The Baxter Ventilator

Final Report for CoVent-19 Challenge

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Abstract

The Baxter Ventilator was designed specifically to address a shortage of ventilators during a pandemic. During pandemic conditions, mass production and supply chains for ventilators may be disrupted, and surges in demand for medical device components and market failures may limit availability. The Baxter Ventilator was therefore designed to be built using commonly available parts and by individuals with limited skills in remote locations. Following IKEA-style assembly instructions and videos, an individual will be able to assemble the ventilator in four to eight hours, using only a few basic hand tools. These simple but robust ventilators can be individually built for around $2,500 at retail prices including the cost of a 3D printer, with possible production models costing between $500 and $1,000.

The Baxter Ventilator is well suited for use in both modern hospitals and emergency field settings. Because it creates its own pressure, the Baxter Ventilator does not require pressurized air or oxygen. The only requirement for operation is a power outlet, and if desired oxygen tanks are easily mounted. If power is disrupted the Baxter Ventilator can run on backup power for over 90 minutes. All control and operational power is supplied at low, non-hazardous voltages.

Baxter Ventilator current prototype

The Baxter Ventilator can provide both controlled and assisted ventilation. In controlled mode the operator can specify volume controlled continuous mandatory ventilation (VC-CMV) or pressure controlled continuous mandatory ventilation (PC-CMV). In assisted mode, the operator can set up pressure-support ventilation (PSV) or volume-support ventilation (VSV) and can choose synchronized intermittent-mandatory ventilation (SIMV).

The design of this ventilator is based on a large pneumatic cylinder driven by a motor via a belt and pulley system. The ventilator's control software synthesizes sensor measurements and inputs from the user into a schedule that determines piston location and speed, providing the patient with the desired rate and volume of air. The control software is built on Python subroutines that communicate with a graphical user interface (touch screen) through an inter-process communication framework provided by the ZeroMQ library. Positive end expiratory

pressure (PEEP), peak inspiratory pressure (PIP), and fraction of inspired oxygen (FiO2), are controlled manually, but monitored by the software. The Baxter Ventilator features numerous mechanical and software redundancies and alarms to ensure safe operation.

The current prototype was evaluated on both a Gaumard HAL S3201 patient simulator, and on a QuickLung and monitored by ADInstruments' PowerLab DAQ. The prototype met the target criteria and produced results similar to industry-standard ventilators, across a range of settings and various ventilation modes. More importantly, the Baxter Ventilator proved to be very repeatable, creating almost identical breaths during ventilation at all settings. Additionally, the Baxter Ventilator was easily tuned to produce different ventilation output by adjusting the motor profiles. Repeatability and tunability allow the Baxter Ventilator to be configured to meet the needs of clinicians.

Ventilator Capabilities

Ventilation Rate (BPM)	8-30	Software limited
Flow Rate	0-60L/m	Software limited
PEEP pressure	0-20cm of H2O	Mechanical limited
PIP (max pressure)	60 cm of H2O, but can be adjusted	Mechanical and Software limited
I:E ratio	1:1 to 1:4	Software limited
Tidal Volume	0-700cc	Software limited
Oxygen available (FiO2)	21-100% Adjustable Range	Mechanical adjustment, software monitored
Run time on battery backup	>1 hour 30 minutes	

Ventilator Features

Flexibility
The Baxter Ventilator can be operated in a range of environments. Because it generates its own pressure, the Baxter Ventilator does not require pressurized oxygen or air. An oxygen tank mount that can accommodate A-D sized tanks makes it practical for use in field hospitals, as well as modern hospitals with an oxygen supply. If power is interrupted, the Baxter Ventilator can operate for over an hour and half on its own backup batteries. Riding on lockable caster wheels, it can be moved easily and has the footprint of an IV stand.

Additionally, the modular design allows for component adaptation. In the COVID-19 pandemic supply disruptions may make it difficult to obtain medical components. The Baxter Ventilator design can easily be modified based on available components. For example, during construction of the prototype PEEP valves were not available so the Baxter Ventilator used its backup PEEP manometer. When the $170 low pressure regulator was delayed in shipping, a $25 scuba regulator was easily mounted to the frame to fill in its place. An industrial flow meter was swapped in when there was a shortage of medical flowmeters. Other than the fittings that

interface with standard medical equipment, there is only one medical component on the ventilator - the oxygen sensor - and it is not critical to the ventilator's operation. This ability to easily replace components allows the Baxter Ventilator to maintain a robust capability in the event of supply chain distributions.

Tunability

Testing of the Baxter Ventilator has shown it to be very repeatable in the volume and pressure it delivers. No members of the Baxter Ventilator team are experts in respiratory therapy, so it is difficult for the team to determine the optimal profiles for the pressure and flow curves. However, the Baxter Ventilator can easily adjust pressure and flow by tuning the motor control to deliver the desired profile for tidal flow, I:E ratio and respiratory rate. More on tuning the Baxter Ventilator can be found in the Testing Section. Having a ventilator that is very precise and highly tunable allows for development of optimal profiles to meet the needs of clinicians.

Safety

The Baxter Ventilator was designed around safety being paramount. There are a number of redundancies built into the ventilator to keep patients safe. High pressure gas must go through two regulators. Pressure regulation and FiO2 are manually controlled with hardware, rather than software controlled. However, FiO2 and pressure are monitored by sensors, creating redundancies in pressure and FiO2 delivery. If there is a discrepancy between the manual pressure or FiO2 settings and software monitored settings, alarms will be triggered. The Baxter Ventilator only has one control loop, which runs on the motor controller and is monitored by the microprocessor in positioning the cylinders' piston. This operation has triple redundancy, and a failure in this operation would only produce at most one breath, which would be vented. The Baxter Ventilator is also fitted with a suite of alarms monitoring all operations. More on the safety features can be found in the Safety Features section.

