staff required to utilize them. Many patients critically ill with COVID-19 require extended periods of time on invasive mechanical ventilation (MV); however, these shortages have led to delayed treatment and worsening patient prognosis.[1] One of the reasons for the shortage was the staggering cost of ventilators, with costs ranging from $25,000 to $50,000 for ICU-equipped ventilators.[2] This financial barrier was especially difficult for hospitals to overcome early on in the pandemic, when the scope of COVID-19 was not well-known and hospitals could not afford such inventory increases.[3] This also disproportionately affected rural hospitals that did not have the funds necessary for such costly resources.

In emergency situations outside of the COVID-19 pandemic alone, current emergency-use ventilators and bag-valve devices have a variety of limitations. A bag-valve device requires the rescuer to manually squeeze the bag to administer air delivery, and therefore also determine the respiratory rate and tidal volume appropriate for the patient.[4] To do so manually requires a great deal of concentration and skill to consistently administer breaths. However, in stressful situations and over prolonged periods of time, this method can falter, and it is possible for too high or too low volumes of air to be delivered. High volumes can lead to barotrauma in patients, "caused by rapid or extreme changes in pressure affecting enclosed cavities within the body."[5] However, it was found in a study with 130 medical professionals that a majority of them "ventilated the simulator mannequin with over 800 mL of tidal volume using the adult BVM [...], which is over 200 mL higher than the upper threshold of most recommended lung-protective ventilator settings.”[5] When emergency-use MV is available, more consistent and accurate ventilation can be provided, but heavier designs and extraneously long and disorganized tubing delay care administration. Such inconveniences impede both the caregiver and the patient when time is of the essence.

Our project is centered around Ventis Medical’s low-cost emergency-use ventilator, the VM-2000, that can automatically administer appropriate ventilation to patients with a press of a button. The VM-2000 costs about $3,000 and only weighs about 3 lb.[6] Currently, the VM-2000 requires each of its seven cables to be plugged into its own connection port, features a tubing length of 1.8 meters, and has a ventilation function that is enabled by a manual breath button on the main body of the device (Figure 1). These features may prolong the assembly of the device and delay the delivery of patient care, even though the VM-2000 addresses several problems with current standards of care. A manifold that encompasses several connection ports would shorten the device assembly time and improve usability by ensuring that the cables and tubing are connected securely each time. Shortening the tubing would decrease the chances of tubing entanglement to save time and space during ventilation administration. A tubing sleeve would contain the components into one cohesive arrangement, decrease entanglement, prevent wire/tubing damage, and help the caregiver quickly locate all attachable components. Moreover, when ensuring a secure seal of the ventilation mask to the patient’s face, two hands are needed. Implementation of a remote button would eliminate the need for another caregiver to give the patient a breath, as the button will be close to the mask, allowing for one person to fully administer care. With the advancement of the VM-2000, this project can reduce the amount of manpower and expertise needed to provide quality care to patients, and ventilator treatments can be more broadly used across different facilities and situations. The ultimate goal of this project is to improve the design of the VM-2000, specifically the ease of use of the tubing configuration and the convenience of the ventilator function (Figure S1). More specifically, researching limitations of current treatments and surveying emergency responders will guide design considerations for enhancing the breathing circuit. A manifold and tubing clamp will be 3D-printed using Fusion 360 to encompass tubing components and improve organization. Lastly, shortening ventilation tubing to an optimal length will ensure ease of use in emergency situations. Prototype testing of these components will be done with emergency responders and other certified personnel to ensure the effectiveness of the devices and design specifications will be refined accordingly per user feedback. To improve more convenient ventilator function, the demand for a remote, wired button external from the main ventilator body will be evaluated and the ideal placement of the button will also be considered.

