Helpful Engineering Proposal Submission template

Please note: This proposal will be made publically available after submission to HE, as part of an open-source repository.

Project Name	Pandemic Ventilator Project
Date	3/26/20
Owner(s)	Curtis Kline, Ethan Chaleff
Project Slack Channel	N/A

Project Summary

Category

Hardware

Problem and Background (200 words max)

There are not enough ventilators for COVID-19 patients in any country, let alone in developing countries that lack the capital resources of the developed world. These countries too often depend on used medical equipment from wealthier nations, or they must purchase expensive devices from the very same supply chains that the US and Europe rely on. While there is a proliferation of simple ventilator designs, treating COVID-19 patients requires relatively sophisticated ventilation, with both pressure and tidal monitoring, in addition to PEEP. Because ventilators are life support equipment, they must have a high quality design, with design controls, thorough review, and a well documented verification plan. As a group of mechanical and software engineers with experience designing life support systems and nuclear power plants, we're focused on developing designs for multiple low cost, high performance ventilators attuned to the unique challenges and constraints of developing countries. Our open source designs will enable engineers and medical workers in developing countries to build affordable ventilators themselves, with parts available from local supply chains. While we have developed a prototype, we must finalize the design, test it, complete documentation, and prove that our partners around the world can build it.

Solution summary in simple terms (150 words max)

Our dream is to develop a library of high quality, open source ventilator designs that anyone with a moderate level of mechanical and electrical experience can use, with no need for advanced manufacturing. The first step to getting there is to develop our first design. Our current design has little mechanical complexity and is heavily dependent on software and controls. This design will simplify assembly and manufacturing, while a global volunteer workforce develops high quality software that is easy to reproduce and transmit. The design's most specialized parts include a high-performance fan found commonly in sleep aid devices, as well as pressure sensors and an open source microcontroller. The remaining parts are simple tube and pipe fittings, power electronics, and the device's case. By using software controls for the fan, our design can produce a full range of ventilation features, while offering the simplicity of construction found in much lower functionality ventilators.

Solution summary in technical terms (200 words max)

Our design centers around a low inertia centrifugal blower, currently sourced from CPAP machines. These brushless fans with lifetime lubricated bearings can spin to high speeds very quickly, allowing a fine degree of time-resolved pressure control. At the same time, they can develop pressures well above 40 cmH2O; even accounting for flow losses, our test model exceeds 100 cmH2O. By monitoring patient airway pressure using high-frequency pressure transducers and measuring patient tidal volume using an orifice flow sensor, we can reproduce any flow/pressure signal required. While our current design uses commercial NXP sensors, we are testing whether three BME280 sensors would provide sufficient resolution and redundancy at reduced cost.
The other essential component of our design is the algorithmic controls. The software design must be able to detect inspiratory effort while maintaining PEEP, and it must control fan speed to hit a constant flow rate with variable compliance lungs. By using software-in-the-loop development—we have a simulated model of a lung and ventilator in Modelica—and a large team of software engineers around the world, we can rapidly accelerate algorithm development. What you end up with is a physically simple, low cost system that can be produced at scale.

Assumptions of Project (100 words max)

One of our main assumptions is that access to CPAP blowers will be uninterrupted. We believe both that they are sourced in large quantities (the vendors we've contacted in China have more than 5,000 in stock), and that they do not present manufacturing difficulties (fundamentally, it is only three injection molded parts and a brushless DC motor).
Another assumption is that we can demonstrate sufficient reliability and feedback using commercially available cell phone pressure sensors to control the device. If our testing proves this will not work, we will turn to medical pressure sensors as a more costly back-up.

Project Timeline: Please provide a projected project timeline in bullet point form.

We have spent the past couple of weeks organizing, ordering parts, and producing a first working prototype that can do basic volume cycled ventilation. We also built the software model to allow software-in-the-loop testing of our algorithm development. Our next steps are outlined below.

