

Tech. & Team	Mission Alignment	Technical Viability
<p>- Open-source, non-invasive, water or electrical pump driven BiPAP type ventilator for austere environments. Can be constructed and utilized by people with minimal fabrication and clinical skills using inexpensive COTS parts from a hardware store.</p> <p>- The 3SILK team has over 100 years of medical / pharmaceutical device development experience:</p> <p><a href="https://www.linkedin.com/in/chuck-pell-1a170216/">https://www.linkedin.com/in/chuck-pell-1a170216/</a>  <a href="https://www.linkedin.com/in/ruth-proctor-72b392/">https://www.linkedin.com/in/ruth-proctor-72b392/</a>  <a href="https://www.linkedin.com/in/ericespenhahn/">https://www.linkedin.com/in/ericespenhahn/</a>  <a href="https://www.linkedin.com/in/hughccrenshaw/">https://www.linkedin.com/in/hughccrenshaw/</a>  <a href="https://www.linkedin.com/in/rmmoody/">https://www.linkedin.com/in/rmmoody/</a></p>	<p>The 3SILK WDV satisfies ~80% of the evaluation criteria and was designed to address the recently changing standards of care for COVID-19 patient ventilation. The WDV is designed for low-resource, austere environments, being made from readily available parts, eliminating supply chains and making availability nearly universal. It is for patients that need breathing assistance and have not developed ARDS. Standards of care are changing to include earlier non-invasive breathing assistance such as CPAP and BiPAP. The WDV is a low-cost, easily accessible alternative for use inside and outside a hospital.</p>	<p>WDV operators can vary the respiration rate, tidal volume, exhalation time and temperature of the inspired air. WDV is engineered for long-term continuous use. The WDV is simple, reliable, inexpensive and easy to construct and operate. COVID-19 ventilation protocols prescribe warm, humidified air. The WDV provides humidified air due to its water-driven design and the inspired air temperature can be controlled by adjusting the temperature of the water source or heating the hoses to the patient.</p> <p>Evolving COVID-19 ventilation standards of care:  <a href="https://www.medscape.com/viewarticle/928259#vp_1">https://www.medscape.com/viewarticle/928259#vp_1</a></p>
	Regulatory	Speed
	<p>Our WDV is not an FDA-cleared medical device and is being made available open-source. We do not warranty the design or make claims of efficacy. The WDV is intended to be a highly-accessible, non-invasive ventilator and is to be interpreted, constructed, modified, and utilized at the user's risk. The design is intended for use with an Ambu-bag or BiPAP face mask and valve assembly with an integrated over-pressure relief valve to protect patients from pressure related injuries. The WDV is intended for patients that could benefit from non-invasive breathing assistance and was not designed to ventilate patients with an artificial airway.</p>	<p>The 3SILK WDV is an open-source ventilator design and thus not restricted to factory production. The 3SILK WDV contains 23 parts, all of which are readily available from hardware stores. The WDV now contains 3 parts that require precision inner diameters, and a primary goal of this proposal is to reduce this remaining manufacturing burden. With additional engineering, this design could be further simplified and made globally available as a kit for internet purchase or, preferably, as freely downloadable plans needing only locally available parts. If successful, it could vastly and forever improve ventilator support in under-resourced communities.</p>