Project Title: Reliability Testing of Do it Yourself (DIY) Ventilator Project for Low Resource Settings

A. Statement of Need: Unfortunately, at this point in time, we have no therapeutic methods to stop people from getting COVID-19 pneumonia. There are clinical trials for all sorts of medications and there is hope that we may discover that various combinations of viral and anti-viral medications are effective against COVID-19. The best care that patients with COVID-19 pneumonia get is supportive treatment in intensive care. *"The standard approach to treat COVID-19 pneumonia is to ventilate patients and maintain high oxygen levels until their lungs are able to function in a normal way again as they recover."* Last year, 77,000 new ventilators were enough to meet the market demand of the entire planet. In April, New York City alone forecasts a need for 30,000 additional machines[1,2]; Some ventilator manufacturers have already boosted their production by 30-50% but, by themselves, can't deliver the 500 or 1000% growth in production required. *There is a need for ventilators.*

There was a need for ventilators in the developing world before COVID 19.[3] Thus, COVID-19 spreading to the developing world sounds ominous. COVID-19 has been slow to arrive in Africa, or at least has been slow to be detected there. But the wave is coming.(Wood 2020). There is an urgent need for low cost ventilators for Africa. The PI gained interest in ventilators through the Ethiopian Covid-19 Response Team (ECRT). The ECRT is a global volunteer network of engineers, doctors, and other industry professionals working to respond to combat COVID-19 in Ethiopia in partnership with the Ethiopian Ministry of Health. As a result, the DIY Ventilator project is led by a San Jose State Alumni with the guidance of the PI from the SJSU Biomedical Engineering Department.

B. Problem to be addressed: There is a list of open source ventilators ranked based on openness, buildability, community support, functional testing, reliability testing, COVID-19 Suitability, clinician friendliness and manufacturability. Some of the ventilator designs that are clinician friendly rank low in openness, while some that are open are not clinician friendly or have not been tested. The problem is that the reliability test results of the buildable open source ventilators are unknown for designs that have a high level of openness. This means if you build an open source ventilator plan, you may not know if you're *building a reliable ventilator because there was no testing on the reliability of the ventilator*. If people all over the world are going to build low cost ventilators, they should know if the ventilators are reliable. We will set up a system to test ventilators for reliability. We will test them using the Biopac ventilator validation system.

Table 1. A sample list of ventilator rankings. To understand the ranking system please visit the evaluating open source ventilator projects page.

Project Name	Project Link	Openness	Buildability (1 unit)	Community Support	Functional Testing	Reliability Testing	COVID-19 Suitability	Clinician Friendly	Average
COVID-19 Rapid Manufacture Ve	https://www.instructables.com/	5	4	4	3	0	3.5	3.5	3.29
PREVAIL NY	https://jmawireless.com/prevail	4.5	4	3	2.5	0	4	3.5	3.07
Low-Cost Open Source	https://github.com/jcl5m1/venti	5	4	4	3	0	2	2	2.86
VentilAid	https://www.ventilaid.org/	5	4	4	3	0	2	2	2.86
CoRescue	https://corescue.org	4	1	4	3.5	0	3	3.5	2.71
VentCore Ventilator	https://www.ventcore.health/	5	4	3.5	2	0	2	2	2.64
Jeff Ebin's Prototpye	https://www.ebcore.io/?fbclid=	5	4	3	1	0	2	3	2.57
CoroVent	https://www.corovent.cz/	2	2	4	4	0	3	3	2.57
INSPIRE - OpenLung	https://github.com/emersonmo	5	2	4	3.5	0	3	0	2.50
Vortran G02VENT	https://www.vortran.com/go2ve	1	2	2.5	4	0	4	4	2.50
DRM127 Ventilator/Respirator	https://www.nxp.com/docs/en/a	1	2.5	1	5	0	4	4	2.50
Protofy Team OxyGEN	https://oxygen.protofy.xyz/	4	4	4	1	0	2	1	2.29

C. Contribution to knowledge and scholarship in the discipline. The DIY Ventilator Project will contribute to the field of Biomedical Engineering, particularly medical devices in respiratory by providing a "recipe" to rapidly manufacture a low-cost ventilator and ensuring via reliability testing that they meet minimum clinical and performance requirements without compromising safety and efficiency. In addition, it will be integrated into the SJSU courses. The SJSU courses that would benefit from this project include: BME 178 Biomedical Product Realization (The Final Project for Spring 2020 is already on COVID 19. Future Final classes will include results of this proposal.) BME 274: Regulatory, Clinical and Manufacturing Aspects of Medical Devices (Sections of this course will include regulatory, clinical and manufacturing aspects of devices for COVID 19); BME 115 Foundations of Biomedical Engineering (implementation of a ventilator reliability testing lab); and BME 177 Physiology for Engineering (Physiology of the Lungs Lecture and Labs)