- Over the next 3 weeks, we need to:
    - Finish the 1.0 build of the software
    - Develop a test program for that software
    - Perform an initial Risk analysis following the guidelines of ISO 14971.
- Identify and form a partnership with someone who can perform system testing using lung simulators higher fidelity than what we currently have available.
- Quality control
    - Review our requirements document with our medical advisors.
    - Develop a requirements compliance matrix, with test protocols to confirm

device compliance.
    - Run the ventilator prototype through the compliance matrix to identify shortfalls in requirements.
- Our team of engineers in Guatemala is checking on supply chain and ordering parts they can't find, setting up a work space, and making contacts with hospitals.
- In 4-6 weeks we hope to be manufacturing ventilators in Guatemala.

Project Implementation

Design **(1500 words max)**

Please include at least one diagram. What are the plan/schematics/coding elements required? (Note: You can freeform edit this document for ease of diagram addition OR attach a design document link)

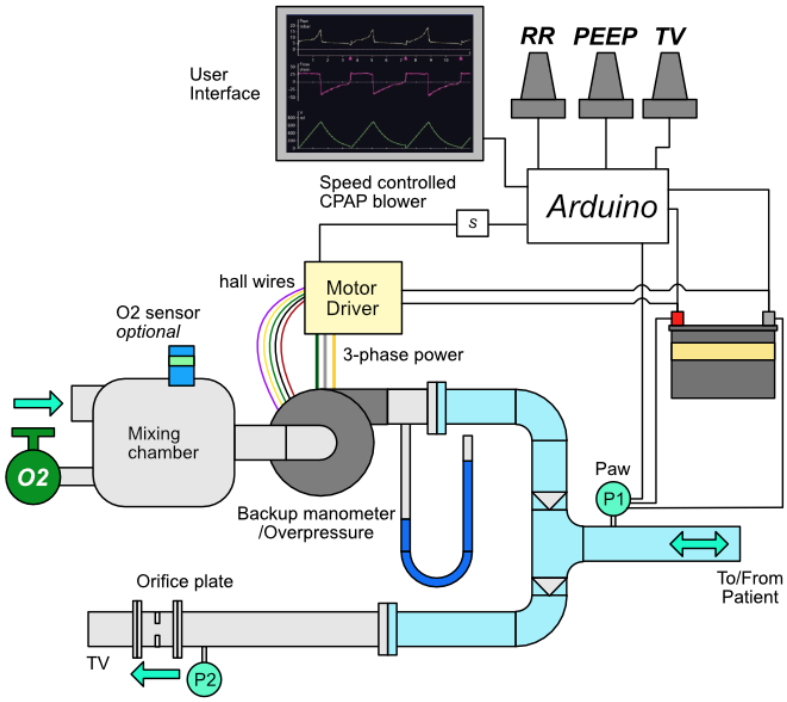
The implementation is based around closed loop control of a centrifugal blower as the pressure source. The inner loop is closed around a pressure sensor, providing real-time continuous pressure control, and an outer loop is closed around a flow sensor, providing volume control. The operating modes have been selected specifically to target COVID-19 treatment. An electronic controller commands respiration cycles in PCV (pressure controlled ventilation), PRVC (pressure regulated, volume controlled ventilation). We understand for a patient to fully recover from ARDS, it is important to wean them off mechanical ventilation gradually, so this design provides ACV (Assist-Control Ventilation) mode operation as well, via pressure-reduction sensing of patient inspiratory effort.

A mixing chamber upstream of the blower draws in pressurized hospital oxygen and ambient air through a filter and provides adjustable FiO_2. The device can not control FiO2 directly, but can be instrumented to provide a readout of FiO2 through an optional oxygen sensor. A manometer on the blower exhaust provides backup overpressure protection. The oxygen-air mix is delivered to the patient via standard 22mm/15mm ventilator tubing and passes through a pair of check valves placed as close to the patient connection (ET tube) as possible to minimize the volume of recirculated gas returning to the patient. The expired gas is directed to an outlet orifice to provide the backpressure required for PEEP control, and then out through an exhaust filter to capture expired fluids and particles. By controlling fan speed during the exhale, the

