MIT Emergency Ventilator (E-Vent) Project

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1 Title: MIT Emergency Ventilator (E-Vent) Project

1.0.1 Reference:

All the info compiled here can be found in this link

1.1 Background & Need

We are one of several teams who recognized the challenges faced by Italian physicians, and are working to find a solution to the anticipated global lack of ventilators. In the US alone, the COVID-19 pandemic may cause ventilator shortages on the order of 300,000-700,000 units (CDC Pandemic Response Plans). These could present on a national scale within weeks, and are already being felt in certain areas. An increase in conventional ventilator production is very likely to fall short and with significant associated cost (paywall warning).

Almost every bed in a hospital has a manual resuscitator (Ambu-Bag) nearby, available in the event of a rapid response or code where healthcare workers maintain oxygenation by squeezing the bag. Automating this appears to be the simplest strategy that satisfies the need for low-cost mechanical ventilation, with the ability to be rapidly manufactured in large quantities. However, doing this safely is not trivial.

Use of a bag-valve mask (BVM) in emergency situations is not a new concept. A portable ventilator utilizing an ambu-bag was introduced in 2010 by a student team in the MIT class 2.75 Medical Device Design (original paper here and news story here), but did not move past the prototype stage. Around the same time, a team from Stanford developed a lower-cost ventilator for emergency stockpiles and the developing world. It looks similar to a modern ICU ventilator (Onebreath), but "production for US hospitals would start [in] about 11 months", making it "a second wave solution" (MIT Tech Review Article). Last year, the AMBU® Bag concept was re-visited by two student teams, one from Rice university (here & here), and another Boston-based team who won MIT Sloan's Healthcare prize (MIT News: Umbilizer). Other teams currently working on this challenge can be found linked on our "Additional Resources" page.

1.2 Key Research Question

We have launched an emergency research project with a team of MIT Engineers and American clinicians to address the question:

Is it possible to safely ventilate a COVID-19 patient by automatically actuating a manual resuscitator?

Our process in approaching this question is to first identify the minimum requirements for a low-cost ventilator, based on the collective wisdom of many clinicians, design against these requirements, conduct immediate testing, report the results, iterate and facilitate discussion.

Manual ventilation with an Ambu-bag is a short-term solution in a critical care environment, without any apparent clinical evidence regarding the safety of long-term use (days-weeks). There are multiple scenarios in which respiratory support could be needed: patients can be awake or asleep, sedated or sedated and paralyzed, breathing spontaneously, weaning off of a vent, etc. Furthermore, changing clinical presentations with ARDS require shifting minute ventilation (tidal volume x respiratory rate) to "lung-protective" strategies, which place patient's at risk for things like auto-PEEP. Some of these situations are simpler than others, with the simplest being ventilating a sedated, paralyzed patient, and at a minimum a safe emergency ventilator could be used in such a situation to free-up a conventional ventilator.

Any solution should be utilized only in a healthcare setting with direct monitoring by a clinical professional. While it cannot replace an FDA-approved ICU ventilator, in terms of functionality, flexibility, and clinical

efficacy, the MIT E-Vent is anticipated to have utility in helping free up existing supply or in life-or-death situations when there is no other option.

Further, any low-cost ventilator system must take great care regarding providing clinicians with the ability to closely control and monitor tidal volume, inspiratory pressure, bpm, and I/E ratio, and be able to provide additional support in the form of PEEP, PIP monitoring, filtration, and adaptation to individual patient parameters. We recognize, and would like to highlight for anyone seeking to manufacture a low-cost emergency ventilator, that failing to properly consider these factors can result in serious long-term injury or death.

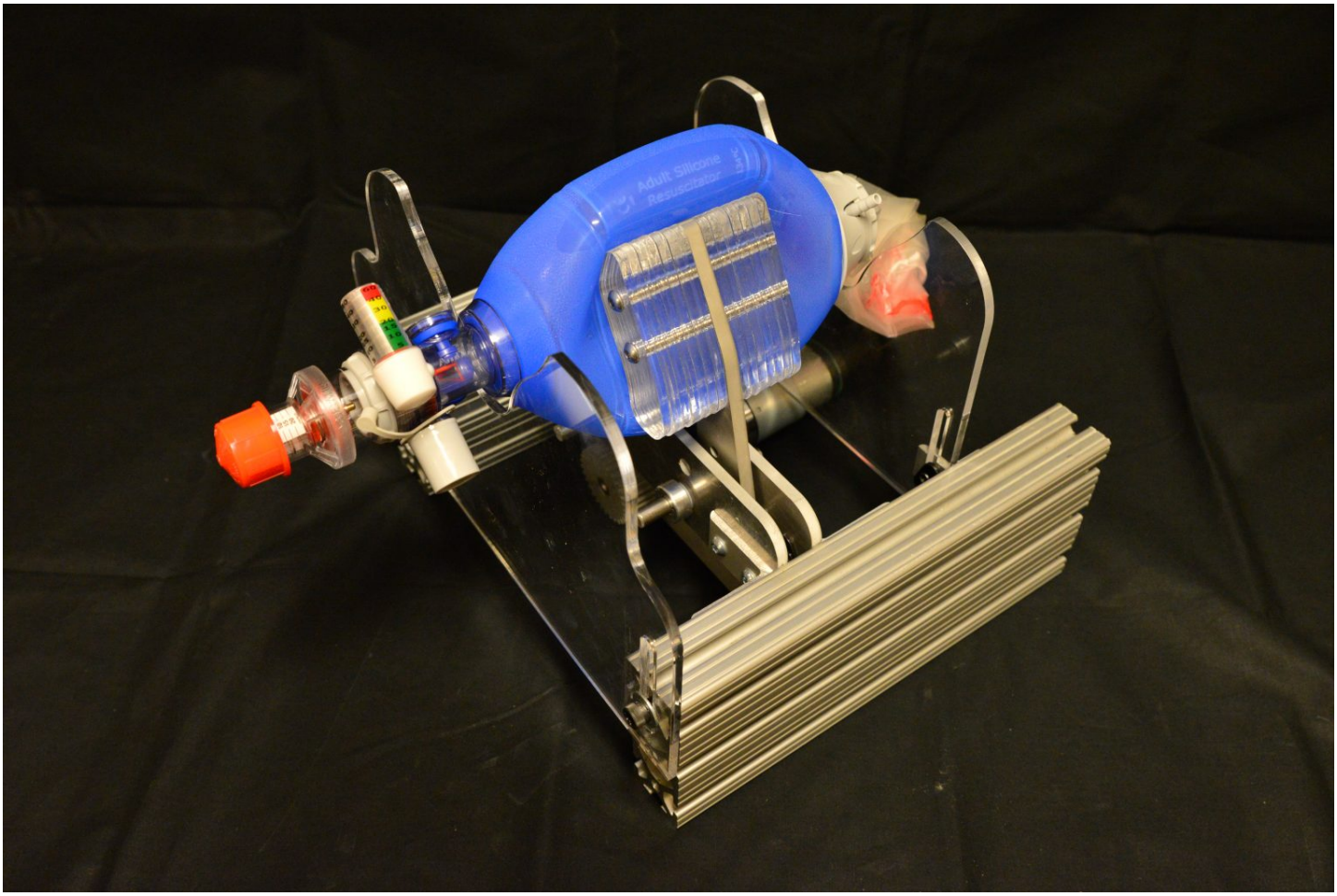


Figure 1: MIT E-vent Unit 002 setup

1.3 Open Source Design

At the present time, we are producing four sets of material, which we will be releasing and updating on this site in an open-source fashion:

1. Minimum safe ventilator functionality based on clinical guidance
2. Reference hardware design for meeting minimum clinical requirements
3. Reference control strategies and electronics designs and supporting insights
4. Results from testing in animal models

We are releasing this material with the intent to provide those with the ability to make or manufacture ventilators, the tools needed to do so in a manner that seeks to ensure patient safety. Clinicians viewing this site can provide input and expertise and report on their efforts to help their patients.

As with any research to design to scale-up to manufacture, we anticipated that there will be many problems and it is our goal to provide this site as a tool to "close the loop" and receive feedback. We will also do our best to publish the most relevant pieces of information in the discussion forum for all to see.

We invite anyone who is interested to follow this work.

2 Key Ventilation Specifications

From the Clinical Guidance this document summarizes the minimum set of requirements for ventilation:

1. Patients must be under the management of a trained clinician.
2. The minimum controllable parameters in order to ventilate a patient include:
   - BPM (breaths per minute): between 8 – 30 BPM
   - Tidal Volume (air volume pushed into lung): between 200 – 800 mL based on patient weight
   - I/E Ratio (inspiratory/expiration time ratio): recommended to start around 1:2; best if adjustable between range of 1:1 – 1:4[1]
   - Assist Detection pressure. When a patient tries to inspire, they can cause a dip on teh order of 1 – 5 cm H2O, with respect to PEEP pressure (not necessarily = atmospheric).
3. Airway pressure must be monitored
   - Maximum pressure should be limited to 40 cm H2O at any time; Plateau pressure should be limited to max 30 cm H2O
   - The use of a passive mechanical blow-off valve fixed at 40 cm H2O is strongly recommended
   - Clinician require readings of plateau pressure and PEEP (refer to clinical documentation tab)
   - PEEP of 5-15 cm H2O required; many patients need 10-15 cmH_2O
4. Failure conditions must permit conversion to manual clinician override, i.e. if automatic ventilation fails, the conversion to immediate ventilation must be immediate.
5. Ventilation on room air is better than no ventilation at all. Blending of oxygen and air gas mixture to adjust FiO2 is not important in an emergency scenario. It is certainly nice to have that ability and can easily be implemented with a oxygen / air gas blender that some hospitals already have.
6. Covid-19 can get aerosolized (airborne), so HEPA filtration on the patient's exhalation is required or between the ventilator unit and the patient (at the end of the endotracheal tube) to protect clinical staff from certain infection. In-line HEPA filters can usually be purchased alongside manual resuscitator bags.
7. Heat and moisture exchanger should be used in line with the breathing circuit.
8. Failure conditions must result in an alarm.

This is a minimal requirement set for emergency use. Equipment designed for more regular use, even if for emerging markets, will require additional features to be used on a regular basis.

3 Mechanical design

How does the E-vent looks like?

See how the emergency ventilator works here

3.1 Files to download

Follow this link where there are all the .dxf files.

This section documents the mechanical design of the MIT E-Vent.

[1] Range determined based on several COVID-19 patients' ventilator settings reported from Boston area ICUs

Please understand that we are designing, testing and posting information as fast as we can. We have no hidden information and more detailed plans will post as soon as we draw them!

Note: Any mechanical design must meet the specifications outlined in the Getting started section.

This is a prototype. We are in process of testing and refining this concept design to increase robustness. The basic concept consists of two arms that gently close in sync to compress the bag. This must be coupled with a closed loop control system. Major mechanical design requirements included:

- Be nice to your bag and its hoses! Up to 2x7x24X60x30 = 604,800 cycles.
- Fail-Safe operation! If the machine fails, a clinician must be able to convert to manual bagging.
- Keep It Simple & Make It Super! Enable others to fabricate.
- Many drive motor possibilities! Enable multiple motors and configurations.

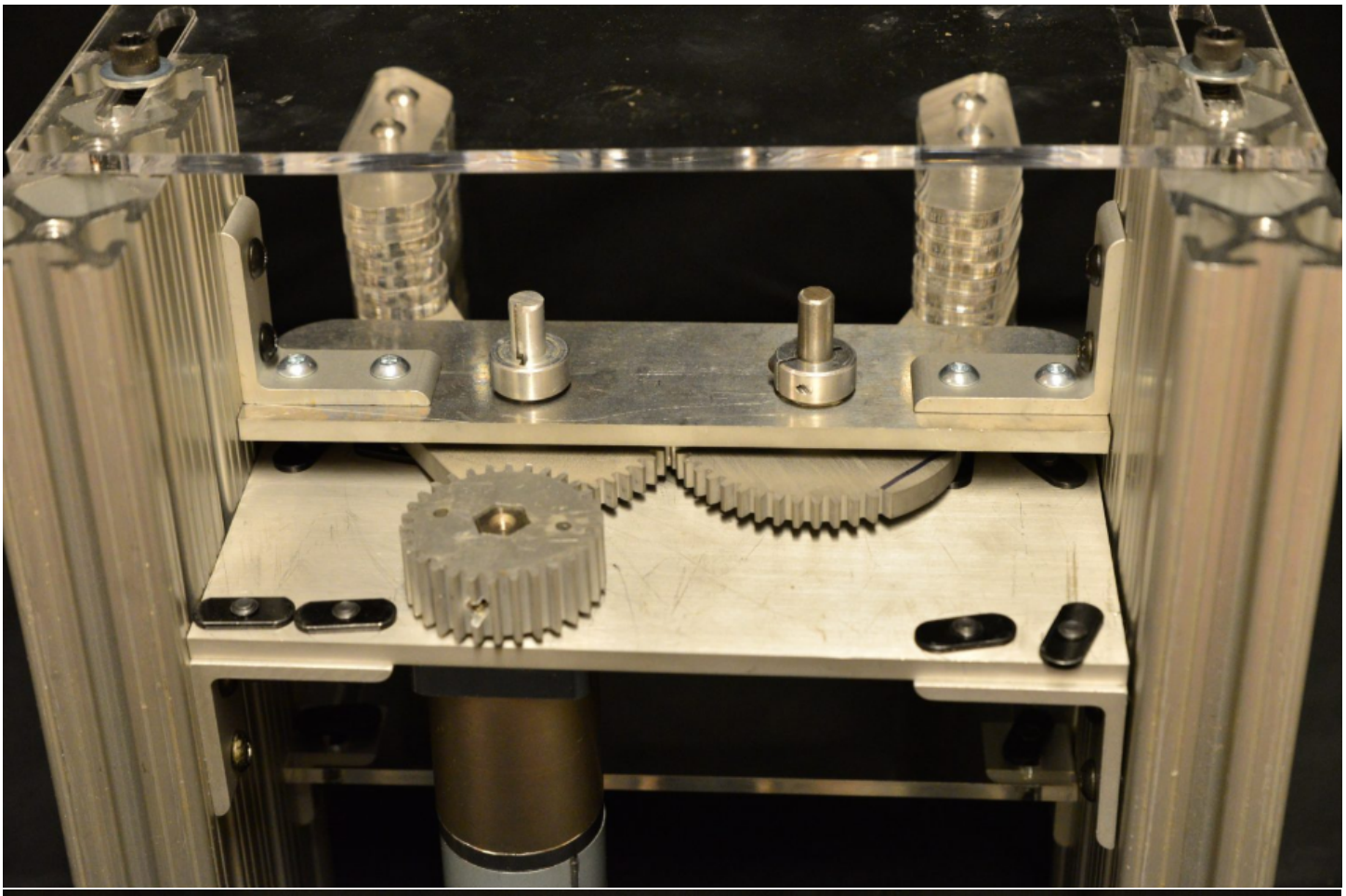
The Units version 002 shown here were developed to maximize flexibility during testing, so that the bag and motor position could be adjusted. None of this adjustability is needed once a particular bag is selected.