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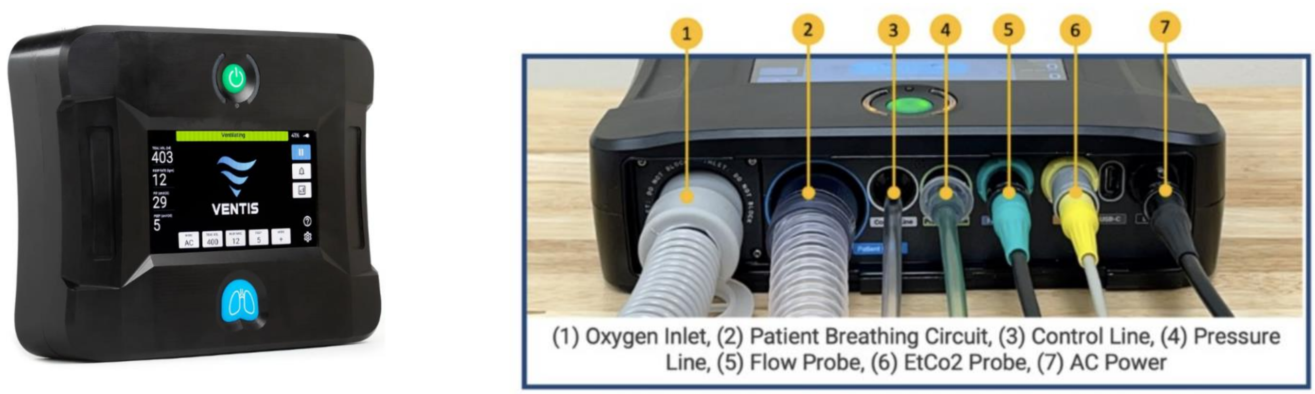

Fig. 1. The VM-2000 and its connection ports. (A) The main body of the device. In its current state, ventilation can only be administered by the blue button on the main body. (B) The VM-2000 requires individual connections for each component. The manifold will allow components 3-5 to be simultaneously inserted into the device.

Results

Design Considerations

Research was conducted on the limitations of current ventilation techniques and mechanisms. A Google Forms survey on the user friendliness of current models was administered to ten individuals associated with emergency medicine to determine optimal design specifications (Figure 2). Survey results also indicated that current tubing lengths and organization may impede ventilation administration (Figure S2). The plausibility of a wired button to improve the functionality and capabilities of the VM-2000 in delivering care external from the main ventilator body was also considered.

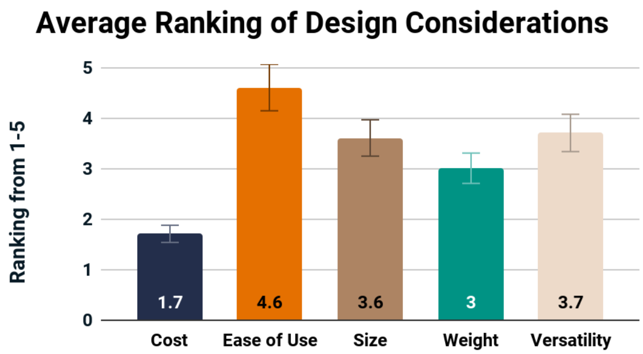

Fig. 2. Ranking of Design Considerations from Pre-Survey. Ten emergency medicine personnel were asked to rank the importance of 5 different ventilator design considerations on a scale from 1 to 5, 1 being least important and 5 being most important. Ease of use was shown to be the most important feature, with an average ranking of 4.6.

Prototyping & 3D Printing

Manifold

A manifold with a hinge design was decided to be the best way to encompass several tubing components to reduce the number of connections needed. It was determined as per advisor instruction that the manifold should hold the control line, pressure line, and flow probe, as those components are always required when administering care and are adjacent to each other. The manifold adhered to the dimensions of these three components and their spacing on the main ventilator body. The idea of the manifold was to place each tube to its corresponding space within the manifold, close the manifold via the hinge, and plug in the prototype into the ventilator for further use. Early prototypes of the manifold introduced a latch to further improve security of the prototype, but was abandoned due to ineffectiveness (Figure 3). The manifold was designed and 3D-printed with settings listed in the 'Materials and Methods' section.