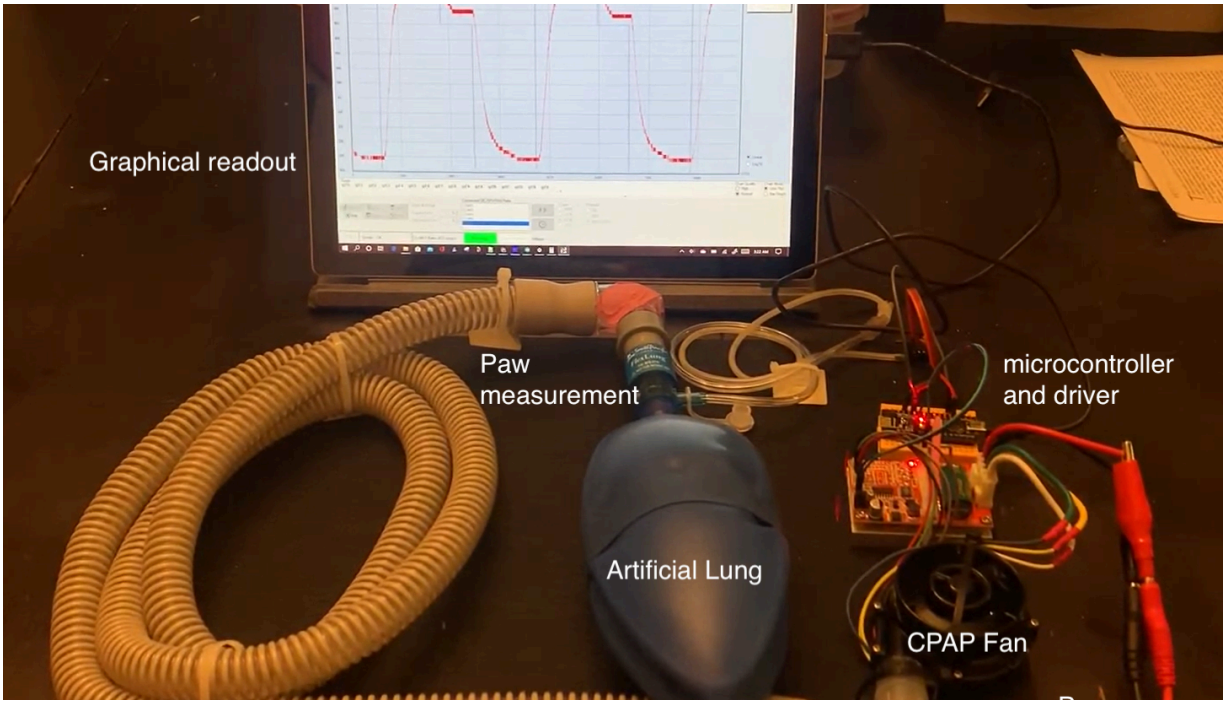
PEEP can be set without adjusting the orifice pressure, eliminating the need for an additional driven PEEP valve, an expensive and sensitive component.

Because this design makes use of continuous pressure control, it is possible to adjust PIP, plateau, and PEEP pressures independently, as well as timing variables RR, I/E, and TV. A display of pressure and volume time history for the patient provides feedback to the therapist so that they can make the appropriate decisions regarding treatment. An audio alert provides industry-standard alarms. The controller running the display and user interface is separate from the respiration cycle controller to ensure reliability in the real-time control of the system. The software and user interface will be designed specifically to cater to treatment of COVID-19 patients by technicians that are medically-knowledgeable but may have received limited or emergency training on artificial ventilators. Pursuant to this, the interface will be designed to automatically detect conditions specific to the progression of COVID-19 and ARDS and to provide relevant alarms and directed information to the therapist. For example, the device will enable the calculation of patient effective minute ventilation based on the initial settings of TV and RR. If lung compliance changes, the ventilator will automatically decrease TV and increase RR within a limited range while also alerting medical staff of the change.

