Testing Questions

Here is a list of quick questions that medical providers should answer prior to initiating testing at their institution of the **4 way ventilator splitter** created by Helpful Engineering.

Regarding **testing**:

- What is your goal in testing the splitter?
- External testing
 - Does all testing have to be done by an internal team? If the answer is no:
 - Can an external, large hospital system vet the system?
 - Can a small clinic vet the system?
 - What kind of quality control documentation will you require if not done in-house?
- In-house testing
 - What kind of quality control and documentation will you execute in-house?
 - Do you have the capacity to take photographs or videos to illustrate test results?
 - Are you willing to share your quality control documentation back with the project?
- Liability
 - What kind of liability coverage are you expecting?
 - Do you need Internal Review Board reviews?

Regarding manufacturing the splitter:

- Do all parts have to be built through your institution's printers/equipment? <u>If the</u> answer is no:
 - Will you accept parts from other printers?
 - What kind of quality control will you use for those externally sourced parts?
- What sterilization method will be applied to the splitter at the hospital? (UV, bleach or submersion, autoclaving, etc.)
- What sterilization method do you require manufacturers implement prior to shipping to the hospital?
- Do you plan to reuse any parts of the splitter design?

(<u>Optional</u>) These are some questions for Helpful Engineering to better understand hospital needs regarding ventilation:

- How long will a patient use the device?
- How are you expecting to determine each patient's expiratory and inspiratory volumes? Is displaying information in an analog system sufficient, or do you require some form of digital display?
- How are you expecting to adjust FiO2?
- How are you expecting to sanitize the expired air?
- How are you expecting to humidify the inspiratory air?
- How are you planning to handle line kinks, or is this not a serious concern?