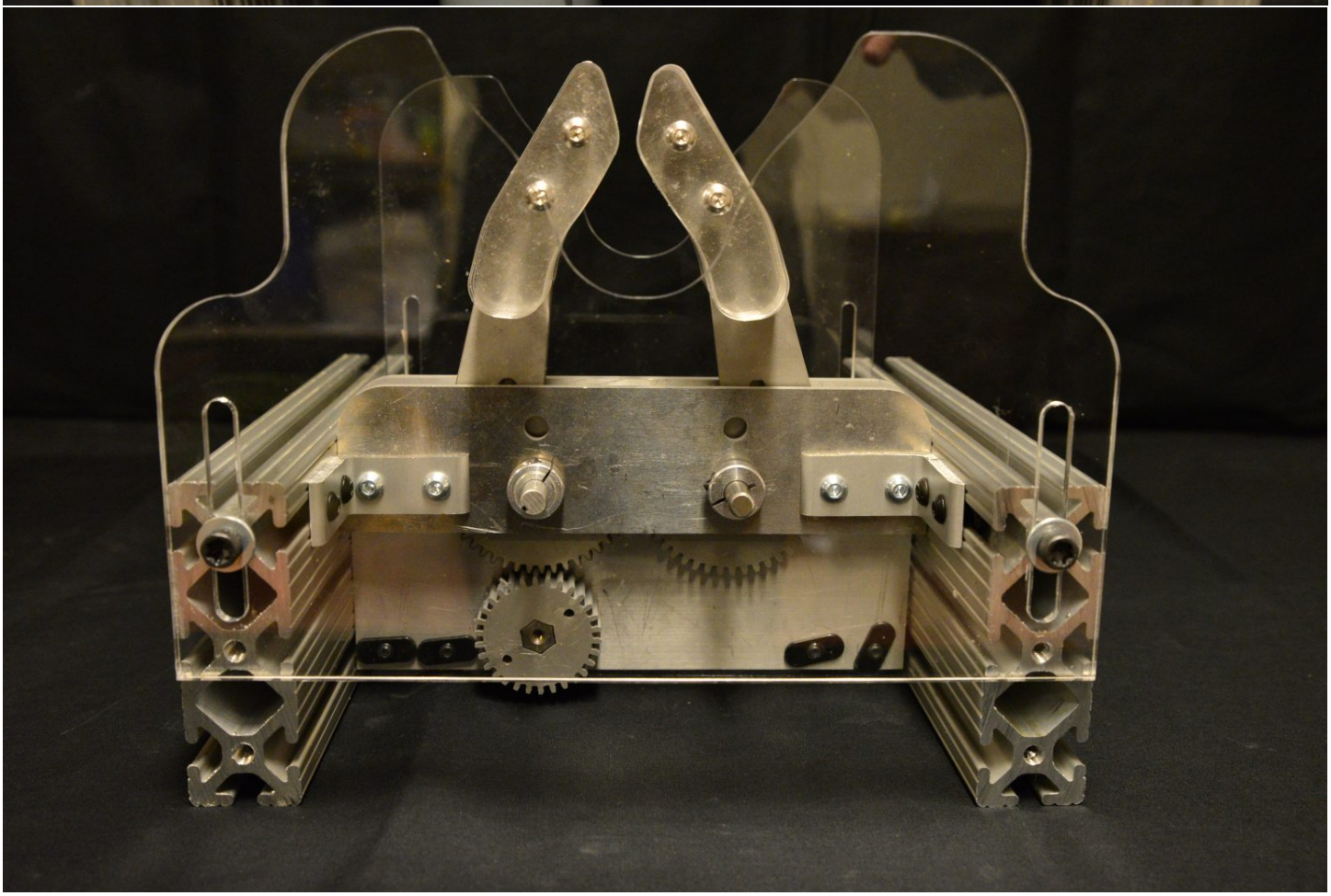
The basic dimensions are now set and any skilled mechanical designer will be able to execute this design and adjust it to suit locally available materials and fabrication technologies.

