Jet Propulsion Laboratory
California Institute of Technology

April 23, 2020

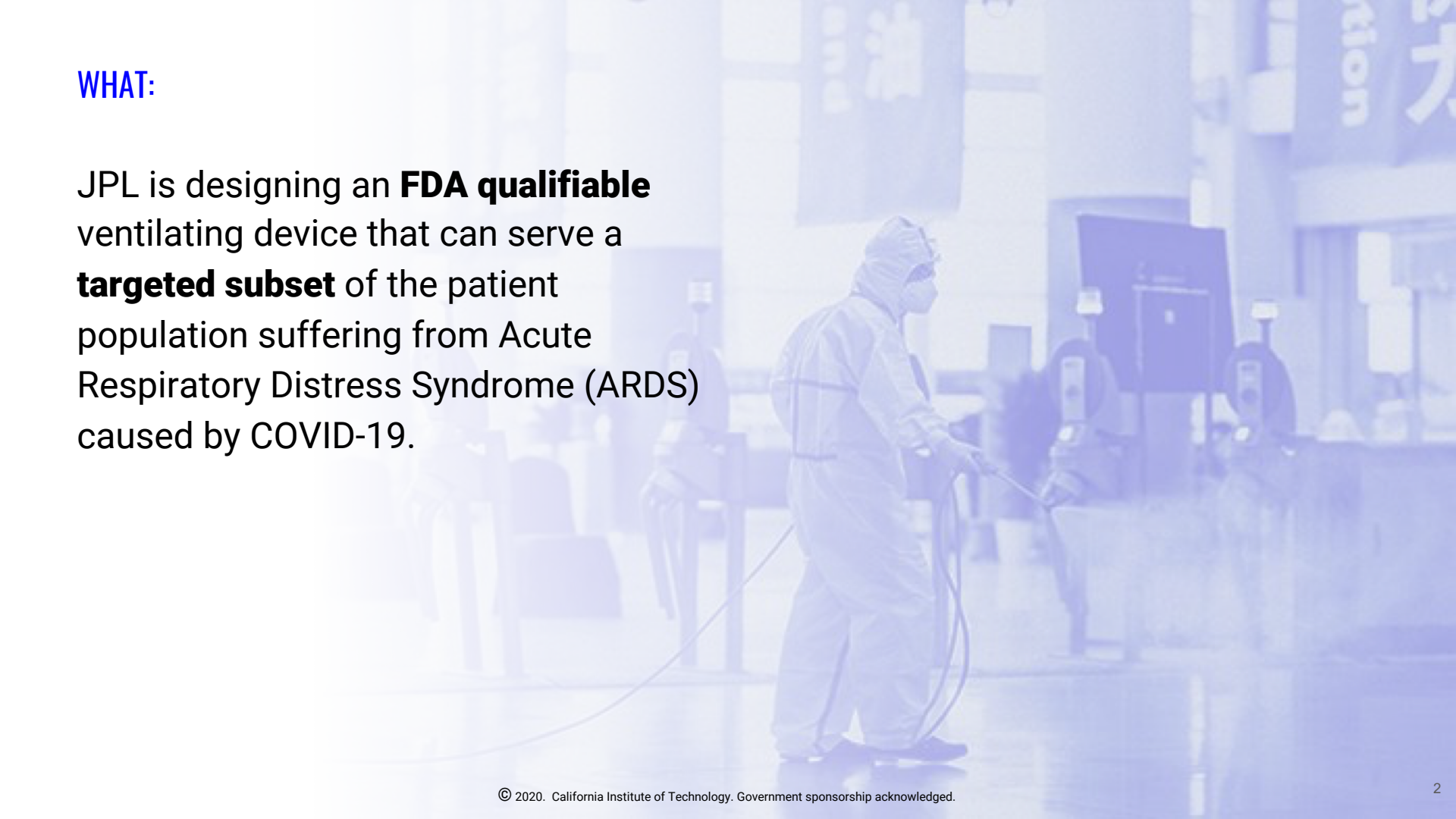
VITAL

VENTILATOR INTERVENTION TECHNOLOGY ACCESSIBLE LOCALLY

A Ventilation Device to Combat the Current COVID-19 Global Crisis

WHAT:

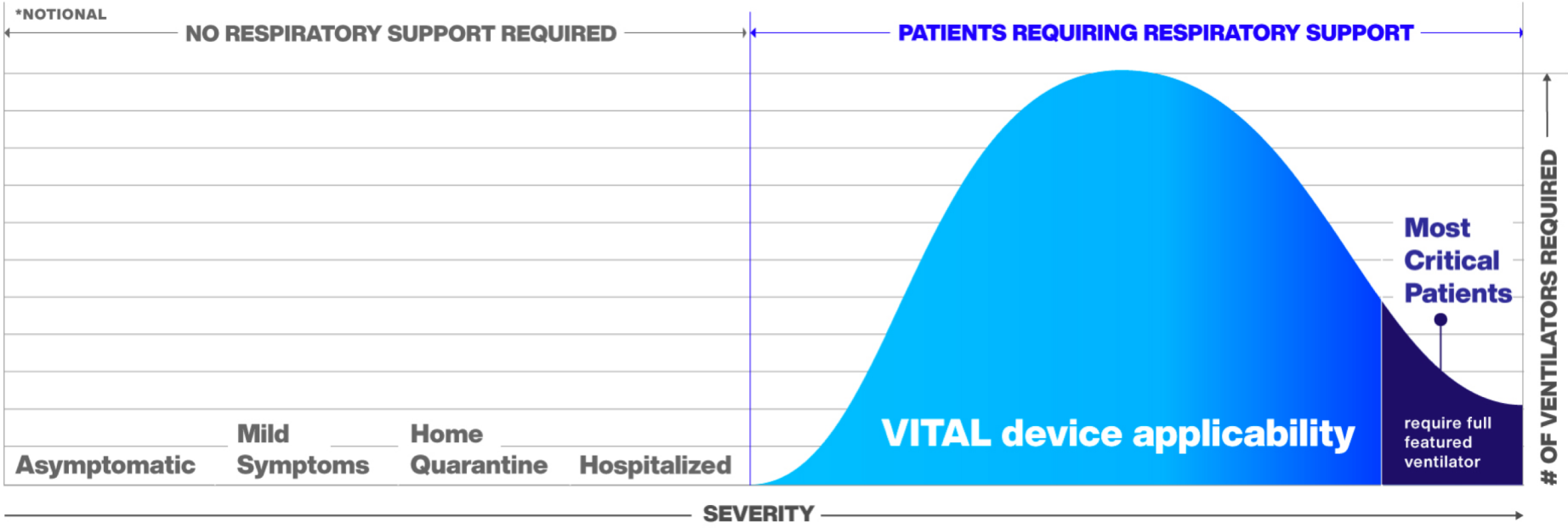
JPL is designing an **FDA qualifiable** ventilating device that can serve a **targeted subset** of the patient population suffering from Acute Respiratory Distress Syndrome (ARDS) caused by COVID-19.



HOW:

License to **industry production partners** to produce ventilators that will meet the domestic and worldwide demand during the COVID-19 pandemic.

WHO: TARGETED SUBSET OF THE PATIENT POPULATION SUFFERING FROM ARDS



VITAL DEVICE INTENDED USE:

PATIENT

- Unable to maintain adequate/safe oxygen level with nasal or mask oxygen
- Variety of clinical states including low compliance, high resistance, hypoxia, hypercapnia
- Intubated, sedated

ENVIRONMENT

- Healthcare Facility
- Stationary Field setting
  - Benign temperature and water exposure
- Transit operable when used with UPS

OPERATOR

- Trained healthcare professional

INTENDED PATIENT

The VITAL ventilator is unique, versatile, and designed for more acutely ill patients. It will satisfactorily meet the demands of those who require aggressive ventilatory support in a variety of clinical states, which may include low compliance, high resistance, hypoxia and hypercapnia.

DESCRIPTION OF VITAL DEVICE

VITAL is an assist/control device that provides pressure set, volume targeted, time limited ventilation for a wide range of operator set parameters.

Capability	Value
Supplemental Oxygen	21<p<100%
Positive End-Expiratory Pressure (PEEP)	5-35 cmH_2O
Back-Up Rate	4-40 breaths/min
Tidal Volume	150-800 mL

INTENDED USE ENVIRONMENT

The target patient population may or may not have access to traditional hospital settings. Therefore, the VITAL device would need to **handle the dirt and dust of a field setting** similar to the EMS Use Environment, but would operate in an environment with **relatively benign temperature and water exposure**. Moreover, the devices do not need to travel with the patients between venues (EMS ventilators can be used for that role), though it is transit operable for movement within a facility when connected to a Uninterruptible Power Supply (UPS).

INTENDED OPERATOR

The intended operator is a trained healthcare professional. Ventilator settings are to be specified and set by a healthcare professional familiar with mechanical ventilators. The healthcare professional is directly responsible for ensuring ventilator settings are appropriate based on patient clinical needs and is responsible for monitoring patient progress.

As seen during testing of the device at Icahn School of Medicine at Mount Sinai on a high fidelity human patient simulator (monitor in foreground shows data from the test venue).

INTENDED OPERATIONAL LIFE

The VITAL device is designed to be compatible with usage during the declared Emergency Use Authorization period. It is designed and tested to allow continuous operation for up to 20 days without maintenance, with total operational time prior to disposal of 4 months. The design has been analyzed to allow at least 24 months of storage in a controlled environment (further analysis/testing is expected to allow for longer storage duration).

Description	Value	Unit
Continuous operational time without maintenance (100% duty cycle)	20	days
Total operational time prior to disposal (multiple patients)	4	months

DEVELOPMENT STRATEGY:

Rapid prototyping of ventilating device based on inputs from healthcare advisers

Partner with industry, government and medical institutions during the design process

Work with the FDA from initiation to validate requirements and establish qualification strategy

Design for manufacturing

Design for supply chain simplicity

Design for scalability

Facilitate manufacturing of the design by industry partners

Design for minimal expected training of end users

ADVANTAGES OF THE VITAL DEVICE DESIGN

Leverage focused device capability set to:

Minimize number of mechanical and electronic components, minimizing cost and the time to assemble and deliver working and tested units

Avoid using components that are critical to the production of full-featured ventilators by industry

Exclude patient exhalation gases from the circuit to avoid **a device sterilization cycle prior to use by the next patient**

FROM ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI

Image credit: Human Simulation Lab at the Icahn School of Medicine, Mount Sinai Hospital, New York