D. Scope of Work and Methodology. The PI is already part of a team of doctors, engineers and volunteers primarily from Ethiopia working on the OxyGEN ventilator (highlighted in table 1). From the table above, the OxyGEN ventilator has high rankings for openness, buildability, community support, but its reliability testing ranking (highlighted in table), COVID-19 suitability, and clinician friendliness are low. The reliability testing is rated as 0 because it has not been done. It has not been done for many open source ventilators. The objective of this work is to test reliability for open source ventilators and to make or suggest design modifications to support the goal of having a clinically valid ventilator that can be used anywhere. The PI is or will be involved in the design and development plan that is developed according to following standards i.) ISO 13485: 2016 Medical Device Quality Systems, ii.) Code for Federal Regulations Title 21-- Part 820 -- Quality Management Systems--Sub Part C Design Controls, and iii.) ISO 14971 Application of risk management for medical devices. The PI has taught courses in the aforementioned areas over the past 5 years so he will be guiding the team as they establish and maintain a plan that describes design and development activities, and defined responsibility for implementation. Please refer below for a brief description of the product development stages and deliverables. Overall the plan is to put together a reliability testing station that enables those making the ventilators to test reliability. To achieve this, the PI will engage in the work described above with the DIY team and also set up a reliability station that fits into the standard Biomedical Engineering Laboratories that we run in the College of Engineering. SJSU BME students will build the same ventilators the DIY Team Build as part of their senior project. Reliability testing will be performed and will include analysis of pressures, volumes and Oxygen levels of ventilator circuits. The PI is already disseminating his work by presenting about COVID-19 on a webinar for the NGEX virtual Diaspora Speaker Series on April 18th, 2020 and will continue to do so.

