Jet Propulsion Laboratory
California Institute of Technology

Date: April 24, 2020

Subject: Notice of Time Limited Royalty Free Licensing Opportunity: NASA/JPL COVID-19 Ventilation Intervention Technology Available Locally (VITAL)

Purpose: Licensing for the commercialization and deployment of VITAL ventilator technology

Technology: Simplified, low cost ventilator system technology specifically targeting pre-ICU COVID-19 patients. Publicly available details of JPL's VITAL ventilator designs are available at https://medeng.jpl.nasa.gov/covid-19/ventilator/

Potential Customers: Department of Human Health Services (HHS), Department of Homeland Security (DHS), Federal Emergency and Management Agency (FEMA), United States Agency for International Development (USAID), international organizations, other

Quantity: The United States Government is planning to purchase tens of thousands of ventilators in 2020, and there is anticipated international demand for this type of product

Regulatory: An application for Emergency Use Authorization (EUA) was submitted to the FDA for the VITAL ventilator on April 22, 2020

Field Test: A VITAL prototype is undergoing field testing at Mount Sinai Hospital in the Human Simulation Lab at the Icahn School of Medicine in New York City

JPL Role: Caltech/JPL will provide a free nonexclusive technology license along with a detailed technical information package and limited technical assistance to qualified licensees

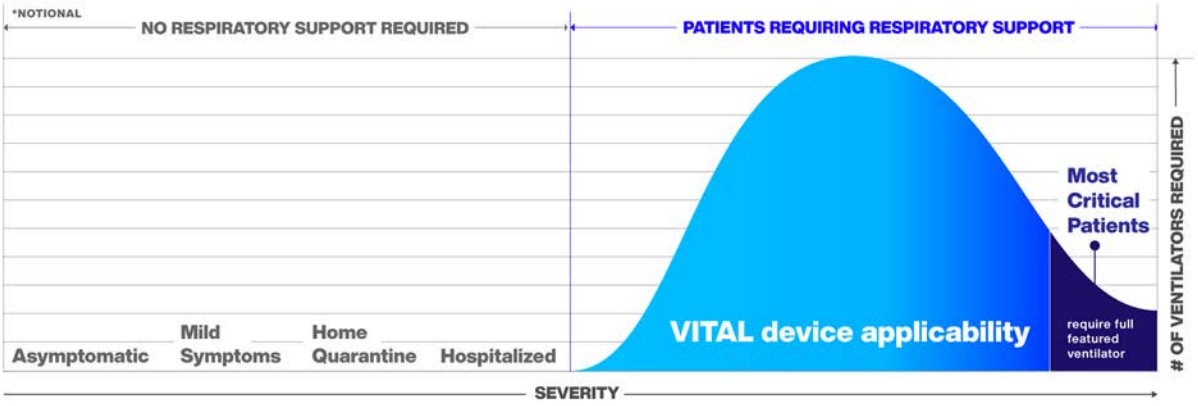
Registration: Registration is required at https://medeng.jpl.nasa.gov/covid-19/ventilator/ starting on April 24, 2020 to be considered as a licensee and to participate in a Q&A session hosted by JPL

Q&A: An interactive video conference Q&A will be held for registered applicants on April 29, 2020

License Award: Licenses will be offered to qualified registrant applicants on or before May 7, 2020

Background

In response to the predicted surge of the COVID-19 pandemic and the current critical shortage - and expected future worldwide shortages of ventilators, NASA's Jet Propulsion Laboratory (JPL), an operating division of the California Institute of Technology (Caltech), has developed two different prototypes of reduced-functionality ventilators (or ventilation devices) known as VITAL: 1) a pneumatic ventilator, and 2) a compressor ventilator. JPL's ventilators are targeted to treat the segment of COVID-19 patients who are symptomatic and in need of pre-ICU respiratory ventilation. Further technical details of JPL's designs are available at https://medeng.jpl.nasa.gov/covid-19/ventilator/. The detailed technical information package will be available to all qualified licensees of the VITAL design.



The purpose of this notice is to enable the rapid transition of the JPL ventilator prototypes, via a free licensing agreement from Caltech, and with FDA EUA approval, to one or more qualified licensees who can demonstrate a credible plan to rapidly scale to deliver ventilators to the field of operation.