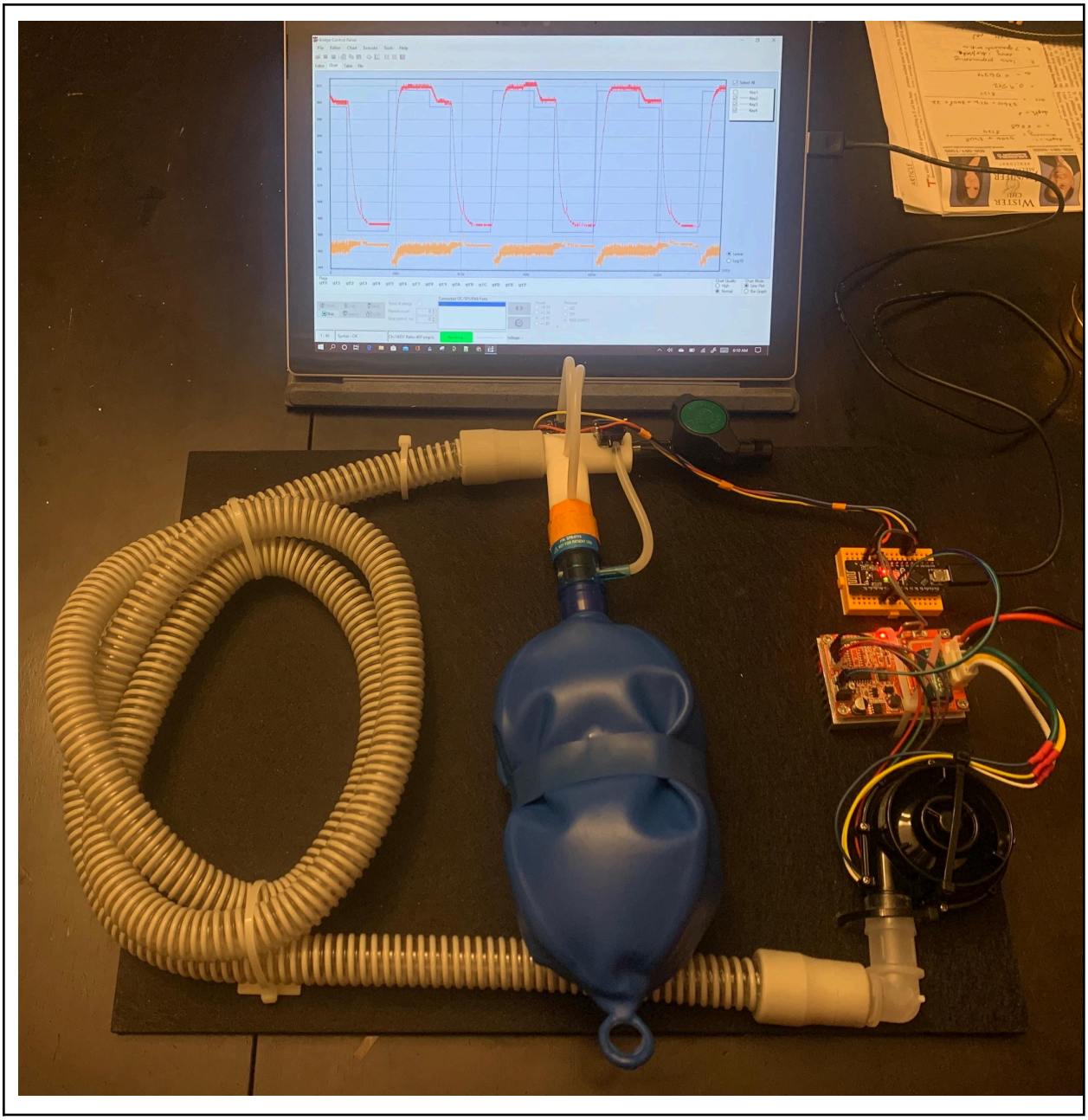
Finally, the entire system is designed to be powered from a 12V car battery, to which a continuous charging supply is attached. This ensures reliable and continuous operation in the event of a power interruption. The low power consumption of the device means a standard car battery will reliably offer well over 1 day of continuous operation.