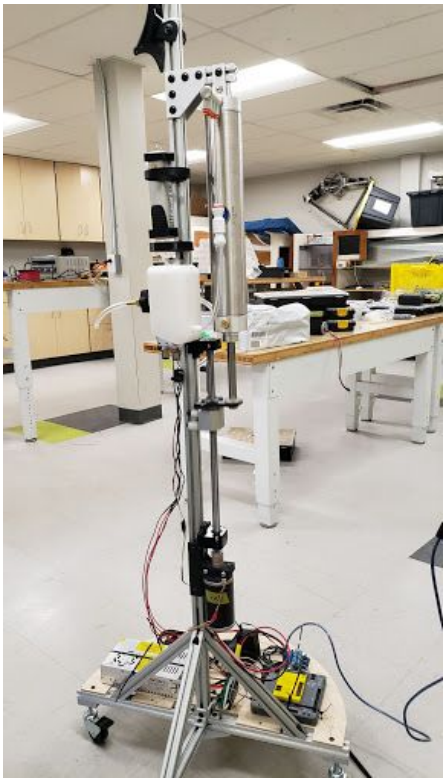
Kittable Construction

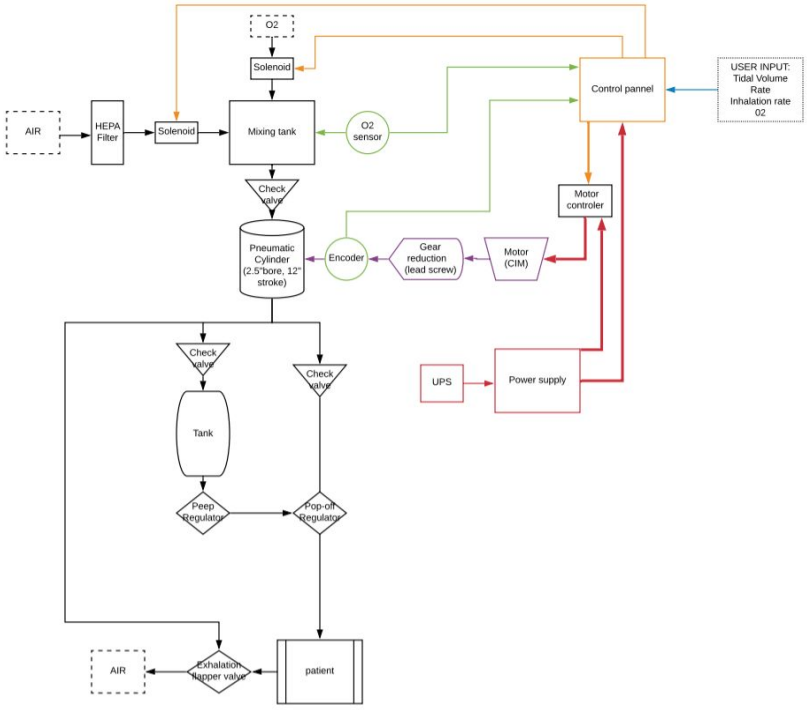
Making the Baxter Ventilator kittable was central to the project. In the early stages of the COVID-19 pandemic factories were closed, supply chains were limited, and field hospitals were being set up in cities. Producing a ventilator kit that could be widely distributed and easily assembled by individuals in remote locations without the need for skilled workers or specialized equipment was critical in order to reach patients where they were. Kits also allow for staged prototype development. While individual components of a kit cost more, kits have virtually no overhead or labor cost as compared to production runs. For initial testing phases, kits become a living design that can easily be modified, iterated, and refined to meet clinicians' needs without interrupting production. In fact, it is suggested, and noted in the BOM, that a 3D printer be included in the first wave of kits so that each ventilator can make modifications and upgrades as needed. Once the design is optimized to local conditions, it can move to lower cost mass production runs.

Design History

The Baxter Ventilator has been in development since March 19th 2020. While the design has gone through numerous iterations, the central means of ventilation has remained the same. The Baxter Ventilator utilizes a large industrial pneumatic cylinder to generate pressure and deliver air. This approach was chosen because it allows the ventilator to operate without pressurized gasses and is simple, robust, reliable, easily sourced, and inexpensive.

Baxter Ventilator Prototype 0.0

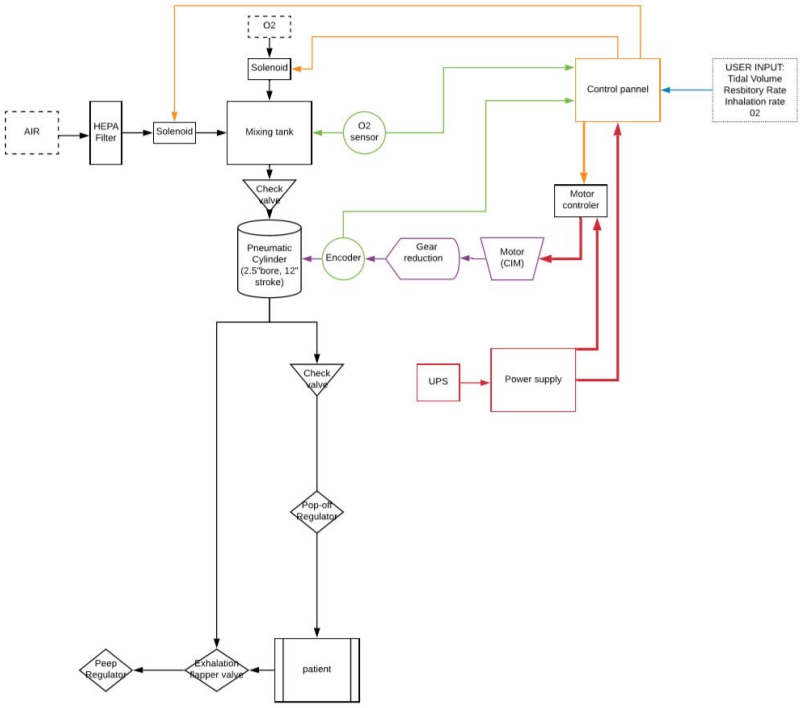




This first ventilator featured:

- A stand made of standard aluminum extrusion
- A large pneumatic cylinder
- A ball screw to drive the cylinder
- An industrial 12V DC motor
- A RoboRio controller and Talon SRX speed controller
- PEEP generated by a secondary air tank
- Numerous check valves and tubing
- A stand alone computer for operation
- Fixed Pop-off relief valve
- Could not regulate or monitor pressure
- Could only provide VC-CMV
- Could not control FiO2, but planned for use of solenoid valves

Baxter Ventilator Prototype 1.0



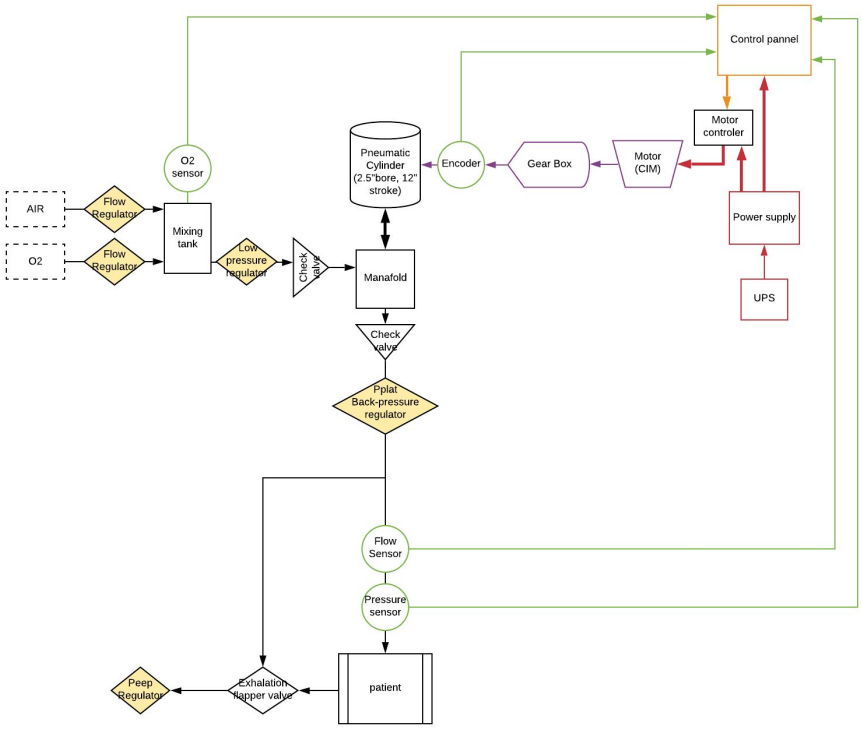
The second iteration of the ventilator made the following improvements:

- Replaced the ball screw with a belt drive. This greatly reduced noise and improved efficiency and reliability.
- Replaced the RoboRio and Talon SRX with a Raspberry Pi and RoboClaw Solo 30. This improved reliability and allowed for on-board control.
- Replaced the stand alone computer with a small touchscreen. This allowed for all controls to be on the ventilator.
- Created a manometer to regulate PEEP
- Added an stand alone pressure monitor
- Added a 425VA Uninterruptible Power Supply

However this device still had the following limitations:

- Numerous check valves and tubing
- Pop-off relief valve didn't have enough flow capacity
- Could only provide VC-CMV
- Could not control FiO2, but planned for use of solenoid valves

Baxter Ventilator Prototype 2.1 (Current Model)

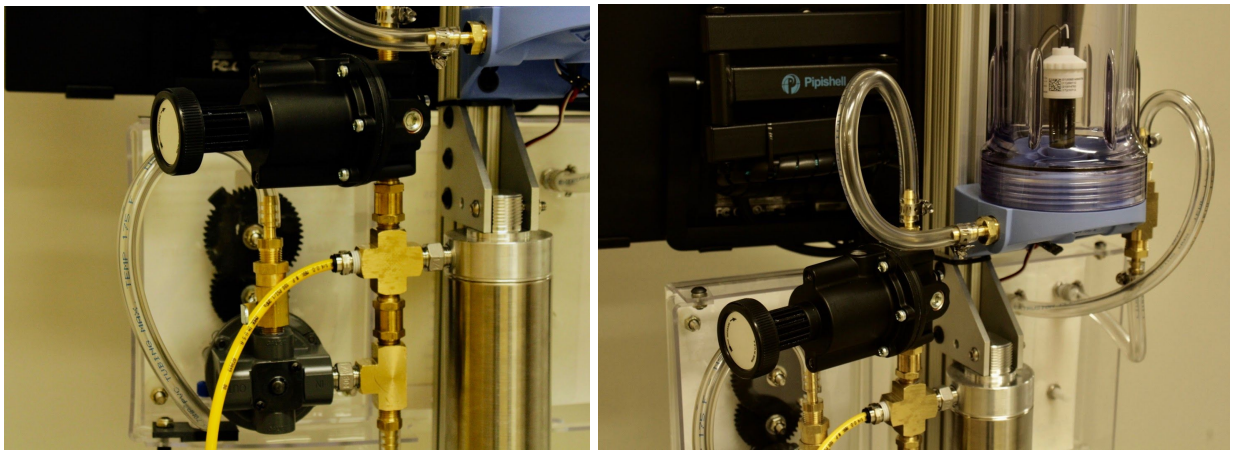


The current version of the ventilator made the following improvements:

- Replaces the small touchscreen with a large touch screen. This provides the operator with much better control.
- Regulates PEEP with either an Ambu PEEP valve or the manometer
- Integrates flow and pressure sensors to monitor machine output
- Uses manual control flow meters to control and monitor Air and O2 levels
- FiO2 has a large mixing tank monitored by O2 sensor
- Adds a low pressure regulator to reduce high pressure gasses
- Adds a manually adjusted back-pressure regulator to both control PIP and vent gas automatically in case of high pressure. Added gauge to read pressure setting and limits PIP to 60 cmH2O
- Adds a manifold assembly to reduce tubes and check valves.
- Increases the UPS capacity to 900VA
- Adds an O2 tank mount