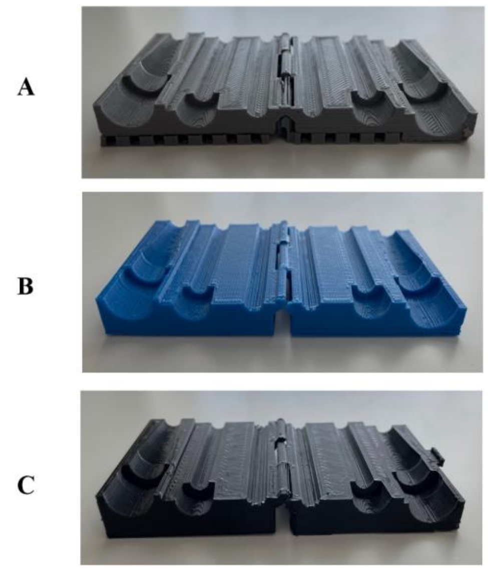

Fig. 3. Failed Manifold Prototypes. (A) Prototype A depicts the first print of the manifold, showing an uneven base and a need for supports. (B) Prototype B builds off of Prototype A with an even base but is limited due to its lengthy hinge. (C) Prototype C introduces a latch design but was abandoned due to its ineffectiveness.

Tubing Clamp

A tubing clamp with an adjustable feature was designed to bundle together the patient breathing circuit, control line, pressure line, and flow probe. Originally, early design concepts consisted of a 'tubing sleeve' that would encompass the aforementioned tubes in a lengthy 3D-printed sleeve that would offer flexible support, but due to 3D-printing limitations, this idea was abandoned. The tubing sleeve went through different material prototypes, as listed in the 'Materials and Methods' section. These failed prototypes mainly involved the inability to effectively grasp and adjust to the tubes which was affected by material and print settings as well as design flaws (Figure 4).

Remote Ventilation Button

The plausibility of a wired button external from the main ventilator body was evaluated. Aside from deciding whether having this feature would be useful to the main device, the placement of the wired button was also evaluated. The best placement was decided, in terms of functionality, to be on the non-invasive mask attachment, which is still being developed. The non-invasive mask attachment paired with the shortened tubing length would greatly improve the usability of the VM-2000 in delivering ventilation care.

Fig. 4. Failed Tubing Clamp Prototypes. (A) Prototype A was printed with TPU in hopes that the flexible nature of the material would help it bend and secure the tubing more closely, but it was too spongy and not durable enough for its intended use. (B) Prototype B was printed with PLA but was too brittle due to too little infill density and was also too large, allowing the tubing to slip through. (C) Prototype C was printed with PLA and PVA supports, but the hinge had stuck together during printing, so the clamp could not close properly even though the PVA supports had entirely dissolved. (D) Prototype D was sized down again but still did not achieve the desired fit with all of the tubing, and the hinge had once again failed and broken off.

Shortened Tubing Length

A tubing length that would be more optimal for emergency situations was determined for a preliminary design after a need for shorter tubing was noted for the pre-survey responses. The components that plug into the ventilator body were shortened from their current length of 1.8 m to a length of 1.372 m based on the height of the average emergency vehicle interior (Figure 5). This would shorten the length by 0.428 m and reduce the potential for entanglement or interference during the administration of care. However, the AC power cable length remained unaltered, as was instructed by our advisor. To experiment with varying tubing lengths, length-modifiable corrugated tubing provided by our advisor was used to emulate the oxygen inlet and breathing circuit tubes, while the remaining components (control and pressure lines, flow and EtCO2 probes) of the VM-2000 could be coiled and held in place to achieve a shorter length.

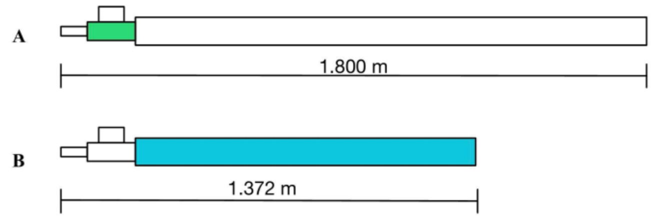

Fig. 5. Tubing Length Schematic Diagram. (A) The original tubing length of 1.8 m. (B) The shortened tubing length of 1.372 m.