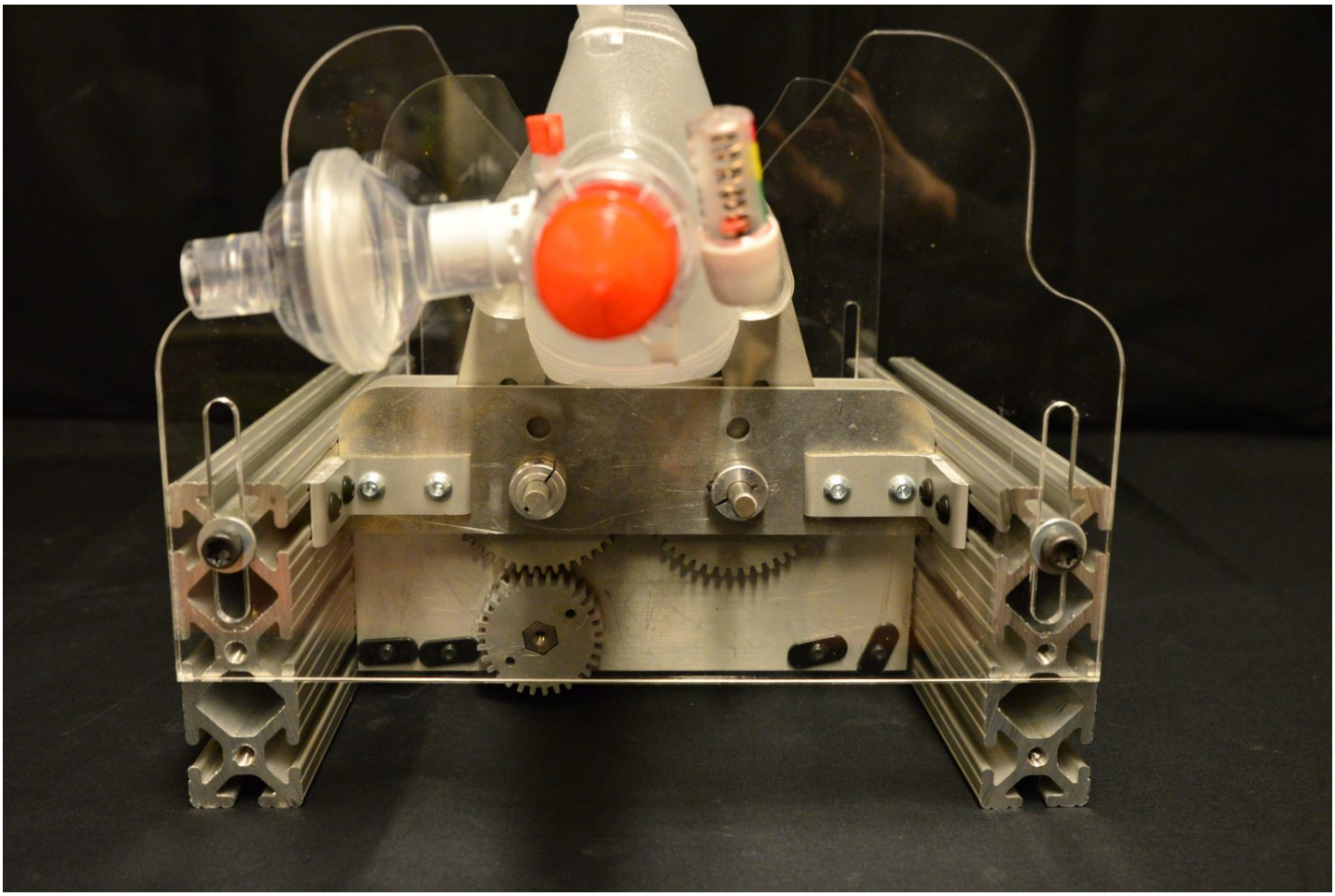
We have ready access to waterjet and laser cutters and 80/20 components, however these parts can be CNC milled and bolted and welded to your specification