License Offer

Caltech will be offering a non-exclusive royalty-free license agreement to make, have made, use, sell, and have sold, and import the VITAL ventilator for the duration of the period the World Health Organization declares the outbreak of COVID-19 a Public Health Emergency of International Concern or pandemic, or until October 1, 2024, whichever is earlier. Any recipient of a free license will bear all responsibility to comply with all applicable legal and regulatory requirements regarding the manufacture and sale of medical devices. JPL offers these device designs in good faith to meet the growing demand for manufacturers to produce ventilators and help healthcare providers and others prevent the spread of and treat patients with COVID-19. Physicians and other healthcare providers should bear full responsibility to convey warnings and obtain patients' informed consent.

Regardless of whether JPL has received an EUA from FDA, the California Institute of Technology (including the Jet Propulsion Laboratory) ("Caltech"), nor its employees or agents, provide any representation or warranty, express or implied, for fitness for a particular purpose, safety, efficacy, or non-infringement of any third-party intellectual property rights.

License Application Process and Deadlines

Those interested in entering into a license agreement with Caltech to the VITAL ventilator technology are required to register at: https://medeng.jpl.nasa.gov/covid-19/ventilator/. Due to the urgency of this matter, JPL requests registering as soon as possible, but no later than April 28, 2020, so that JPL is aware of your interest in responding to this call for licensing.

Upon registration, a follow up email will be sent to each registered applicant with a link to upload a commercialization proposal. Each qualified applicant must prepare a high-level Proposal that will include:

1. **Proposed approach**: List your proposed approach to development, testing, manufacturing, regulatory compliance, raising required capital, planned capital utilization, and commercialization, including any anticipated partnering organizations.

2. **Past experience:** List you and your partnering organizations' experience in transitioning medical devices from a working prototype to fielding a functioning product into a hospital environment.

3. **Ability to Scale Production**: Describe you and your partnering organizations' ability to rapidly scale from a functioning prototype with FDA EUA approval to a manufactured product that will meet anticipated demand. The Proposal should include a discussion of the supply chain, and any known bottlenecks.

4. **Servicing and Product Support**: Provide a high-level description of you and your partnering organizations' abilities for full service product placement, packaging, distribution, customer service, education and training of hospital staff and other relevant customer related services.

You may choose any format for your Proposal, written or viewgraph, but your Proposal must be under 10 pages, and it must be converted to a PDF format before uploading. Please note that the requested information is for preliminary planning and selection purposes only, and does not constitute a commitment, implied or otherwise, on your or JPL's behalf. Please note that neither JPL nor the U.S. government will be responsible for any costs incurred by you or your company in responding to this request and creating the Proposal.

Registered applicants are advised that any information provided shall be deemed to be furnished with unlimited rights to JPL for any purpose, with JPL assuming no liability for the disclosure,

use, or reproduction of such data. Thus, please do not send JPL any confidential business information or other information that would require a non-disclosure agreement.

You must register and upload your Proposal no later than May 4, 2020 to be considered for a license to the VITAL ventilators on May 7th. Subsequent proposals may be considered on a case-by-case basis.

Q&A and Follow-Up

In order to provide additional details regarding JPL's ventilator designs and to allow for questions to be answered, JPL plans to conduct a WebEx call on April 29th , 2020 that all registered applicants will be invited to attend. JPL will also entertain questions prior to the WebEx via email.

Registered applicants will be notified on or before May 7, 2020 as to whether or not they are eligible to enter into a license agreement with Caltech for the VITAL ventilator.

Roles of JPL and Licensee

JPL will offer limited technical assistance to your development efforts. JPL may also perform tests on your prototypes, validate your product's performance, and perform other limited services, free of cost, as JPL resources permit. The purpose would be to ensure the rapid deployment of the VITAL technology to benefit COVID-19 patients.

JPL is in the process of obtaining the COVID-19 Emergency Use Authorizations for Medical Devices (EUAs) from the FDA prior to the technology transfer to the licensee(s). JPL expects that you will be able to use this EUA and that you would apply for any necessary modifications.

The licensee(s) will be responsible for all design modifications, assembly, productization, manufacturing, performance verification, FDA approval/qualifications, setup instructions, training manuals, packaging, sales, shipping, setup and calibration, service and technical support, hospital staff training, and the like.

We appreciate your consideration in responding to this important call. We look forward to discussing your response regarding this critically important effort.

Kind regards,

Daniel Broderick
Office of Technology Transfer at JPL
Jet Propulsion Laboratory