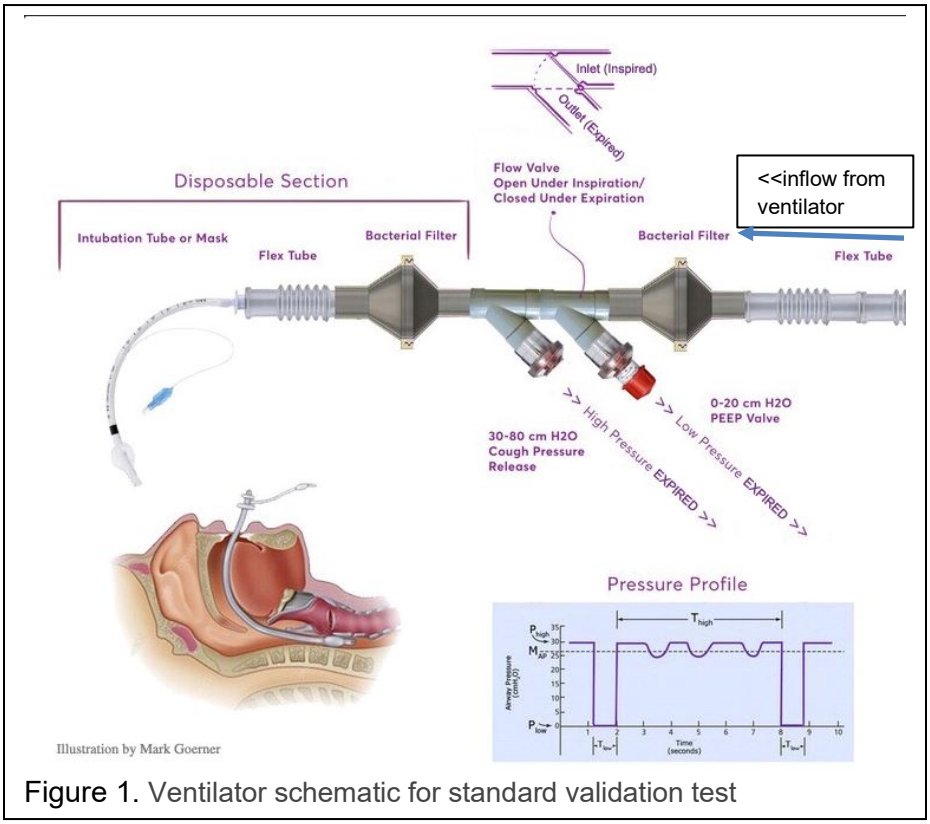

Figure 1. Ventilator schematic for standard validation test

Table 2. Work Details and Benchmarks for success

Work Details	**Benchmarks for Success**	Time
Design and Development Plan	Create: "Bootstrap" Quality System, Proof of Concept Research Results, User Needs analysis, Product Description, Regulatory Strategy & Plan, Design & Development Plan, Risk Management Plan Project Schedule & Plan, Funding Strategy & Plan Quality Plan, Design Inputs, Design Review, Planning Phase Review 80% Done with DIY Team	Q2'20-Q3'20
Ventilator Prototyping	Obtain: Design Outputs, Risk Analysis (hazard identification), Risk Evaluation, Risk Assessment(s), Design Verification Plans, Human Factors, Sales & Marketing Strategy, Working Prototypes, Define Regulatory Path, Design Review, Design & Development Phase, Review 50% Done with DIY team	Q2'20 - Q4'20
Reliability Testing with Biopac	Expiration and inspiration pressures match settings on e.g. OxyGEN ventilator Ventilator Delivers constant volume with each breath	Q4'20 - Q2'21

system	Oxygen levels in ventilator are tunable to be greater than atmospheric conditions The testing above will also be performed on iterated designs	

E. Plan for Dissemination and Future Applications

The PI will present on a COVID-19 Panel on April 18th, 2020 and plans to continue giving invited presentations. He will disseminate information through his youtube channel, website (erogbogbo.com) and publications. For now, the priority is grant applications. The PI has applied for a major grant this year, and has been accepted to the College of Engineering Grants Academy. The PI plans to apply for three COVID-19 grants.

Table 4: Pending and projected grant submissions

Application Agency	**Project Title:**	**Direct Cost**	**Due Date (2020)**
Newton Award Transformative Ideas during the COVID-19 Pandemic	Biolung to bypass the need for a ventilator	$100,000	May 15
Office of Biomedical Advanced Research and Development Authority (BARDA) Broad Agency Announcement (BAA)	Easy to set up, low maintenance, low cost ventilators	$1,000,000	October 17th
$1.39 Billion Dollar Fund for COVID-19 Nigeria	Low Cost COVID-19 Solutions for Nigeria	$500,000	June 30th

Table 5: Deliverables, Anticipated Start times and duration of deliverables

Deliverables	**Anticipated Start Time**	**Duration and Frequency**
Receive Award	2020	
Notify Collaborators	2020	
Planning	February 2020	2 months
Design Development (iterations)	March 2020	~ 8 Months
Design Verification	July 2020	~ 8 months
Design Validation	January 2021	> 6 Months
Market Release	After July 2021	
Grant	May 15, June 30, October 17th	
Manuscript submission	December 2020	

F. Brief budget justification for fellowship summer salary: Funds are requested for the fellowship salary award for June 2020 to lead a team in modifying, designing and testing prototypes. The PI will be responsible for coordinating a bay area collaborative ventilator effort across organizations in different countries (US, Nigeria, Ethiopia) and non-profits (Ventilators for Africa). His efforts will facilitate a project with diverse aspects that include ventilator design, reliability testing, and regulatory standards. He will coordinate with department analyst, student assistants and the research foundation to account for lab expenditures. He will facilitate the dissemination of research finding by attending, presenting and organizing conferences.

The RSCA Related Expenses include: The funds will go towards setting up a reliability testing station for ventilators. SJSU students will work on the project as part of their Senior Design Project.

G. References

1. Readfearn, G. What happens to people's lungs when they get coronavirus? *the Guardian* http://www.theguardian.com/world/2020/apr/15/what-happens-to-your-lungs-with-coronavirus-covid-19 (2020).
2. A better answer to the ventilator shortage as the pandemic rages on. *World Economic Forum* https://www.weforum.org/agenda/2020/04/covid-19-ventilator-shortage-manufacturing-solution/.
3. Krishnamoorthy, V., Vavilala, M. S. & Mock, C. N. The need for ventilators in the developing world: An opportunity to improve care and save lives. *J. Glob. Health* **4**, 010303 (2014).
4. COVID-19 – 'Enormous gap' in ventilators for Africa - the worry is no one is sure how big. - CNBC Africa. *CNBC Africa* https://www.cnbcafrica.com/west-africa/2020/04/02/covid-19-enormous-gap-in-ventilators-for-africa-the-worry-is-no-one-is-sure-how-big/ (2020).
5. Website. https://www.wefhttps://www.theatlantic.com/ideas/archive/2020/04/why-covid-might-hit-african-nations-hardest/609760/orum.org/agenda/2020/04/covid-19-ventilator-shortage-manufacturing-solution/.