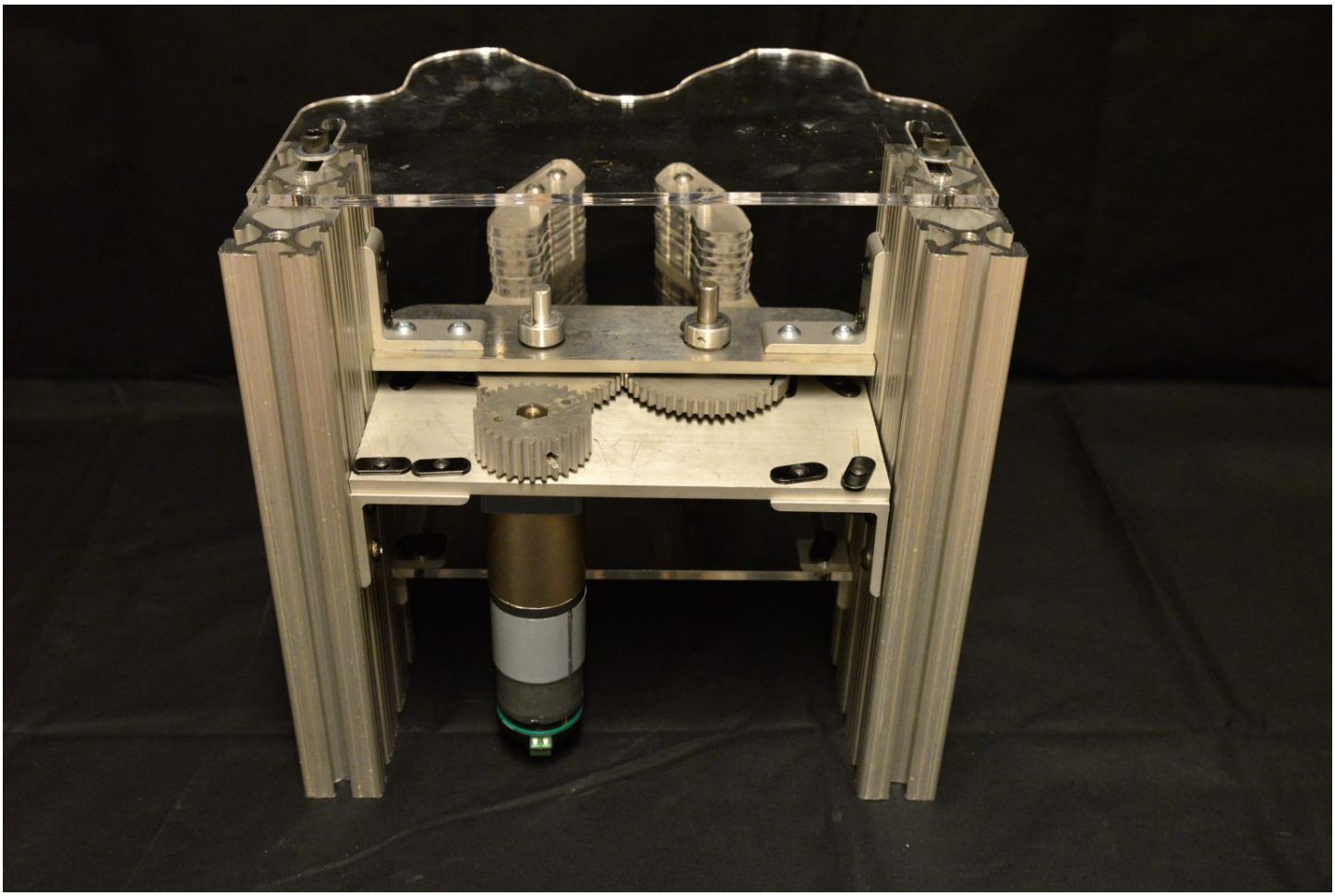
3.2 Documentation useful pictures

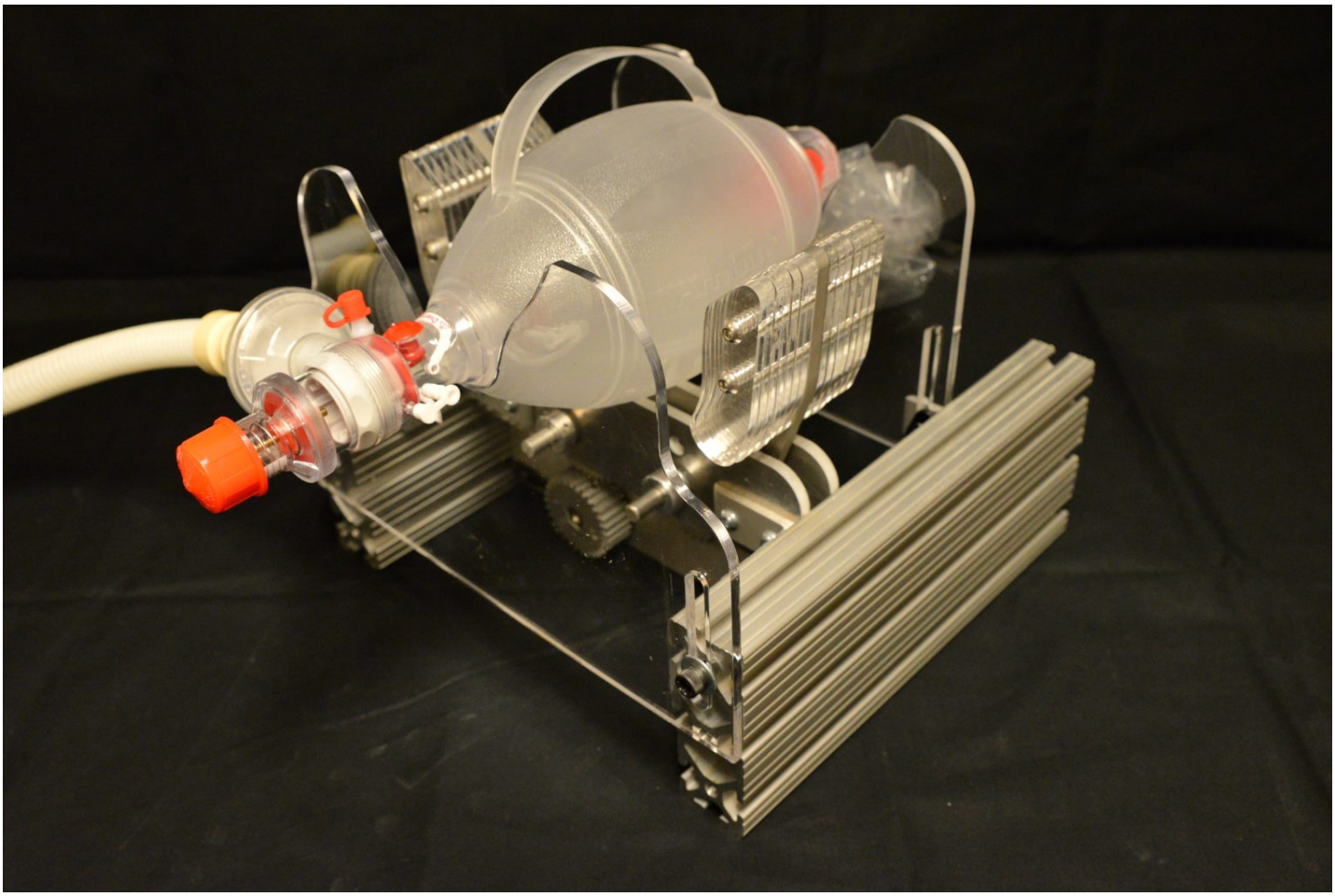
Caution: Forces and torques are much higher than expected when an Ambu bag is connected to a human respiratory system pressures can range up to 40 cm H2O and, potentially, even higher depending on breath rate. There must be a pressure release valve set at 40 cm H2O; without this higher pressures will risk permeant injury or death. Diseased lungs can have compliance on the order of 10x lower than that of healthy patients and this further compounds the problem.











3.2.1 Early design (Unit 001)

An early prototype unit is show below in laser cut acrylic. Unit 001 was similar and underwent testing. Unit 002 been fabricated with an 80/20 metal frame, to address durability and maximise flexibility during testing, is undergoing testing today.

The collection of pictures from early designs are found in this folder

4 Electrical Design

This section shows a description of the minimum hardware set required to control the ventilator as described in the other documentation.

4.1 Motor & Encoder

The mechanical system should be driven with a motor under closed loop control. For feedback measurement, we are using a quadrature encoder on the motor, and a potentiometer (POT) on the moving arms to measure the absolute angle.

4.1.1 Motor Options:

Brushed DC motor with gearbox and position feedback. Any sufficiently high-torque, back-driveable motor with angle sensing, integrated or separated, should work. Power is estimated at 36 W or greater, with a safety factor recommended.