- Adds a circuit attachment panel. All circuit attachments have different fittings so the operator cannot inadvertently connect the tubes to the wrong port.
- Adds a face plate with clear colors and instructions to control FiO2 and PIP.
- Packages all electronics in a self contained case.
- Adds additional limit switches to top and bottom of cylinder strokes to detect malfunction.
- Adds a guard to protect belt drive
- Improves frame robustness
- Adds Pressure and Flow graphs to the GUI
- Improves GUI usability
- Adds an option to attach a reservoir bag
- Adds alarm functions
- Adds an assisted mode for PSV, VSV, and SIMV operation

Baxter Ventilator Front, Rear, and Side Views



Baxter Ventilator Close-up Views Manifold and Mixing Chamber

Baxter Ventilator Close-up Mixing Chamber and Manual Control Panel

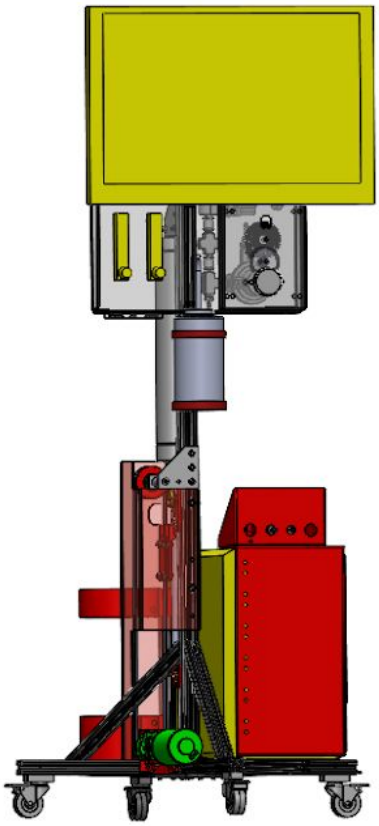
Bill of Materials and Cost

A complete Bill of Materials is provided in Appendix A. Note that all commercial off-the-shelf (COTS) component costs are listed at US retail prices.

The Baxter Ventilator was designed specifically to be shipped and assembled as a kit during a pandemic. Prototype 2.1 would cost around $2,500 (including the cost of a 3D printer) to reproduce using US retail prices for small quantities of available components. Buying components directly from the manufacturer would cut these prices by 40-50% or more. For example the $242 pneumatic cylinder used could be replaced with an equivalent cylinder from Aliexpress for $15.80, and aluminum extrusion purchased in bulk from suppliers would cost less than a quarter of the price sold at McMaster Carr. On Alibaba, 2020 extrusion stock can be purchased for $2.50 per meter, whereas it is sold by McMaster for $10.57 for 3 ft of equivalent material.

Prices could be reduced significantly further by moving to a welded frame. Switching from extrusion to a welded rectangular tube frame, removing the 3D printer, and replacing just four components: cylinder, touchscreen, gearbox, low pressure regulator, with generic replacement parts would save over $1,000, bringing the total price of materials below $1,500.

Additional design refinement, material sourcing, bulk purchasing, and injection molding would reduce the price further, making total material cost in the $500-$1,000 range easily attainable through value engineering.



Solidworks model Baxter Ventilator
Components organized by color:
Gray = McMaster Carr
Yellow = Amazon
Green = Vex
Red = Custom
Blue = Other

Assembly

The Baxter ventilator was designed specifically so that it could be used as a kit and sent anywhere in the world and assembled using only common hand tools. Assembly of the Baxter Ventilator can be completed by a single person in four to eight hours depending on experience with tools. The only tools needed for assembly are:

- Allen key set
- Two crescent wrenches
- Phillips head screwdriver
- Scissors or diagonal cutter

Assembly videos and parts diagrams were created to aid in assembly, and a detailed instruction manual is in the works. Complete assembly videos can be found in Appendix B. Assembly Part Diagrams for the manual can be found in Appendix C or the associated GrabCAD Solidworks files.

Operation

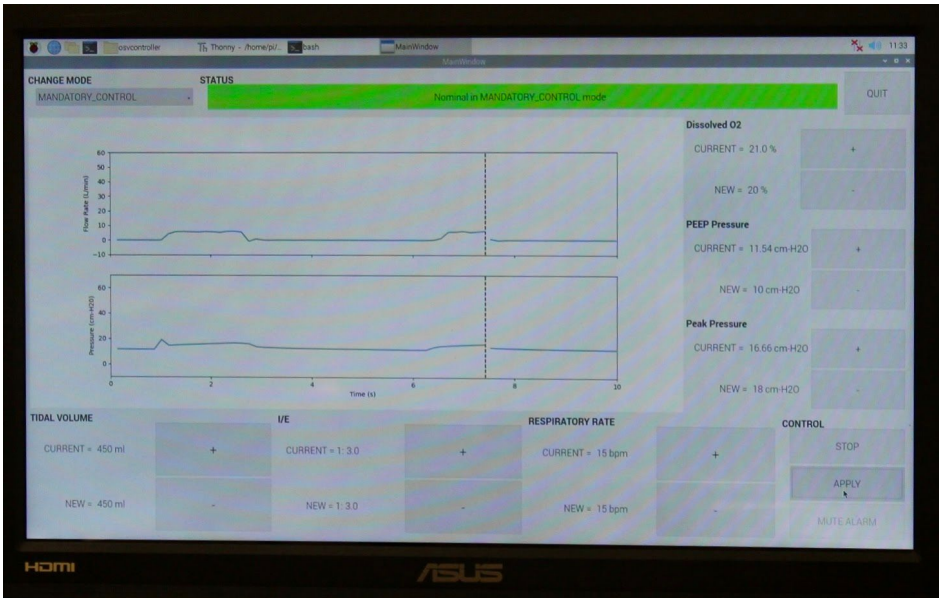
Operating the Baxter Ventilator is relatively straightforward and simple. Manual controls use color coding and clearly labeled knobs and gauges. All fittings are unique so tubes cannot be connected to the wrong fitting. The graphical user interface (GUI) is simple and straightforward with large touchscreen buttons. A complete operational video library can be found in Appendix B.