Design Evaluation

To evaluate the effectiveness of our design, 15 students from the University of Virginia (UVA) were recruited as research participants and timed on their assembly of both the original VM-2000 and a modified version of the VM-2000 that featured the manifold, clamp, wired button, and adjusted tubing length (Figure 6A). Each research participant was given written instructions on how to assemble each version of the device along with a live demonstration. After the tutorial, each research participant assembled the original VM-2000 and was timed. Then, a survey was conducted in which the participants rated the ease of assembly, user-friendliness, and efficiency of the assembly experience on a scale from 1, being the least, to 5, being the most. Lastly, each participant was timed again during their assembly of the modified VM-2000. The same survey was given afterward but with an additional question asking participants to rate the convenience of the button placement in the modified assembly using the same scale (Figures 6B and 6C). After the testing and survey data were collected, the time difference between assemblies was calculated to determine any significant differences.

Discussion

Research participants assembled the modified VM-2000 in less time by an average of 3.82 ± 1.92 seconds (Figure 6A). A paired, one-tailed t-test ($\alpha = 0.05$) was performed on the average assembly times of the original and modified VM-2000s. A resulting p-value of $p = 0.003$ proved statistical significance between the assembly times. Thus, the null hypothesis could be rejected, and there was sufficient evidence to conclude that the observed reduction in assembly time could be attributed to the ventilator modifications.

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To compare participants' perception of each assembly's usability, their average ratings for ease of use, user-friendliness, and efficiency were averaged to

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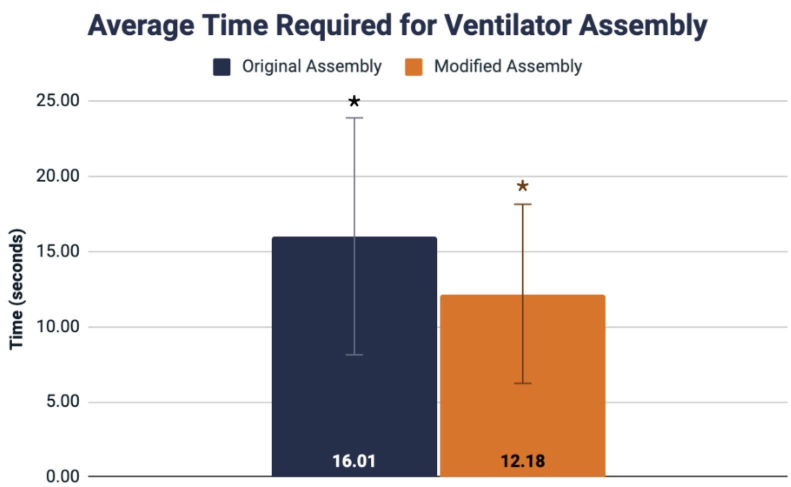

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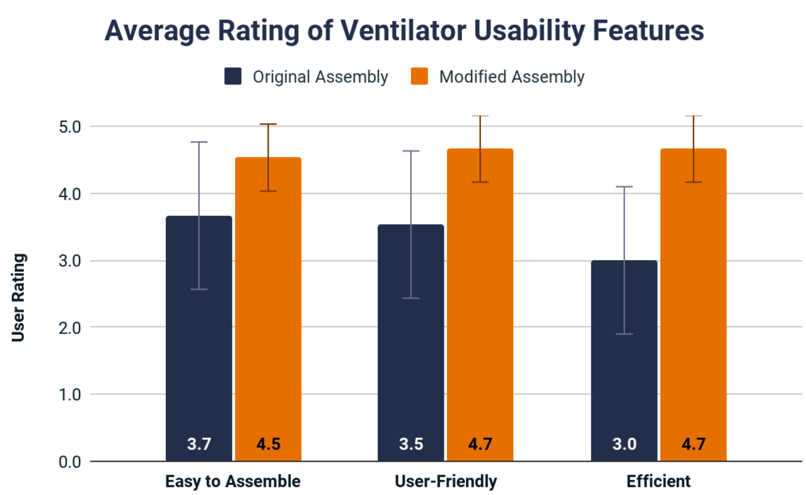
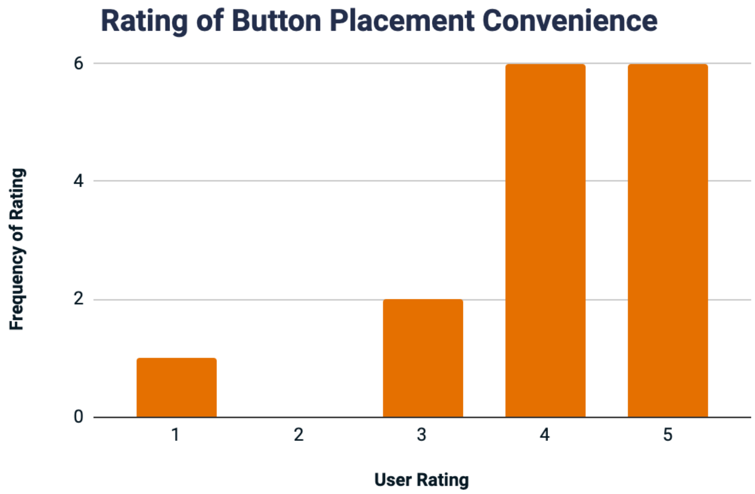


