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How businesses are working together to deliver NASA/JPL-designed ventilators to the world in the fight against COVID-19

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ABSTRACT
In response to the COVID-19 pandemic, NASA Jet Propulsion Laboratory (JPL) engineers had embarked on an ambitious project to design a reliable, easy-to-use, and low-cost ventilator that was made of readily available parts to address the unexpected global shortage of these lifesaving devices. After successfully designing and building the VITAL (Ventilator Intervention Technology Accessible Locally) ventilator in record time, FDA Emergency Use Authorization (EUA) was obtained and then the license to manufacture and sell these ventilators was made available to select companies through a competitive process. STARK Industries, LLC (STARK), located in Columbus, OH, USA, was one of only eight U.S. companies to be selected to receive this worldwide license. Motivated by its mission to improve human health and well-being through innovated medical technologies, STARK accepted the challenge of further developing the VITAL technology and manufacturing the ventilators in large quantities and making them available to those in need around the world. To this end, Spiritus Medical, Inc (Spiritus) was spun off from STARK to focus on the ventilator business. Through collaborative efforts with various corporate, academic, governmental, and non-profit partners, Spiritus was able to successfully begin manufacturing and selling its ventilators. Due to its low-cost nature and its straightforward design, this ventilator is ideal for use in developing countries where ventilators are in short supply and affordability is a major consideration. This is a story of how NASA’s ingenuity, based on space-based know-how and experience, was used to rapidly design this innovative ventilator. And by forging partnerships with highly qualified and motivated partners such as STARK and Spiritus, NASA has succeeded in translating this work into technology that could potentially save thousands of lives in the fight against the COVID-19 pandemic.

1. Global ventilator shortages due to the COVID-19 pandemic

The COVID-19 pandemic in early 2020 spread at an alarming rate, with confirmed cases and deaths increasing dramatically throughout the world. This was especially the case in numerous countries where the number of patients in need of ventilators exceeded the availability of these life-saving devices \cite{1}. The ventilator shortages were felt not only abroad but domestically in the United States (US) as well. This was highlighted in March of 2020, when then New York Governor Andrew Cuomo pleaded for an additional 30,000 ventilator units for his state alone \cite{2}. Stories arose daily in which hospitals, cities, and countries around the world expressed their desperate need for ventilators. Unfortunately, existing ventilator manufacturers both in the US and abroad were unable to meet this soaring demand \cite{3}. This was due to not only the inability to adequately ramp up production by existing ventilator manufacturers but also because of a severe shortage of parts, especially those sourced from outside the US. In developing countries with high rates of infection, the shortage of ventilators was especially alarming. According to GlobalData, there was a global demand for nearly 900,000 additional ventilators due to COVID-19 in the spring of 2020 \cite{4}.
Ventilator shortages were rampant. In India, for example, there was only one ventilator per 30,000 residents. Countries in Africa such as Nigeria were even worse off, where there was only one ventilator available per 1.3 million inhabitants. Due to such worldwide shortages, countries began to adopt near wartime-like efforts and tactics to address this problem and called upon universities and even non-health industries to help address the shortages [1].

2. NASA JPL’s VITAL project

In March of 2020, amidst the sweeping wave of the coronavirus pandemic, NASA Jet Propulsion Lab (JPL) engineers focused their engineering talents towards addressing the outstanding ventilator shortage around the world. In only thirty-seven days, a team of over 50 NASA members designed, built, and tested a novel ventilator they named the VITAL (Ventilator Intervention Technology Accessible Locally) [5]. The timeline was unprecedented, especially in the medical device industry, and was made possible through the passion, focus, and ingenuity of NASA’s best and brightest, and their desire to help the world overcome the devastating effects COVID-19 pandemic (see Fig. 1).

The process of building the ventilator involved tackling the current issues at its core: the limited supply of ventilator parts, high costs, and saturated mass production capabilities...

With all this in mind, the prototype was successfully built. Leon Alkali, then manager of the JPL Office of Strategic Partnerships, immediately contacted Dr. Matthew Levin at the Icahn School of Medicine at Mount Sinai in New York to begin testing of the new ventilator [5]. On April 22, the VITAL ventilator passed all critical tests in the high-fidelity human simulation lab under a wide range of simulated patient conditions. On April 30, upon reviewing a 505-page extensive submission, the FDA approved and granted the NASA JPL-designed VITAL ventilator an Emergency Use Authorization (EUA) [6]. NASA JPL’s accomplishments attracted the world’s attention as on April 25th, JPL Associate Director of Strategic Integration, Dave Gallagher, was in the White House, showcasing the VITAL ventilator to President Donald Trump.

3. About the VITAL ventilator

The VITAL was specifically designed to address the growing shortage of ventilators during the pandemic, and to free up the more expensive full-featured ventilators for use on patients with the most severe forms of respiratory failure [5].