1) Connect Medical Air and Oxygen, if available, to the DISS fittings below their corresponding flow meters. Note that these fittings are not interchangeable.

2) Connect the ventilator circuit to the mounting plate. The Baxter Ventilator uses a standard single limb circuit. Note that none of the ventilator circuit attachments are the same, so they must be attached to their dedicated fitting. If an Ambu PEEP valve is used, connect that to the expiratory end circuit. If an Ambu PEEP valve is not available, use the limb extension to connect to the Expiratory PEEP fitting on the mounting plate.

3) Adjust manual settings. For FiO2 adjust the Air and Oxygen flow meters - a reference chart is on the panel to assist in the correct settings. Next adjust the Back Pressure regulator. If operating in Volume Control or Supported Ventilation mode, adjust this to the maximum allowable pressure or PIP. If operating in Pressure Control or Supported Ventilation mode, set this to the desired Pplat. Finally, set the PEEP pressure. If using an Ambu PEEP valve turn the top of the valve to the desired setting. If using the PEEP manometer, fill the bottle to the desired level.

5) Adjust computer controls on the GUI touchscreen. Enter the Tidal Volume, I:E Ratio, and Respiratory Rate here. Also set the alarm monitor levels for oxygen saturation, PEEP, and PIP. This tells the controlor what levels to monitor and trigger alarms, creating redundancy with the manual controls. Once these settings are correct, hit the start button.



6) Adjustments can be made to the manual and automatic controls. However, if adjustments are made to the manual controls it is important that the adjustments are also made to the GUI alarm monitor levels or alarms will sound. Any adjustments to the GUI will not go into effect until the “APPLY” button is pressed. This prevents accidental adjustments.

7) Tuning for Pressure Control and Supported Ventilation: if Pplat is not being achieved, increase the Tidal Volume control until it is. The tidal volume can be a little higher than the standard settings for a patient size as excess pressure will be vented by the backpressure regulator. However, if the volume is much larger than the recommended levels, pressure might peak just above the monitored setting, triggering the alarm. If this occurs reduce the tidal volume until desired pressure levels are achieved.

8) Tuning for FiO2: If FiO2 levels are not achieved, adjust the oxygen flow meter up or down slightly until the desired level is achieved in GUI. Note that the oxygen sensor can take up to 12 seconds to respond to changing oxygen levels.

Safety Features & Risk Analysis

Safety was paramount in the design of the Baxter Ventilator. A preliminary Failure Mode Effects Analysis (FMEA) was performed to capture the effect and mitigation of various failure modes. Due to the scope of this project, the FMEA was limited to effects of failures on the patient. The FMEA is included in Appendix G. Additionally, a list of safety features is included below.

Safety Features

- High pressure FiO2 passes through two regulators to improve redundancy.
- Ventilator generates pressure during stroke and cannot provide high pressure gas beyond what is capable in a single stroke.
- Back pressure regulator can be set to any value between 5-60cmH2O and will vent gas if pressure exceeds set level.
- All fittings on the ventilator are different, preventing the operator from inadvertently attaching fittings to the wrong port.
- Ventilator is extremely difficult to tip over. The center of mass is very low with a broad base to resist upset. Additionally the circuit connections are low, reducing the chance of pulling the ventilator over if a wire gets caught.
- If power is disconnected the ventilator will continue to run for over 1 hour and 30 minutes. Alarm will sound if the ventilator is disconnected.
- PIP, PEEP, FiO2 are manually controlled and adjusted. These values are additionally monitored by sensors on the ventilator providing redundancy on these important values. If these values fail to meet or exceed set levels, or if a discrepancy between the manual settings and safety margins is detected, alarms will sound.
- The only computer controlled operation of the ventilator is the motor driving the cylinder. This controls the tidal volume, I:E ratio and respiratory rate. There is triple redundancy on this control: 1) The zero position is determined by a hall effect sensor, and position is monitored by a encoder; 2) If the hall effect sensor fails and the controller loses control, physical limit switches connected directly to the RoboClaw at either end of the cylinder's stroke will be triggered, shutting down the motor and sounding alarms; 3) If the limit switches fail, the motor will drive the cylinder to the end of its stroke, and will start loudly skipping gears. This will not break the ventilator, but will prevent it from providing dangerous and uncontrolled ventilation.
- If the ventilator fails, the patient still has access to FiO2 at ambient pressure.

List of Alarms

Failure	Alarm:	Machine State	Solution
Power failure	2 loud beeps every 30 seconds	Will continue to run for over 1.5 hour	Reconnect ventilator to power
FiO2 not achieved	A loud continuous tone and a notification in status bar	Will continue to run	Check Medical Air and O2 connections
			Check Medical Air and O2 flowmeters
			Check montoniored settings in GUI
			Check that there are no leaks in high pressure tubing
Inspiratory pressure exceeding limits	A loud continuous tone and a notification in status bar	Will stop immediately	Check back pressure regulator setting
			Check GUI peak pressure setting
			Check that nothing is restricting expiratory airway
			Decrease tidal volume
			Decrease I:E ratio
PIP not achieved	A loud continuous tone and a notification in status bar	Will continue to run	Check back pressure regulator setting
			Check GUI peak pressure setting
			Check that nothing is restricting inspiratory airway
			Check to see if there are any leaks in Inspiratory airway
			Increased tidal volume
			Increase I:E ratio
PEEP not achieved	A loud continuous tone and a notification in status bar	Will continue to run	Check PEEP valve setting (or PEEP manometer levels)
			Check GUI PEEP setting
			Check that nothing is restricting expiratory airway
			Check to see if there are any leaks in expiratory airway
Tidal Volume not achieved	A loud continuous tone and a notification in status bar	Will continue to run	Check back pressure regulator setting

			Check that nothing is restricting inspiratory airway
			Check to see if there are leaks in Inspiratory airway
Limit Switch activated	A loud continuous tone and a notification in status bar	Will stop immediately	Check hall effect sensor
			Reset, if alarm repeats there is a machine failure.