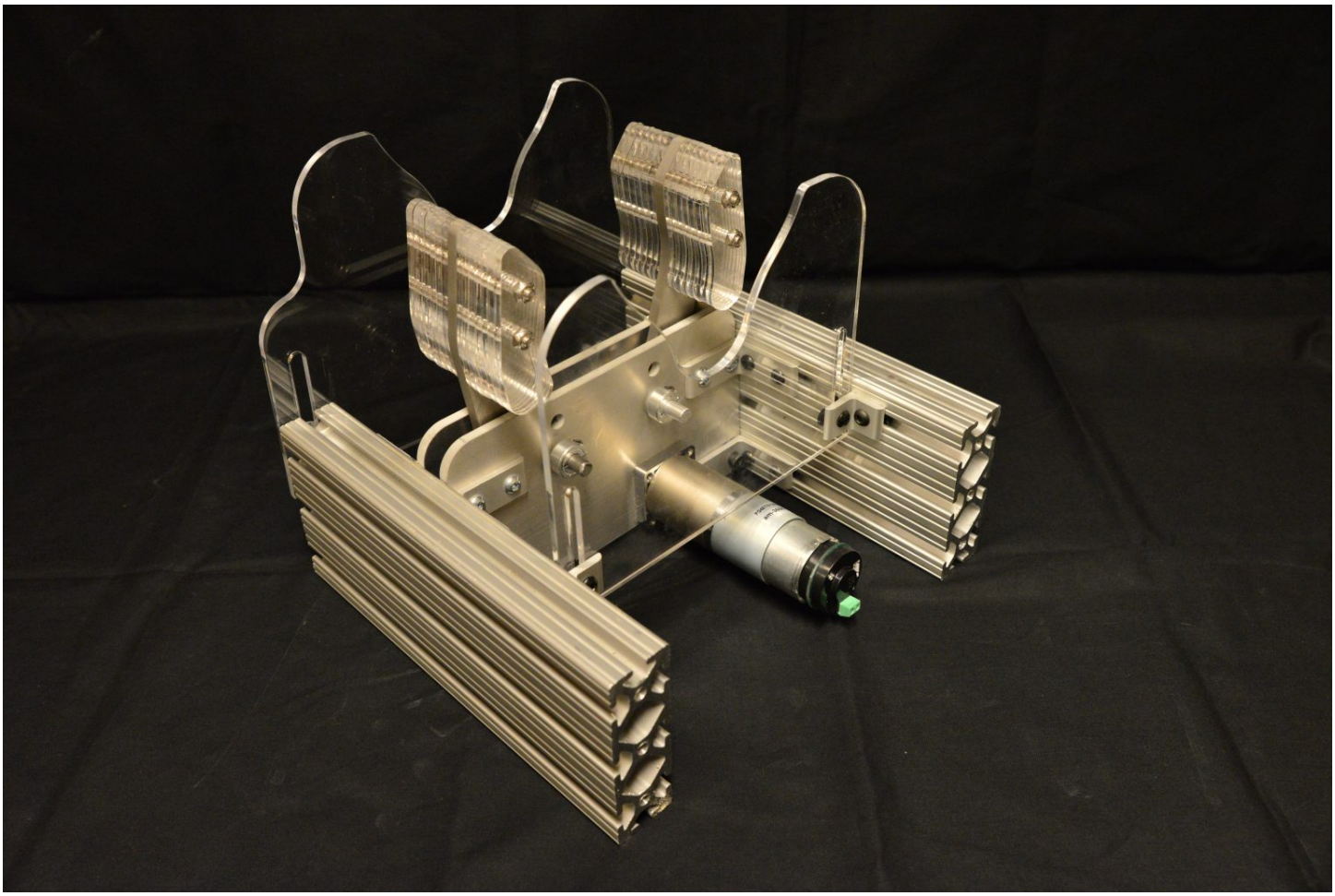


Figure 2: Plates to support the bag

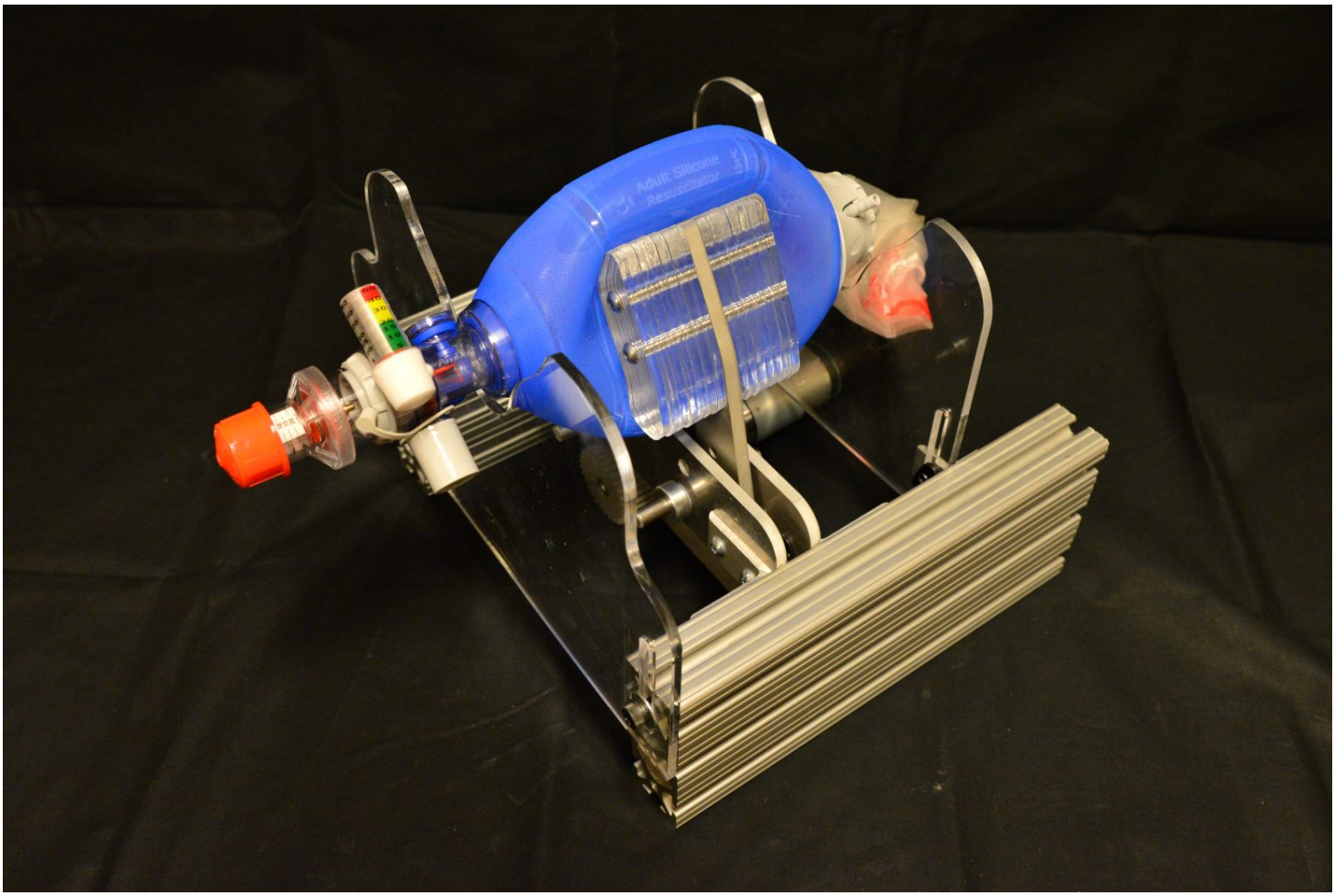


Figure 3: Unit 002-most updated design

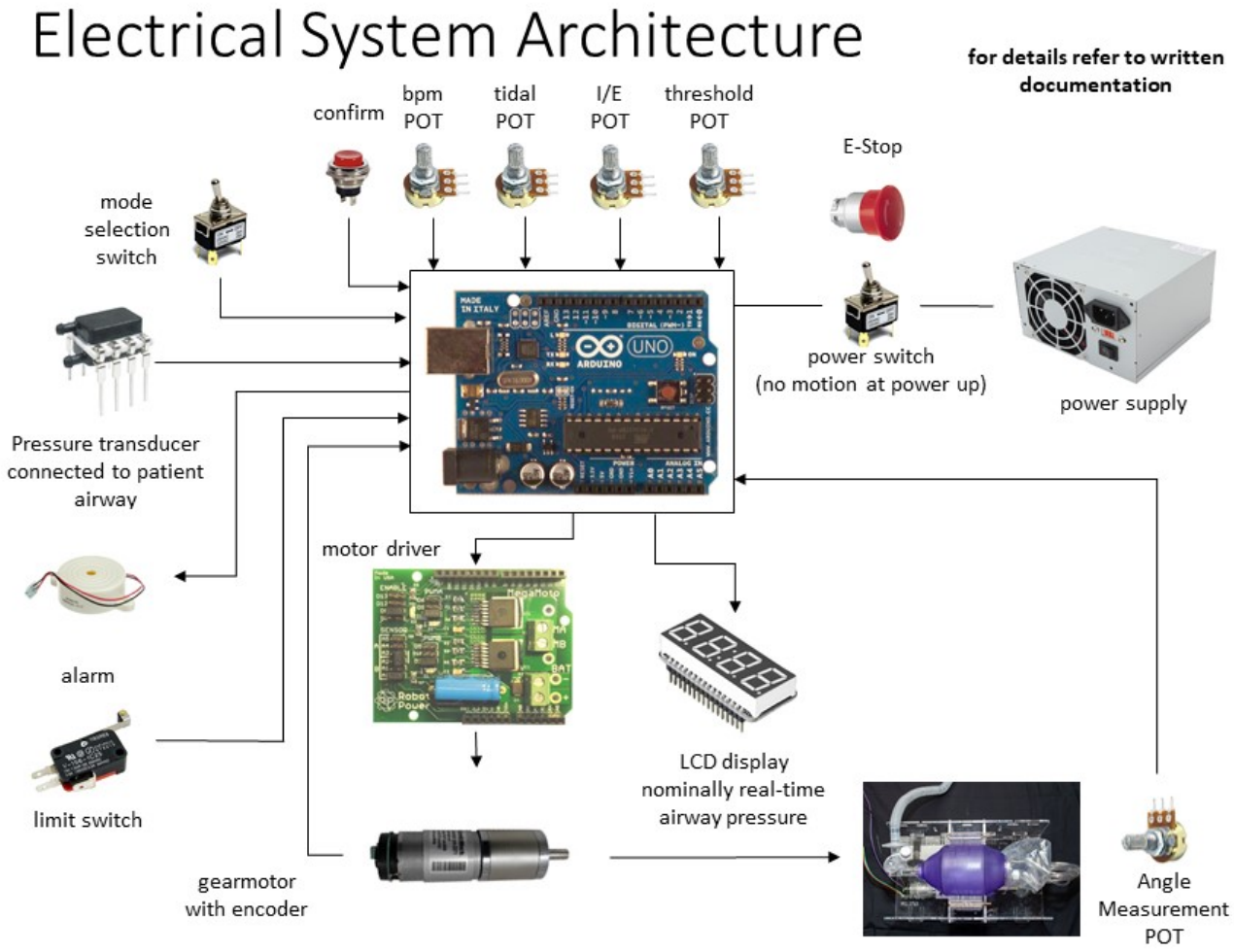


Figure 4: Electrical System Architecture

Caution: If a stepper motor is used, position should still be taken from the angle sensor so that missed steps do not cause position drift

Caution: The motor and mechanism, together, must be back drivable in order to move the mechanism by hand, remove the bag and immediately convert to manual bagging.

- Assumed nominal operating parameters: Referencing clinical documentation: max 25 breath-per-minute (bpm), and up to a 1:3 Inspiration: Expiration Ratio (I:E ratio) (ex: bag squeezed for 1 time units, bag relaxed for 3 time units). Note that COVID-19 patients may need greater I:E ratios.
- Prototype component: Andy Mark AM 2971 gearmotor.

Figure 5: Andy Mark AM 2971 gearmotor

This was scavenged from a FIRST Robotics kit, it is suitable for testing, **but has not been proved for safe longer-term use. Builders will need to source another motor.**

While the machine should be capable of operating continuously at max tidal volume and max bpm, in practice medical professionals often do not operate with large tidal volume and high bpm simultaneously. In normal operation, I:E ratios around 1:2 and 12 bpm are a decent central design point. Tidal volume as a function of position needs to be calibrated.