Above, overview schematic of device.



Above, device version 0.1 showing basic functionality. Below, device version 0.4, with TV measurement and developing controls for low compliance lungs.



Design Documentation

Please include a step by step build or manufacturing summary if possible (if applicable)

We have not yet finished documentation, as we are still refining the physical embodiment. The mechanical build is fairly straightforward as can be gleaned from above (although still somewhat incomplete).

Distribution

Do you need help with distribution or do you have a plan? Please elaborate. (150 words max) Eg: Distribution of hardware product, or distribution of app. What help is required to promote the product?

We are currently planning to distribute these through an open source licensing model. That plan will include quality assurance tests to be placed on the manufacturing process as well as acceptance testing for the completed devices. However, this is a huge lift and would certainly be accelerated by someone more knowledgeable in these processes for medical devices. We also want to expand our network of manufacturing facilities around the world by finding and connecting with qualified partners.

Bill of Materials (BOM)

Please list the materials required for the project, and a supplier/source of these materials exhaustively in the form below.

Supplier	Quantity	Retail Price	USD $
DANIU WM7040 DC 12V/24V High Pressure Blower 7.5Kpa + Driver	1	https://www.aliexpress.com/item/33025679738.html	$46
Pressure Sensor ±1.02PSI (±7kPa) Differential Male - 0.13" (3.3mm) Tube, Dual 0.5 V ~ 4.5 V 8-BSOP (0.475", 12.06mm Width) Dual Ports, Same Side	1	https://www.digikey.com/product-detail/en/nxp-usa-inc/MPXV7007DP/MPXV7007DP-ND/1168438	$18
ALITOVE AC 100-240V to DC 12V 10A Power Supply Adapter Converter	1	https://www.amazon.com/ALITOVE-100-240V-Converter-Transformer-5-5x2-1mm/dp/B07MXXXBV8	$20
The Aftermarket Group Oxygen Cylinder Regulator, Green Anodized Aluminum, 0-8 LPM 870 CGA, TAGTR8-8B	1	https://www.amazon.com/Aftermarket-Group-Cylinder-Regulator-TAGTR8-8B/dp/B07RMBYNPZ	$26

Arduino UNO R2	1	https://www.amazon.com/Arduino-A000066-ARDUINO-UNO-R3/dp/B008GRTSV6/ref=sxin_2_ac_d_pm?ac_md=2-1-QmV0d2VlbiAkMTUgYW5kICQyNQ%3D%3D-ac_d_pm&cv_ct_cx=arduino+uno&dchild=1&keywords=arduino+uno&pd_rd_i=B008GRTSV6&pd_rd_r=e042feed-97ea-4e11-b579-574bb762f778&pd_rd_w=dX9KW&pd_rd_wg=9Xkkr&pf_rd_p=0e223c60-bcf8-4663-98f3-da892fbd4372&pf_rd_r=EG8VWS1BJFV2MSVW5PG4&psc=1&qid=1585239828	$20
Wiring, Molex connectors	20	https://www.amazon.com/LANDZO-Multicolored-Breadboard-Raspberry-Arduino/dp/B01IB7UOFE/ref=sr_1_1_sspa?dchild=1&keywords=ribbon+cable&qid=1585239799&sr=8-1-spons&swrs=C0B9194B3A2069441C011A0B240DDAF3&psc=1&spLa=ZW5jcnlwdGVkUXVhbGlmaWVyPUEyV05RWjBLTDlNTFhMJmVuY3J5cHRlZElkPUEwODMyMzQ1MklMSEJGWkNQR0tMVSZlbmNyeXB0ZWRBZElkPUExMDE4NzY0MjJTNDBIMFU0NEpJRiZ3aWRnZXROYW1lPXNwX2F0ZiZhY3Rpb249Y2xpY2tSZWRpcmVjdCZkb05vdExvZ0NsaWNrPXRydWU=	$5
Case	1		

Hardware: Unit Cost

What is the estimated manufacturing cost per unit (USD)? (if applicable)

<$300

Open Source considerations

What is the build difficulty of this project currently (if applicable)? Eg:

- Home Workshop
- Maker space
- Industrial

Requires basic wiring and mechanical knowledge. With detailed instructions capable of being produced by anyone who has worked with consumer electronics, such as laptop and cell phone repair ubiquitous throughout central/south america.