C

Fig. 6. Design Evaluation Data.
(A) The original VM-2000 had an average assembly time of 16.01 ± 7.87 seconds, and the average time to assemble the modified VM-2000 was 12.18 ± 5.95 seconds. Thus, the average difference in assembly time between both versions was 3.82 ± 1.92 seconds. The results of a paired, one-tailed t-test indicate the statistical significance of the difference between assembly times. (B) For the original VM-2000, participants gave average scores of 3.7, 3.5, and 3.0 for the ease of assembly, user-friendliness, and efficiency, respectively. Taking an average of the individual scores, the original assembly received an average overall usability rating of 3.4. For the modified VM-2000, participants gave average scores of 4.5, 4.7, and 4.7 for the ease of assembly, user-friendliness, and efficiency, respectively. Taking an average of the individual scores, the modified assembly received an average overall usability rating of 4.6. A positive increase of 1.2 was seen in the usability score of the modified VM-2000 compared to the original. (C) The survey data regarding button placement convenience showed that most participants rated the convenience of the wired button placement to be either a 4 or 5, meaning the button was thought of by participants as either "convenient" or "very convenient" in the modified assembly.



achieve an overall usability score for each assembly, with 5 indicating the highest level of usability (Figure 6B). Average overall scores of 3.4 and 4.6 were computed for the original and modified VM-2000s, respectively. The 1.2 point disparity between the scores indicated that participants generally perceived the modified VM-2000 to be more user-friendly and efficient than the original. Twelve of the fifteen participants also noted that the placement of the wired button near the non-invasive mask attachment was either "convenient" or "very convenient," which further reinforced that participants found project modifications to be generally beneficial to the usability and efficiency of VM-2000 (Figure 6C).

Challenges & Limitations

During product testing, several participants commented that the manifold obstructed their view of the connection ports on the VM-2000, made it difficult to ensure that all three of the cables were plugged in, and occasionally opened during insertion, causing the enclosed cables to fall out of the manifold. These qualities of the manifold could have complicated the modified device and led to an increase in assembly time. Additionally, participants may have entered the testing environment with a certain level of bias. Because they were provided with the project title when recruited for the study, they knew that the objective of the project was to optimize the ventilator and decrease its required assembly time, which may have influenced their testing performance as well as their survey responses. They were also informed that the device would be used in emergency situations, and many took it upon themselves to assemble the devices as quickly as possible.

In regards to the research population, product testing would have ideally been performed with emergency medicine personnel or technicians (EMTs), as the VM-2000 is designed to be used by trained professionals in emergency medicine. Due to time and scheduling constraints, UVA students who lacked prior ventilation training were recruited as research participants instead. Participants were given a live, walk-through tutorial before each assembly and were allowed to refer to written assembly instructions during assembly testing to standardize their level of training. It was also thought that if students with no prior ventilation experience found the device easy to use, then trained emergency medicine personnel would also find it user-friendly.