Caution: In deployed use, the motor must be able to operate continuously for several days, 100% duty cycle. This may require larger motors than expected or increased motor cooling to prevent overheating.

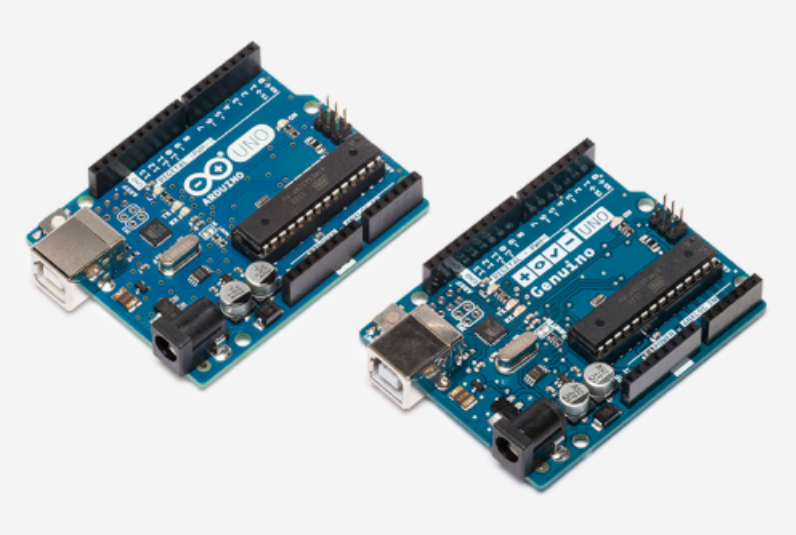
4.2 Power Supply

Nominally, a power supply that can deliver 12 V and 5 A is expected to work. Rapid deceleration of the motor causes supply-voltage spikes and must be avoided via correct motor motion profile design. Capacitors should be added across the H-Bridge power leads for extra protection.

An alternate power supply would be to use a car battery with a 5 A car battery charger connected. This will allow for very high instantaneous power draws and voltage spike absorption. The battery will double as a ~2-3 hour backup in case of building power loss.

4.3 Controller

Microcontroller for timing, measuring, and actuating: Arduino Uno – readily available and easy to program, with extensive online support and documentation. It provides 6 A/D pins (for potentiometers and pressure sensors) and 13 digital I/O pins, including dedicated hardware interrupts (for encoders) and PWM pins for H-bridge driving. Other industry validated controllers can be used, and we may implement them in the future.