Testing

Summary

The Baxter Ventilator has been tested on a Gaumard HAL S3201 simulator at the University of New England and on QuickLung monitored by ADInstruments' PowerLab DAQ. Raw data was unable to be collected from the S3201, however, side-by-side comparisons of the output of Baxter Ventilator and a Drager Fabius GS were made. Raw data was collected from a range of tests on the QuickLung using ADInstruments PowerLab DAQ. Complete testing results can be seen in Appendix E. Neill Gremmel, the simulation specialist at UNE, had this to say after testing the Baxter Ventilator.

Neill Gremmel: *"Consistently we were able to safely administer ventilations to the patient, we were able to change the settings to accommodate any reasonable parameters, and do so safely, quickly, easily, and achieve results that were... surprisingly similar to our full anesthesia machine"*

Methodology

Both the Baxter Ventilator and the Fabius GS were tested on a number of tests with identical settings on a HAL S3201. Readings from the S3201 were captured for both ventilators and compared. It should be noted that the Baxter Ventilator used initial I/E profiles which were corrected in later tests.

More extensive tests were conducted on QuickLung since raw data could be captured. For testing VC-MCV and using parameters outlined in the CoVent-19 challenge, the Baxter Ventilator was first tested with the median value for each setting. Then each setting was tested at the lower and upper limits while keeping the other settings at the median value. Then tests were performed with all settings at the minimum and maximum values. During these tests the QuickLung was set to normal lung settings. VC-MCV was then tested at various lung compliance and resistance settings. Raw data and testing logs were kept for each test and uploaded to grabCAD.

For testing PC-MCV, testing again began with median ventilator settings and nominal lung compliance and resistance. Then ventilation was tested at various pressure levels. Finally, tests were performed at the maximum lung resistance level. Raw data and test logs were kept for each test.

Finally the Baxter Ventilator was tested in assist mode. These test breaths were triggered by lightly lifting the QuickLung, dropping its internal pressure. Tests were also conducted when no breaths were triggered to confirm scheduled breaths would be performed. Tests of assisted ventilation were taken for a range of desired Pplat levels by adjusting back-pressure valve and tidal volume, while keeping other settings at median values.

Pressurized Air and Oxygen were not available during testing, so these were not tested. However, the oxygen sensor was calibrated and accuracy confirmed using various oxygen levels at an earlier time.

Error Analysis

Lack of familiarity with the test equipment may have led to some errors in PowerLab's collection of the data. First, a discrepancy was noted between the actual volume delivered and the volume calculated by PowerLab software. it was observed that the value of the volume calculated depended heavily on the flow at the time of the sampling started. If the sample started expiratory flow, the volume values calculated on PowerLab would continue to rise over time. If the sample was started during inspiratory flow, the volume values would continue to fall over time. These calculations were clearly wrong: the observed volume calculations on PowerLab varied depending on when the test was started in the ventilator cycle even though the ventilator settings remained constant while flow and pressure cycles as observed on PowerLab and by the operator remained constant; and a constantly increasing or decreasing volume per cycle would cause lung collapse or impossible lung volumes -- neither of which were observed.
One possible approach to mitigate this calculation error was to start the test before ventilation began (with no flow). With this approach, however, it would take a number of breaths to reach lung equilibrium, and volume results would be inconsistent during initial breaths. In the end, best efforts were made to start the sample during a period of minimum flow at the transition between

expository and inspiratory flow, however, this was difficult and never perfect. In some tests, mostly during the PC-MVC test, this was nearly impossible and ultimately abandoned. Volume calculations were made by the difference between the volume peak and its nearest trough. However, this does not give an accurate account of the true volume and all PowerLab volume values should be considered suspect and not representative of actual volumes delivered. A better understanding of the use of the PowerLab DAQ might have resolved this issue.

Second, values for the logs were taken directly from the plots generated by PowerLab. The values were identified by the human test operator, and were dependent on mouse location. As a result different operators may have found slightly different values, so there may be some small discrepancies between the raw data the logs generated. Finally, pressure settings were manually entered by the human operator, so those may have differed slightly based on manual entry.

It should also be noted that a digital low pass filter was used on most of the plots. Voltage readings for the various sensors were quite small, so small variations produced some noise. In most cases the low pass filter was set to 25Hz, but in a few plots it was set to 10Hz.

Testing Highlights

Tuning

Ventilation is generated by moving a constant bore cylinder a desired distance. The speed and stroke of the cylinder's piston determines how much and how quickly gas is delivered. This stroke is driven by a motor with a high resolution encoder. As a result, it is easy to tune the volume and speed at which gas is delivered during ventilation by adjusting the motor profile. The stroke cycle of the cylinder can be broken up into phases so that parts of the cycle can be sped up, slowed down, or held. Transitions between phases can also be tuned. This allows for a high degree of fidelity in tuning ventilation.

Results from tests on the S3201 and initial test with the PowerLab showed problems with how the I:E ratio was programmed. Alex Baker from Ximedica observed that our I:E ratio was too long on the first tests using the PowerLung. This problem was confirmed by looking back at the results from the previous testing on the S3201, which showed that the Baxter Ventilator had a longer drawing inspiratory period and held and maintained pressure after initial inspiration. It was determined that the hold phase was too long at the end of the inspiratory period of the motor profile. These changes were implemented and the results looked more consistent with what Alex Baker had recommended. However, given the team's lack of experience these outputs may not be optimal.