The ventilator had to have high-pressure oxygen flow rates to appropriately treat COVID-19 patients with acute respiratory distress syndrome (ARDS) [5]. The global ventilator shortage also made it clear that the fewer the parts the better. NASA JPL engineers made sure of this by keeping the total number of parts to far fewer than that of conventional intensive care unit (ICU) ventilators. These parts were also widely available in the US, allowing for mass production and minimizing supply chain bottle necks. The team also ensured that most of the parts for the VITAL were not the same as for other ventilators to avoid competition with other manufacturers. Ultimately, the unique design made the VITAL ideal for mass production and very cost efficient. The low price tag makes it more affordable and thus more accessible to developing countries. The affordable nature of the VITAL also makes this design an ideal stockpile ventilator.

The ventilator, though not as full featured as traditional ventilators used in most hospitals in developed countries, can adequately treat 80–90% of patients who need mechanical ventilation. The use of the VITAL ventilator in these patients with more basic ventilator requirements frees up the more capable but also much more expensive ventilators for use in the most critically ill COVID-19 patients. The VITAL is a single-mode ventilator with assist/control mode that provides volume targeted, pressure limited, and time limited ventilation for a wide range of operator set parameters. It can vary its supplemental O2 levels (FiO2), Positive End-Expiratory Pressure (PEEP) levels, back-up Respirator Rate (RR), and Tidal Volume (TV). The pneumatic version uses facility-provided air and oxygen to deliver the required pressure, while the compressor version pressurizes ambient air and mixes it with external oxygen.

4. Stark industries and Spiritus Medical inc.

STARK Industries, LLC (STARK) was founded in 2016 in Columbus, OH, USA and has been in the business of bringing together individuals, companies, organizations, and universities to address growing healthcare needs by capitalizing on cutting edge and emerging technologies. Its core technologies revolve around wireless physiological monitoring sensors developed by UK-based company Isansys Lifecare Ltd (Isansys). Together with Isansys, STARK has been promoting the Lifetouch patch, an intelligent wearable biosensor that can continuously sample and analyse ECG signals for clinical use. The patch generates medical grade ECG signals from which heart rate, respiration rate, and heart rate variability (HRV) are determined, all the while providing real-time ECG streaming functionality [7].

In the late spring of 2020, STARK was made aware of the opportunity to be awarded a worldwide license for the VITAL from NASA JPL through a competitive process. Using its in-house expertise and extensive connections in the industry, STARK submitted a proposal for the ventilator license. Out of 331 registered companies across 6 continents in 42 different countries, STARK was one of only 27 licensees in the world, and one of only 8 in the US to be awarded a license to manufacture and sell the VITAL. This launched a series of fast-paced milestones for STARK and its partners as it became one of, if not the first, licensee to produce a fully functional VITAL ventilator.

As production of the ventilators began, STARK Industries created a “spin-off” company named Spiritus Medical, Inc. (Spiritus) and transferred its VITAL license to Spiritus to fully focus on the ventilator business. The ventilator was renamed the Spiritus “VITALITY” ventilator and is already in clinical use in India. The company boasts ongoing NASA support and a strong manufacturing partnership with the ability to manufacture over 200 ventilators a day, if necessary.

The Spiritus VITALITY ventilator has also garnered the attention of the press as the executives of the company was interviewed for the cover of ‘The PPE Magazine’s July/August issue. The ventilator itself was also displayed on loan as part of a Space Center Houston’s exhibit, highlighting how NASA innovations helped address the global COVID-19 pandemic [8]. The VITALITY and the NASA exhibit are also on display at the Center of Science and Industry (COSI), Columbus, Ohio’s award-winning science museum.

Fig. 1. Dr. Matthew Levin and his team testing the VITAL prototype at Mt. Sinai Hospital in New York (Credit: Icahn School of Medicine/NASA/JPL-Caltech).
5. Conclusion

NASA Administrator Jim Bridenstine proudly claimed that the skills, expertise, and knowledge gained over decades of pushing boundaries and achieving firsts for humanity, is exactly how the team at JPL pulled this project off [5]. In NASA JPL terms, the unimaginable timeline at which the team finished this project is the equivalent to cramming an entire planetary flight mission in a little more than a month [4]. Ultimately, the story behind NASA’s process of designing the VITAL ventilator is a testament to how taxpayer investments in space exploration can translate into even medical advancements that ultimately improve quality of life on Earth.

However, the implementation of this engineering innovation required a partnership with industry and we at STARK and Spiritus are proud and honored to be playing an integral part in getting these life-saving devices into the hands of those who need them.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests. The paper describes work carried out as a collaboration between NASA and the for-profit companies STARK Industries, LLC and Spiritus Medical, Inc. Authors Michael Chung, Joe Swantack, and Peter Lee are associated with both STARK Industries and Spiritus Medical. The author Leon Alkalai is now retired from NASA and currently affiliated with the company Mandala Space Ventures, which has no association with the contents of this paper.

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