4.4 Motor Driver

Use any motor driver with sufficient voltage and current ratings to meet the motor power specifications. Closed loop servo controllers can also be employed. Our control strategy is PWM with a H Bridge. For fastest implementation using cheap, off-the-shelf parts, we recommend an Arduino compatible motor shield.

For reference, we are using a RoboClaw Solo motor controller to control a brushed DC gear motor. The RoboClaw firmware uses a velocity PID controller and a position PID controller to command the motor to a desired position at a desired velocity. The PID values must be tuned in advance. Other motor controllers with similar functions will work, we do not recommend any specific controller.

4.5 Inputs

Control knob potentiometers (POTs) should all be single turn, 10 KΩ. Single turn is to allow for specific settings to be marked on the face plate.

Pressure sensor – Receives a voltage proportional to the pressure in the patient's lungs. Used to determine max pressure reached during inspiration, and to trigger when the patient is attempting to breathe in during assist mode. Pressure sensor selected should be differential (to sense negative pressures) with a range of up to 100 cm H_2O. This is a 2x safety factor. Our sensors are sourced from Honeywell.

Note on Plumbing: The pressure sensor must be connected to the Ambu bag's sensing port or somewhere in the airflow, as close as possible to the patient, past any valves.

POT 1 – Varies inspired volume, sets angular oscillation of the arms. During operation, each arm varies by a maximum of approximately 20 grades, corresponding to fully squeezing a large bag. This dial varies position from 0% (fully open) to 100% (fully compressed).

POT 2 – Varies the BPM. This sets the rate from 0 to the maximum BPM given in the clinical document.

POT 3 – Varies the I:E ratio. Range as given in the clinical document.

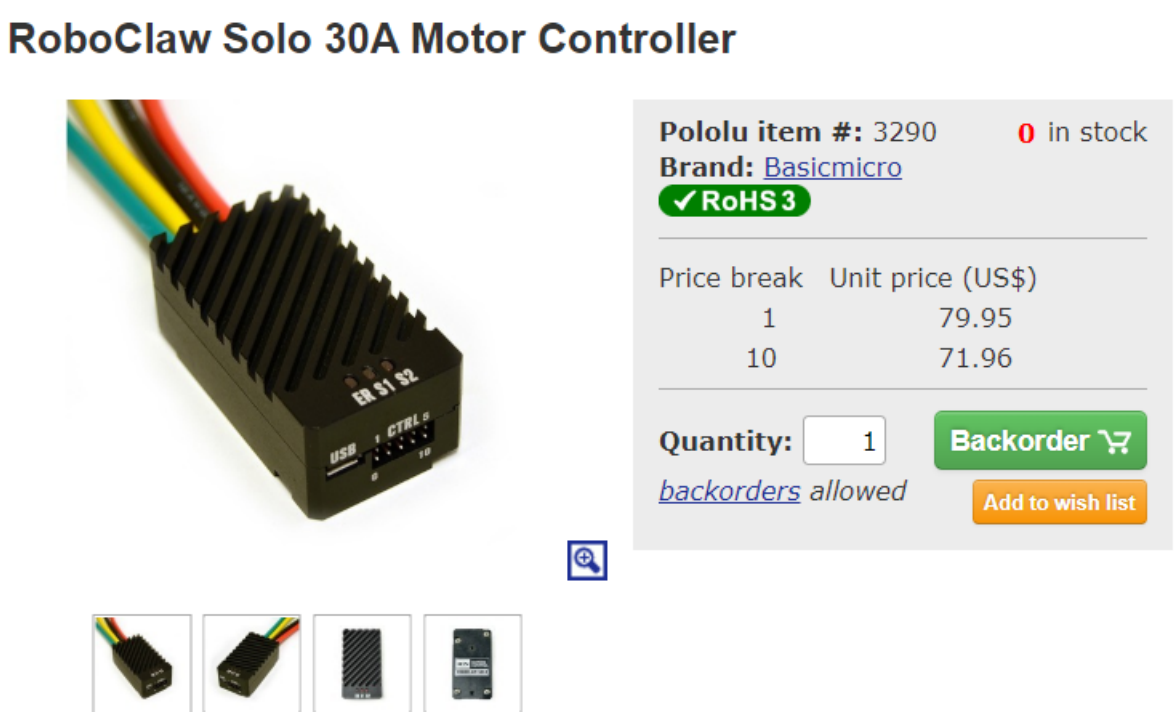


Figure 6: RoboClaw Solo motor controller

Note: It is not essential that this be settable, one value greater than 1:1 can be selected and the POT repurposed as a threshold for over pressure. (Multiple clinicians have indicated that varying I:E is not critical.)

POT 4– Sets the pressure threshold for detecting assist control. This varies as described in the clinical document.

Pushbutton Switch – Confirms user selection of new POT setting. This is an important safety.

Switch – Power on / off

E-stop – Instantly deactivates the system.

Switch – Mode selection from volume to assist control.

Limit Switch – Used for homing the arms positions.

4.6 Output

LCD screen displays airway pressure in cm H2O. Other functions can be incorporated later. We are using a 20×4 character LCD display as this will display the minimum information, described in under interface. Any display better than this will be sufficient.

4.7 Audible alert buzzer will identify multiple fault conditions.

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5 Testing results

They are working with certified animal testing labs to conduct studies in animal models under IACUC-Institutional Animal Care and Use Committee approved protocols. A porcine model was chosen as pigs have a respiratory systems that is most similar to human beings. **This is essential in order to evaluate system performance and safety. We would like to anonymously acknowledge the laboratory staff for their tireless efforts, and the donors who are enabling this rapid scale-up of animal testing.**

5.1 Study 1 – 20 March 2020

Porcine study Nr 1 was conducted at a leading research facility in the Boston area. In addition to the facility staff (veterinarians, technologists, and Study), our on-site team consisted of Emergency Medicine and Anesthesia physicians working along side mechanical design, manufacturing, controls, and electrical engineers. The goals of this study were as follows:

- Conduct a functional test of the prototype MIT E-Vent Unit 001.
- Compare ventilation with the E-Vnet to that of a Puritan Bennet 840 Ventilator system (2016 model year, Medtronic) graciously loaned to us.

5.1.1 Key Learnings (more results will be forthcoming)

- We identifies deficiencies in the all-laser cut design. We have already transitioned to a metal frame design.
- We more accurately defined key parameters related to power requirements for a drive system.
- We investigated potential control strategies and identified key UI/UX requirements as well as human factors.
- We determined key pressures when connected to a real lung and with PEEP set.

5.1.2 Next Steps

The next study will conduct a functional test Unit 002 in a similar porcine model.