Suitable 3D printer type or other equipment type required (if applicable):

- Stereolithography (SLA)
- Digital Light Processing (DLP)
- Fused deposition Modeling (FDM), etc?

Not applicable, though some parts (for example, flow orifices and tube connections) could be 3D printed if they could not be purchased. FDM would probably be applicable for these low pressure internal applications. However, for external devices (for example, hose connections and patient valve housings) if injection molded parts couldn't be found, then SLA would seem to be required.

Quality Assurance and Regulation

What steps have you taken to ensure your solution's safety? How advanced are you in this process (if applicable)?

We are designing our solutions to meet common ISO standards for medical devices. We have a full-time team member who is developing and maintaining a version

controls System Requirements Document as the basis of our verification and validation activities. One team member with experience in nuclear safety has written a draft quality plan to define our design and controls process. The software team is in the process of drafting quality standards for the software development, and we intend to conduct an ISO 14791 risk mitigation review for the design as it matures. We also have a contributing member who has developed and implemented the quality control processes at a small medical device company.
In addition, we have consulted with medical workers. Dr. Harold Picken, a physician formally trained in pulmonary and critical care medicine who serves as an advisor to hospital groups in the Boston area, is in charge of our medical review board. He has also connected us to other doctors. We have also consulted with two ICU doctors, one pulmonologist, and three emergency medicine doctors.

Have you planned the conduct of your manufactury process that ensures quality, what are the steps you have taken? How advanced are you in this (if applicable)?

Ultimately our products would be assembled by partners in developing countries around the world. Our first ventilator could be assembled in the U.S. from off-the-shelf components as described in our bill of materials. We have not yet determined the exact timing or process for manufacturing our initial product, and would welcome additional help in this area. We have started conversations with manufacturing partners who could be engaged to produce certain components if we have supply chain issues.

Will you need assistance with the regulation system? if not which Regulatory system do you plan on distributing the product? Please elaborate (please see: Regulatory-Strategies) (if applicable)

At some point we hope to be in the “We provide instructions” category, although initially we expect to be in the “We manufacture” category. Since our efforts are focused on countries with little regulation, we feel this is of lesser concern that for those teams working on products destined for use in the US, Europe or Canada.

Have you talked to medical staff about the feasibility of your project? What did they say?

As noted above, we are working with Dr. Harold Picken, who is trained in pulmonary and critical care medicine and advises a number of hospitals in the greater boston area. He has been advising us to ensure feasibility of our design though has yet to

review the exact mechanical implementation.
In addition, we have consulted with two ICU doctors, one pulmonologist, and three emergency medicine doctors who have advised us on the requirements and needed function.
We have also been speaking with medical staff in developing countries who would be using the devices we are designing. These conversations have informed the expanded feature set of the device compared to simple ventilators and pushed us to design something that can help with difficult ARDS patients.

Have you planned the testing, verification and validation of your solution? How advanced are you? (if applicable)

Testing is in three phases: 1) software testing 2) hardware testing 3) acceptance testing. 1) will be used running a software simulator to run the control algorithm against various patient conditions, designed to check logic/state flaws in the controller. We are currently building the test cases as we improve basic functionality. Hardware testing will be performed in cooperation with Richard Read of the Open Source Innovation Library who has been developing an instrumented test lung to verify the combined hardware/software. Finally we will develop a checklist of acceptance tests for the manufacture of the devices to ensure that final builds meet acceptable functional and quality standards.