Future Work

Future expansions of this project could include the development of a Bluetooth button instead of a wired button. This could be accomplished with Arduino microcontrollers that integrate with the existing software of the VM-2000. Different placements of this button within the device assembly could be evaluated as well. The prototypes could also be further refined in future iterations by experimenting with different sizes of the manifold and tubing clamp and different 3D printing materials such as acrylonitrile butadiene styrene (ABS) and/or nylon. Further developments of the project also include conducting product testing with actual EMTs/emergency caregivers as well as field testing in emergency situations to gain more valuable insight on how the products function in their intended environment with their intended users.

Materials and Methods

Materials

Polylactic acid (PLA) plastic filament was used for 3D printing. This material is affordable, recyclable, and accessible. Physically, it has a lower melting point, allowing for easier processing, high durability, high adhesion, and low thermal expansion.[7,8] PLA was also used to print the breakaway supports in the prototypes. Polyvinyl alcohol (PVA) was occasionally used as support material because of its ability to dissolve in water, but was excluded from the final prototypes. Thermoplastic polyurethane (TPU, known commercially as NinjaFlex) was used for one of the tubing clamp prototypes for its flexible and rubber-like properties, but was also excluded from the final prototype.

A blue PLE adjustable breathing circuit was used to visualize the predetermined, shortened tubing length of 1.372 m.

Methods

Prototype Modeling and Printing

All prototypes of the manifold and tubing clamp were designed in Autodesk Fusion 360 CAD. The first three prototypes for the manifold were all printed with PLA using the Ultimaker 3/S5 and Makerbot Replicator Plus. All manifold prototypes were printed with PLA supports, except for one with PVA supports. Basic functionality of the manifold was tested by evaluating the fit of the cables and if the hinge worked properly to allow for the manifold to close. The fit of the smooth

clear tubing was adjusted by adding three thin corrugations to each side of the manifold to prevent slipping when plugging into the ventilator. The hinge

width was adjusted on multiple accounts for added security and durability. The final manifold was printed using PLA with PLA supports using the Ultimaker 3. The print settings were as follows: 0.15 mm extruder, 0.15 mm layer height, wall/top/bottom thickness of 1 mm, infill density 20%, gyroid infill pattern, 80 mm/s print speed, print cooling enabled, supports generated, and brim plate adhesion.

Three of the four total tubing clamp prototypes were printed with PLA, and all but one of those had PVA supports instead of PLA. One of the prototypes was printed with Ninjaflex, but was too sponge-like. Basic functionality of the tubing clamp was tested by evaluating its ability to securely hold together all of the tubing and wiring components of the ventilator, if the ridge-locking mechanism worked, and if the hinge was functional. For the final tubing clamp, the size was greatly scaled down to hold all of the components together more tightly, and the spacing of the ridges was adjusted to ensure that the locking mechanism worked, and the hinge clearance was adjusted to ensure that full movement was achieved. The final tubing clamp was printed with PLA with PLA supports using the Makerbot Replicator Plus. The print settings were as follows: Smart Extruder+ extruder, balanced printmode, raft base layer, 15% infill density, diamond fill infill pattern, 0.2 mm layer height, 2 shells, and supports enabled.

Tubing Length Adjustment

The adjustable breathing circuit was cut at a non-corrugated section using scissors so that the end attachment could be removed from the cut section and then resecured at the new end of the now shortened breathing circuit. The breathing circuit length was cut down by 0.428 m.

End Matter

Author Contributions and Notes

C.N.A., C.P.D., and C.S.M. designed and performed research, created surveys, conducted testing, and wrote the paper. C.P.D. and C.N.A. performed CAD modeling for the manifold; C.S.M performed CAD modeling for the tubing clamp. C.P.D. analyzed data.

The authors declare no conflict of interest.

