LAWRENCE LIVERMORE NATIONAL LABORATORY

Rapid Response **Ventilators** *for* COVID–19 Patients

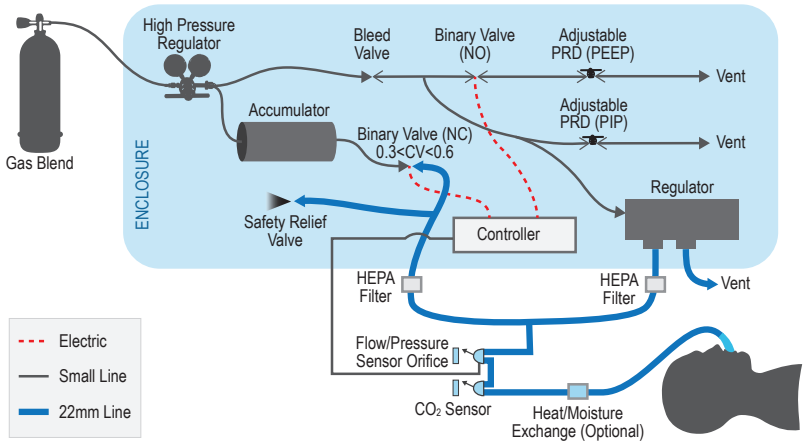
LLNL's Ventilator is being tested now and is on a **path to rapid deployment**

The LLNL Skunk-works Ventilator Prototype

About the time the COVID-19 pandemic began to sweep across the nation, a group of engineers and scientists at Lawrence Livermore National Laboratory (LLNL) initiated a "skunk-works" effort to address the projected shortfall in mechanical ventilators. Their goal was to prototype and test a ventilator design using as few parts as possible and sourced from a supply chain completely separate from that of traditional ventilator manufacturers. The team gained insights from medical professionals, ventilator manufacturers, and published guidance on ventilator functional requirements, particularly for COVID-19 patients.

Ventilator Design

The LLNL team prototyped a design that is intended to be safe, simple and easy to build, while still achieving the minimally required functionality



Although existing ventilator manufacturers as well as new industrial partnerships are ramping up production, the U.S. government predicts a severe shortage in the next three months. To address this challenge, LLNL initiated a rapid development effort to design and prototype simple ventilators whose functionality meets medical requirements and whose parts and manufacturers are separate from the existing medical supply chain.

Schematic of ventilator.
The ventilator uses COTS components from outside traditional medical supply chains to enable manufacturing scale-up.

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necessary to treat patients with COVID-19. The ventilator has two functional air flow circuits: an inhalation and an exhalation circuit. The pressure in each circuit—Peak Inspiratory Pressure (PIP) and Positive End-Expiratory Pressure (PEEP)—is controlled by two high-accuracy back pressure regulators. Thus, the device operates in pressure-controlled continuous mandatory ventilation (CMV) mode, which appears to be the most commonly used configuration for late-stage COVID-19 patients who require mechanical ventilation. The system is also designed to adapt to a patient in the case they spontaneously breathe on their own. Other critical patient parameters, such as inhalation/exhalation ratio (I:E), respiratory rate (RR), and tidal volume (VT), are managed by timing solenoid valves for each circuit.

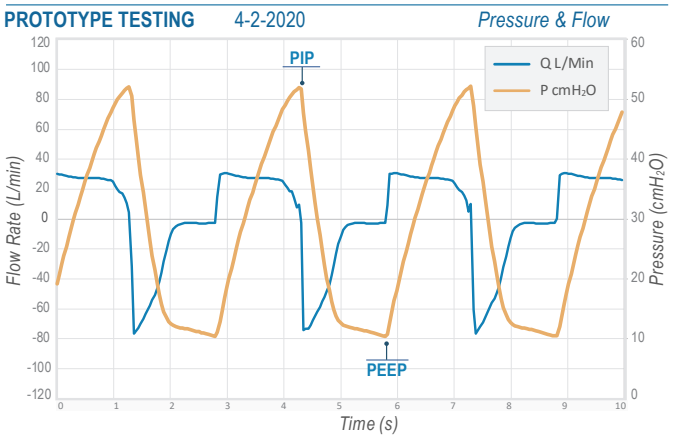
User Interface and Safety Features

The user interface is designed to be simple, robust and familiar to trained clinicians to minimize training time and facilitate the ventilator's safe use. As required by the FDA and standards for medical devices, there are a number of alarms included in the design that alert a user visually and audibly if critical parameter values such as PIP, PEEP, or VT fall out of range, or if a system failure occurs such as a power failure, high airway pressure, low supply gas pressure, disconnection or the obstruction of an air-handling line. In the case of power failure, a back-up battery provides temporary power. No provisions were made for visualization of data and closed-loop feedback. These features, typical of modern ventilators, were excluded for the sake of simplifying the manufacturing process and expediting FDA approval through Emergency Use Authorization.

Manufacturing Simplicity

To aid in rapid manufacturing of the device, the assembly was kept simple and the components were selected based on availability. The approach allows for rapid prototyping, testing, production, and deployment into the clinical care system. The system makes use of standard ventilator accessories and controls typically available at a critical care center, including:

Early version testing shows ***Positive End-Expiratory Pressure and Peak Inspiratory Pressure at reasonable respiratory rates*** *and* ***tidal volumes.***



1. House or bottle of Air/O_2 mix supplied
2. Measurement indicator of fraction of oxygen (FiO_2) input into the device
3. Thermal and humidity control of inhalation gas delivered to patient
4. Endotracheal tubing (ET) and associated fixtures, traps, viral filters
5. CO_2 or pulse oximeter (O_2) measurement sensors

System Tests are Under Way

Preliminary performance and verification testing is being performed on mechanical components measuring and controlling the necessary PIP, PEEP, and VT commonly necessary for Acute Respiratory Distress Syndrome (ARDS) patients. The testing evaluates the LLNL ventilator's ability to control breathing parameters and deliver all safety features and alarms. Additional tests will assess physical robustness of the ventilator assembly to ensure it will safely and reliably sustain a minimum of 21 days of continuous operation.

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Lawrence Livermore National Laboratory is a Federally Funded Research and Development Center operated by Lawrence Livermore National Security, LLC, for the U.S. Department of Energy, National Nuclear Security Administration, under Contract DE-AC52-07NA27344.

LLNL-BR-808757