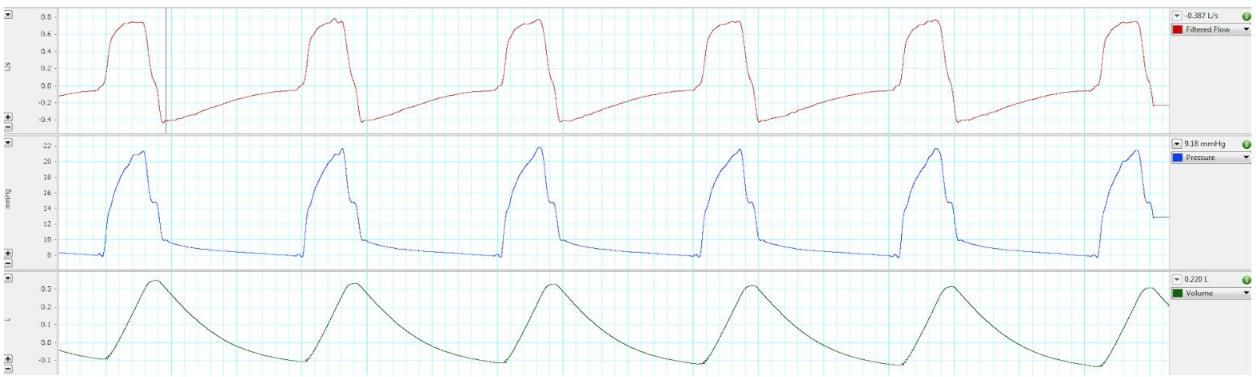
Figure 1 below compares the Baxter Ventilator with the Fabius GS with the same settings.

Baxter Ventilator *Fabius GS*

Figure 1: Comparison of Baxter Ventilator and Fabius GS

Figure 2 compares before and after I/E tuning. Before tuning the inspitory period is too long and there is a significant pressure hold after. After tuning the I/E ratio by decreasing inspiration time, removing the hold, and modifying the ramping on the motor profile, this has been addressed.

Before I:E tuning



After I:E tuning

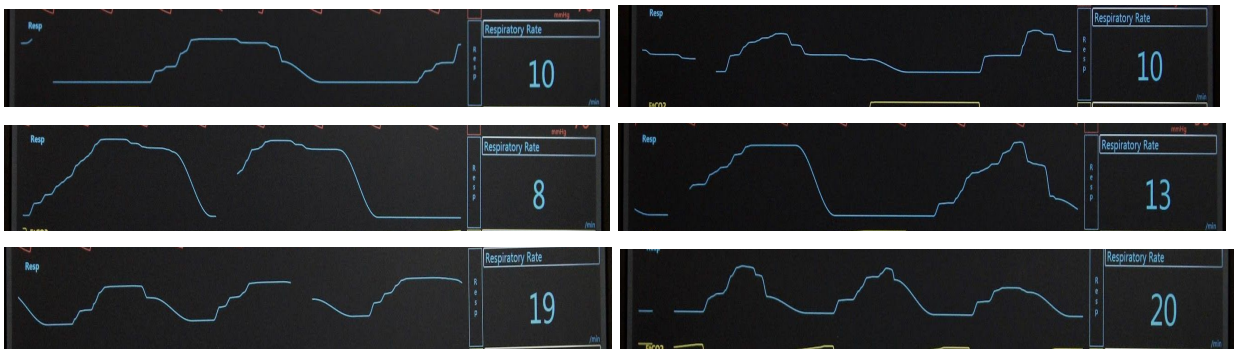
Figure 2: I:E Tuning Effects

While the Baxter Ventilator team does not have the expertise to determine if the tuned plots are optimal, these results show that the Baxter Ventilator can be easily tuned. After only a few simple modifications, the profile changed from stretched inspiratory phase with a long hold to one with a short steep inspiratory phase with no hold period. This is just one example of the range the Baxter ventilator can be tuned. Adjusting the motor profile algorithm is relatively simple, so with guidance from expert clinicians, the Baxter Ventilator can be adjusted to produce optimal ventilation output.

Consistency

Throughout testing, the Baxter Ventilator has been shown to provide repeatable precise ventilation. Each ventilated breath was delivered consistently at all settings. While the output plots might not be optimally tuned, they demonstrate the precision with which the Baxter Ventilator produces ventilation.

While the Baxter Ventilator had the wrong I:E ratio calculation during initial testing at UNE, it was apparent that it was very consistent in its ventilation. When looking at the flow of the Baxter Ventilator compared with the Fabius GS ventilator as tested on a S3201 simulator manikin, it was clear that the Baxter Ventilator delivered more precise ventilation over a range of settings.



Baxter Ventilator Fabius GS

Figure 3: Comparison of Baxter Ventilator and Fabius GS flow at same settings - Output plots generated by S3201

Later testing on the QuickLung also showed precise ventilation. Below are some examples at various settings - for a complete list see Appendix E.

Figure 4: Sample Plots of the Baxter Ventilator at Different Settings Demonstrating Precision Ventilation

Pressure Regulation

A ventilator's pressure regulation is critical to patients' safety. The Baxter Ventilator features a manually adjusted back pressure regulator with a fixed range of 5 to 60 cmH2O. This regulator acts as an adjustable pressure relief valve: whenever the pressure exceeds the settings, the regulator will vent gas until desired pressure is achieved. This allows pressures to be automatically regulated without the need of software, solenoids or sensors - all of which add additional points of failure. Evidence of the back pressure regulator working to maintain pressure can be seen in a number of the tests. Below is an example of one test where the limits were being pushed. This test used assisted pressure control ventilation with a pressure set to 35cmH2O, a tidal volume to 600ml/m; I:E to 1:3; and a respiratory rate set to 30bpm. At these settings a lot of air was pushed in a short time. It can be seen in the plots that the flow drops in the middle of the inspiratory phase, but the pressure is maintained. This is a result of the backpressure regulator successfully venting excess air to maintain desired pressure.