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Supplementary Material

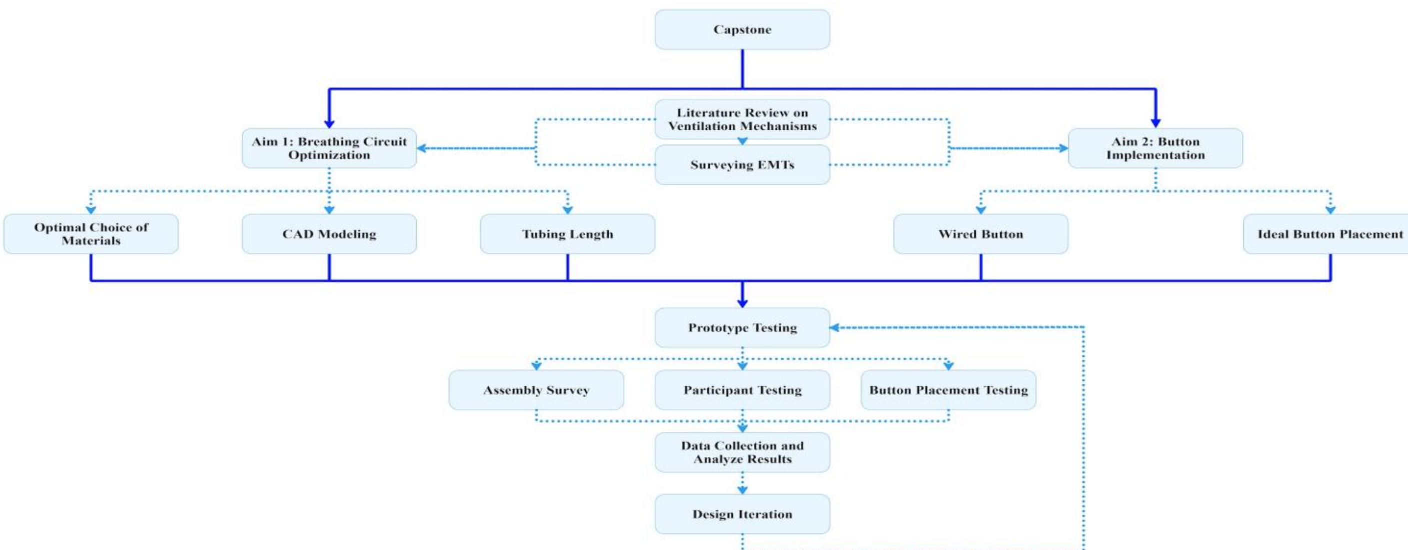

Fig. S1. Flowchart of Design Process. The left side of the flowchart depicts the design and testing process for achieving Aim 1. The right side of the flowcharts depicts the implementation process for the button for achieving Aim 2.

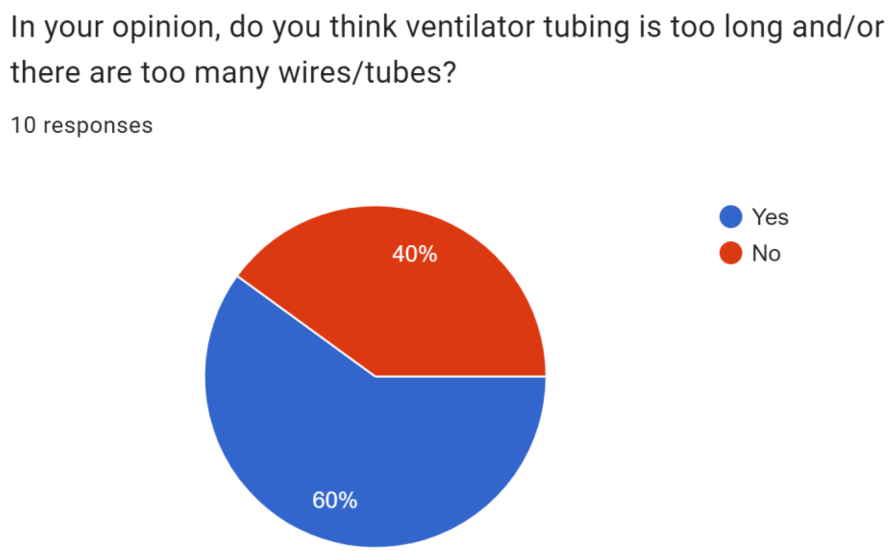

Fig. S2. Pre-Survey Tubing Length Response. Six out of ten emergency responders voted that current ventilator tubing is too long and/or there are too many wires/tubes.