NovaVent Emergency Ventilator

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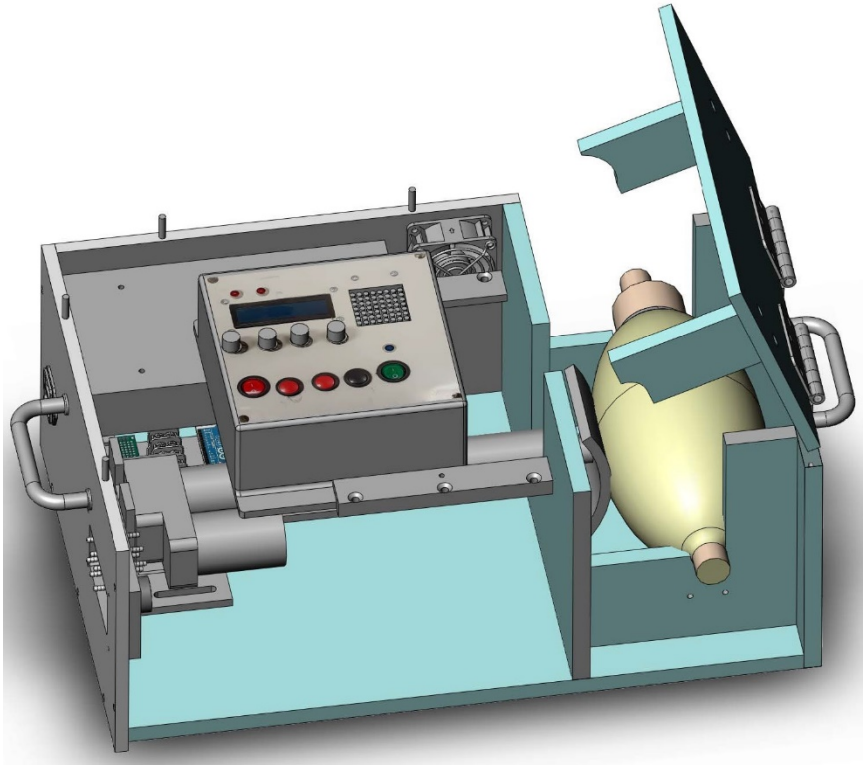
<u>The product has not yet been reviewed, approved or cleared by the FDA.</u>



Motivation

Ventilators are complex medical devices that pump air and oxygen into the lungs and remove carbon dioxide, assisting patients whose lungs otherwise cannot perform the job. The most critically ill coronavirus patients develop severe pneumonia, who often need ventilators to survive and get better. The Society of Critical Care Medicine has projected that 960,000 coronavirus patients in the US may need to be put on ventilators during the outbreak, but the organization estimates that there are only about 200,000 of the devices. Typical ventilators have thousands of parts and come from many parts of the world. Many manufacturers are now finding out that they are not able to find some critical parts in order to be able to produce the machines quickly.

Objectives

Motivated by the above need we have designed and built an emergency ventilator, “NovaVent”- at Villanova University with the following objectives.

- Low-cost, < $500 in parts, and <$1,000 total.

- As few parts as possible
- With as few kinks in the supply chain as possible, something available now in the US market
- Works with ventilator circuits already in the hospitals
- Has essential safety features, alarms and displays to help clinicians
- Fully tested and validated prototype
- Focused on COVID cases – CMV continuous mandatory ventilation mode with patients who need a certain level of intervention. Controllable I/E ratio, breaths per minute, tidal volume, inspiratory pressure limit.
- *The engineering team has the goal of making the complete ventilator design, including the computer codes, open source, enabling anyone to make the devices rapidly and with the same performance and reliability.*
- Seeking to make it available under FDA Emergency Use Authorization directive
- Continue to make improvements to hardware and software

Scaling up

Since we are not equipped to make large numbers of these devices, we have been talking to PA DCED about engaging local industry in the manufacture and distribution of the devices. Along with so many such initiatives nationwide, we hope our NovaVent project will help to save lives in addition to aiding the local economy.