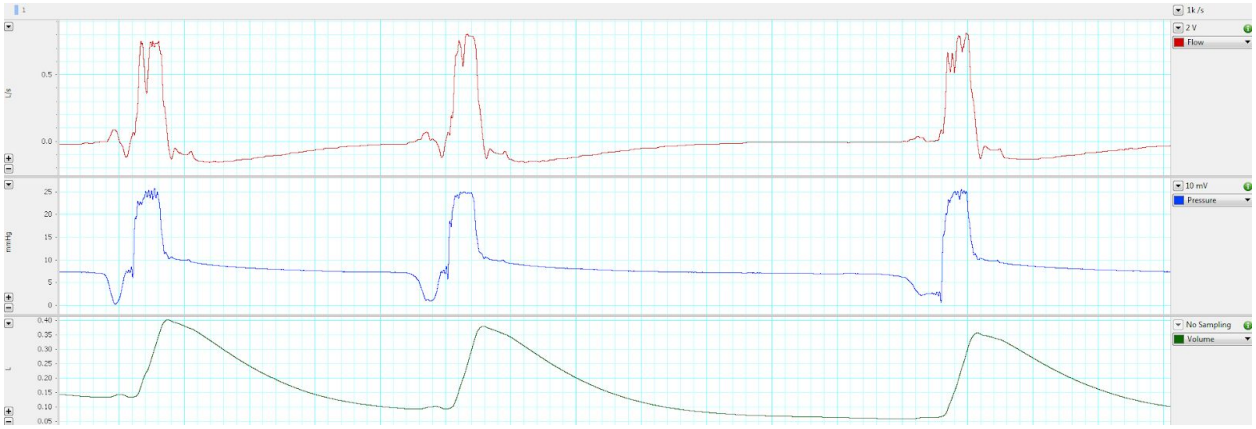


Figure 5: Demonstration of Pressure Regulation

Noise Levels Test

Tidal Volume = 450ml
Respiratory Rate = 12 bpm
I:E = 1:2
PEEP = 5 cmH2O
Operational: Average of 53 decibels at 1 meter distance
Alarm: Average of 68 deciBels at 1 meter distance

Battery Backup Endurance Test

Tidal Volume = 450ml
Respiratory Rate = 12 bpm
I:E = 1:2
PEEP = 5 cmH2O
Battery Life: 1 hour, 48 minutes

Requirements Compliance

The Baxter Ventilator has two modes of operation: mandatory ventilation and assisted ventilation. In mandatory mode, the operator can choose to use either volume control continuous mandatory ventilation (VC-CMV) or pressure control continuous mandatory ventilation (PC-CMV). In assisted mode the operator can choose pressure-support ventilation (PSV) or volume-support ventilation (VSV) and can choose synchronized intermittent-mandatory ventilation (SIMV).

The first step in formal validation of the device will be a combined Installation Qualification and Operational Qualification (IOQ) protocol. The protocol is included with this report as Appendix G. The Traceability Matrix that links the elements of the IOQ protocol to the System Requirements can be found in Appendix F.

The Baxter Ventilator currently meets all CoVent-19 requirements:			
SR-01	SR-10	SR-20	SR-29
SR-02	SR-11	SR-21	SR-30
SR-03	SR-12	SR-22	SR-31
SR-04	SR-13	SR-23**	SR-32
SR-05	SR-15	SR-24	SR-33
SR-06	SR-16	SR-25	SR-35
SR-07	SR-17	SR-26	SR-36
SR-08	SR-18	SR-27*	
SR-09	SR-19	SR-28*	

*currently capable but needs testing for validation

**at the moment a bug in the code makes this unreliable, but small amount of tuning should correct issue

SR-32 In addition to operation at 115V 60Hz power, the ventilator power supply can be used with the 230V 50Hz power available throughout much of the world. 50Hz power is not available at the Baxter facility.

SR-27 This cannot be tested at Baxter's facilities (sea level), but there is nothing about the design that should limit the ventilator's operation at altitude.

SR-28 The ventilator has been run for over one hundred hours, but not continuously for more than eight. The ventilator should be capable of running for thousands of hours without issue, but more time and testing is needed to confirm.

SR-23 The code is written for this, but some debugging is needed to improve reliability.

Assistance is requested to obtain appropriate FDA approval for this device. Baxter Academy does not have the resources to produce this ventilator in-house at a commercial scale.

Next Steps

Tuning - Working more closely with respiratory therapists would allow the Baxter Ventilator to improve performance. With expert guidance, motor profiles could easily be tuned to produce optimal flow and pressure output. Additionally, more experienced insight would be needed to tune assisted ventilation modes.

Testing - Much more rigorous testing is needed to validate use of the Baxter Ventilator for FDA or other regulatory approval, but that is beyond the scope of the current program.

Electronics - A small revision to the Raspberry Pi shield would allow for simpler electronics set up.

Detailed Assembly Documentation - While the assembly videos and and drawings should be sufficient for most assembly needs, creating a detailed step-by-step set of written and illustrated instructions would be helpful. Additionally, providing assembly instructions in multiple languages would help this design meet the global need for ventilators.

Complete IOQ Validation Protocol - The IOQ protocol is a controlled document intended as the first step in a formal validation process for the ventilator. One next step for the program should be to perform and document rigorous testing in accordance with the developed IOQ validation protocol seen in Appendix G.

Government Approval - All required approvals will have to be obtained before use in specific countries or jurisdictions.

Packaging - Depending on the circumstances at the intended place of use, cost and other parameters, the decision must be made whether to ship the Baxter Ventilator as a kit or a fully assembled machine. In either case, BOM must be refined to optimize price and performance and take advantage of locally available materials as needed.

Conclusion

The Baxter Ventilator is a safe, robust, effective and affordable ventilator. It meets all metrics specified by the CoVent-19 Challenge, assuming the few that require further testing are validated. The Baxter Ventilator can provide mandatory ventilation (VC-MVC, PC-MVC) or assisted ventilation (PSV, VSV, and SIMV).

The ventilator's outputs are repeatable over a large range of settings. Output can easily be tuned to meet clinicians' needs. Through consistent repeatability and tuning, the Baxter Ventilator can produce desired outputs with a high degree of fidelity. It has robust safety features, including manual control of pressure and FiO2 regulation, multiple redundancies, and numerous alarms.

The Baxter Ventilator's flexibility allows for use in both modern ho
spitals and in the field. Easily swapped components make the ventilator viable anywhere in the world and less susceptible to supply chain disruptions. Early models shipped in kit form don't require large production overhead and allow for design evolution. Additionally, easily assembled kits can be distributed and built remotely, something that may be necessary during a pandemic.

The Baxter Ventilator can help save thousands of lives during the COVID-19 crisis and future pandemics.