Impact

What impact do you feel your product could have? (100 words max)

We believe our ventilator designs could help medical crews in developing countries by providing local engineers, makers, and technical experts with the ability to produce life-saving equipment for hospitals with limited supplies. The US and rest of the wealthy world are so far behind in ventilator production that they are long away from being able to help developing nations. Unfortunately COVID-19 won't respect these economic distinctions. We need a solution for developing nations to be able to help themselves.

Criteria for Success

What do you think would make your project a success?(100 words max)

Producing a complete design, including technical validation, assembly instructions, and supply chain assistance, could save hundreds or thousands of lives. If we can double the ventilator capacity in a Guatemalan city, then that is success. Unfortunately that is a very high bar, and yet still seems like a drop in the bucket.

Issues and risks

Please list the known issues, potential risks, grey-areas, etc in your project

We have identified a list of technical risks for our approach, but they are somewhat embodiment dependent.
In terms of project level risks:

- **Inability to meet quality thresholds on manufacture**—patient outcome is our ultimate metric. The gap between the design and the device is the manufacturing. It will be difficult to assure quality in the manufacturing and supply chain, especially from industries that may not be used to the high standards in the assembly of medical devices. We also do not have extensive internal experience on setting up those manufacturing facilities.
- **Supply chain on fan**—While we have done what we can to ensure there is ample supply chain for the fans that does not overlap with existing medical demand, there are still only a limited number of these fans and companies currently tooled to manufacture them. We have already seen customs offices close in central america limiting the ability to ship items to the country. We have not undertaken the process of developing the design/fabrication process for additional fans if they cannot be sourced.
- **Medical staff**—Some of the hospitals we have been in discussion with are simply not staffed to deal with more ICU patients. One hospital we talked to has one person capable of performing intubations, for example. More ventilators won't help those facilities, as they will need more trained staff.

Team Experience

Please list the team members, their roles and experience

Name	Experience	Role
Ethan Chaleff	PhD Nuclear Eng, worked as a systems engineer for advanced nuclear power plants.	Project lead
Edwin Chiu	M.S. Electrical Eng, designed life support systems for	Engineer

	submarines	
Elizabeth Hillstrom	B.S. Mechanical Eng, extensive work doing engineering in remote environments, built a methane flare in the arctic	Engineer
Riley Wilbur	Embedded software engineer	Software Lead
Jaimeen Kapadia	Masters in engineering, medical device systems engineer	Quality Control Lead
Dr. Harold Picken	MD, MPH. Principal at Huron Consulting. Advisor to boston area hospitals.	Medical Director

Please list the team member roles you don't have and their required level of experience

Role	**Experience**
Quality Assurance Lead	4-5 years in medical device quality assurance. We have lots of people giving us guidance, but we're mostly engineers and someone who can be fully focused on quality and standards compliance would be a huge asset.
Supply Chain Lead	Experience in facilitating supply chain in central and south america.
Verification lead	2-3 years experience in medical device test protocols and procedures for testing

Budget/Costings

Please provide a costing of your project. Be as detailed as you can.

Ideally we would like to pay for the initial batch of ventilators (roughly 50 to supply hospitals in Guatemala City and Antigua). This will speed the adoption and allow us to order parts. If we think our design is really that good, we may also want to try and apply for the accelerated FDA EUA, but that seems like it is not suited for a DIY ventilator.

Have you identified a revenue stream/source of funding?

We expect primary funds to come through direct donations, grants, and other traditional non-profit sources.

Are you expecting HE to fund your project? Partly or totally?

We're focused on locating funding sources independently but could definitely use HE's financial support.

Needs

What are your other needs? Eg: Experts/funding/distribution/media exposure

We need assistance with fundraising and accessing major media for exposure. We also have been targeting a very focused market, but if this design is good, we may need a larger team to consider developing this as a non-open sourced project, but instead as something that can be manufactured at scale as a product.

References

(with summary of findings in relation to this project for ease of review)