Future Steps

We expect to have the prototype designed, built and tested by May 30th. Application to FDA has been submitted and we hope to qualify under EUA. While we are waiting for FDA, we will connect with industry for manufacturing and distribution. *The product has not yet been reviewed, approved or cleared by the FDA.*

Beyond this immediate need, we will continue the development to help fulfill a long-term need for low-cost emergency ventilators in resource-limited situations and countries.

Design Specifications

NovaVent will operate only in the Continuous Mandatory Ventilation (CMV) mode. The principal variable to be controlled is tidal volume (V). The following parameters can be set using a control panel.

- Inspiration/Expiration (I/E) Ratios selectable: presets 1:1, 1:2, 1:3
- Respiratory rate: from 10 to 30 breaths per minute in steps of 2
- Tidal volume: 250-800 (50 ml increments); error tolerance of 10%
- Inspiratory pressure limit: 15-40 cmH_2O in steps of 5

Although NovaVent cannot directly set the following, it will integrate with standard clinical set-ups where it would be possible to set them.

- PEEP: 5-20 in no more than 5 cm steps
- FiO_2 over the range of 21% (ambient) to 95% (or 90%?) of the source oxygen concentration input to the EUV in no more than 10% steps

Display

The following items are shown in the displays.

- The current settings (inspiratory pressure, tidal volume, frequency). PEEP and FiO_2 settings are not shown, but are available through inspection. PEEP.
- The ventilation mode is always Continuous Mandatory Ventilation (CMV) and is displayed on a sticker.
- The current delivery (inspiratory pressure, tidal volume, respiratory rate). PEEP and FiO_2 at the patient-connection port are not shown, but are available through inspection.
- Flow rate vs. volume graph on an 8x8 LED array.

Alarms

NovaVent provides ventilation at the patient-connection port within the alarm limits set by the operator or inform the operator via an alarm condition that ventilation within the alarm limits is not occurring. Alarm notifications are a combination of sounds and lights. Such alarm conditions include the following.

- Ventilator not delivering because of gas or electricity supply failure or if the ventilator is switched off, or if there is a loose or broken connection.
- Inspiratory airway pressure exceeded.
- Inspiratory pressure not achieved (equivalent to disconnection alarm condition).
- Tidal volume not achieved or exceeded.

NovaVent Team

The NovaVent team consists of a sizeable number of enthusiastic volunteers who have been selflessly donating their time and expertise to the project since April 1st. While it is always challenging to work in a highly interdisciplinary group, it is especially so now under the present circumstances of restricted movements. It is astonishing that most of them did not know each other before the project; they have nonetheless come together to contribute to this worthwhile project. This has meant a lot of hard work for people who are already very busy in their regular line of work. For instance, we met every day including weekends (Easter Sunday was an exception!). The resulting accomplishment of researching, designing and fabricating a complex, real, working device in such a short time illustrates the unstinting dedication of this team.

The following is a rough outline of the tasks we had to accomplish to make NovaVent a reality, with the primary drivers for each task listed by their initials. It should however be noted that, through daily meetings and emails, everybody had the opportunity to interact with everybody else. In fact, almost everybody had inputs to every task at some point or another. The end product hence represents the *collective* expertise and hard work from a lot of motivated people.

Engineering

- Mechanical and fluid system design (AO, CT)
- Sensor integration, electronics and control algorithms (GC, CN)
- CAD and Fabrication (CT, ZN); with help from Southco, TDI Tek and ExOne

- Testing & Validation (GC, CN, AO); with help from Children's Hospital of Philadelphia (TK) and Emergency Care Research Institute (ECRI)
- Modeling and simulation (FF, KS, GFJ)

Medical (MP, EH, LH, SD)

- Treatment issues
- Operational issues
- FDA

User interface

- Usability (PT, EH)
- Alarms (PA, PT, MP)

Safety

- Hazard operability analysis (FN, FF)
- Safety shut offs (PA, GC)
- Failure analysis of AMBU bag (SS)

Project management

- Lead and coordination (CN)
- Funding (CN, AO, GC, KA, CR)
- Legal issues (CN, KA)
- FDA EUA application (All)
- Reports and Documentation (All)

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