Project –Vacuum powered DIY pandemic Ventilator prototype

A COVID19 initiative, to create a prototype respirator/ventilator from basic household and 3D printed components, powered solely by a vacuum source such as a ducted vacuum system or household vacuum cleaner, and devoid of any electronic control apparatus.

Aim

To establish a baseline for assessing the feasibility and suitability of a rudimentary low cost respirator/ventilator concept, as a possible aid in alleviating critical shortages of such equipment as being experienced in the medical industry resulting from the COVID19 pandemic.

Some of the discovered techniques, and ideas may provide benefit to unrelated applications.

Motivation

At the rise of the pandemic, the terrible prospect of severe triage denying access to hospital and hospital ventilation equipment was felt. As a last resort option, attempts to purchase AMBU resuscitation bags failed with money being refunded due to shortage of supply. Many open source ventilator projects attempting to fill the shortage of ventilators during the pandemic are based on mechanical automation by actuation of the basic AMBU resuscitation bag. Without supply of AMBU resuscitations bags, is there an acceptable or at least a workable DIY home use alternative?

Objectives

- To perform the basic essential function of a medical respirator/ventilator – provide active cyclic aspiration and expiration of breathing air.
- To use only 3D printed plastic components and items obtained from household supermarket and hardware stores (readily available materials and items)
- To use benign materials - For materials in contact with breathing air supply
- To minimize the number of types of materials and items needing to be acquired
- To have low sensitivity to construction tolerances
- To provide provision for input of supplementary oxygen
- To be reliable
- To be adjustable
- To be serviceable

- To be simple to operate
- To be easily constructed
- To be devoid of any custom electronic or electrical components
- To eliminate reliance on electrical components and software
- To be low cost

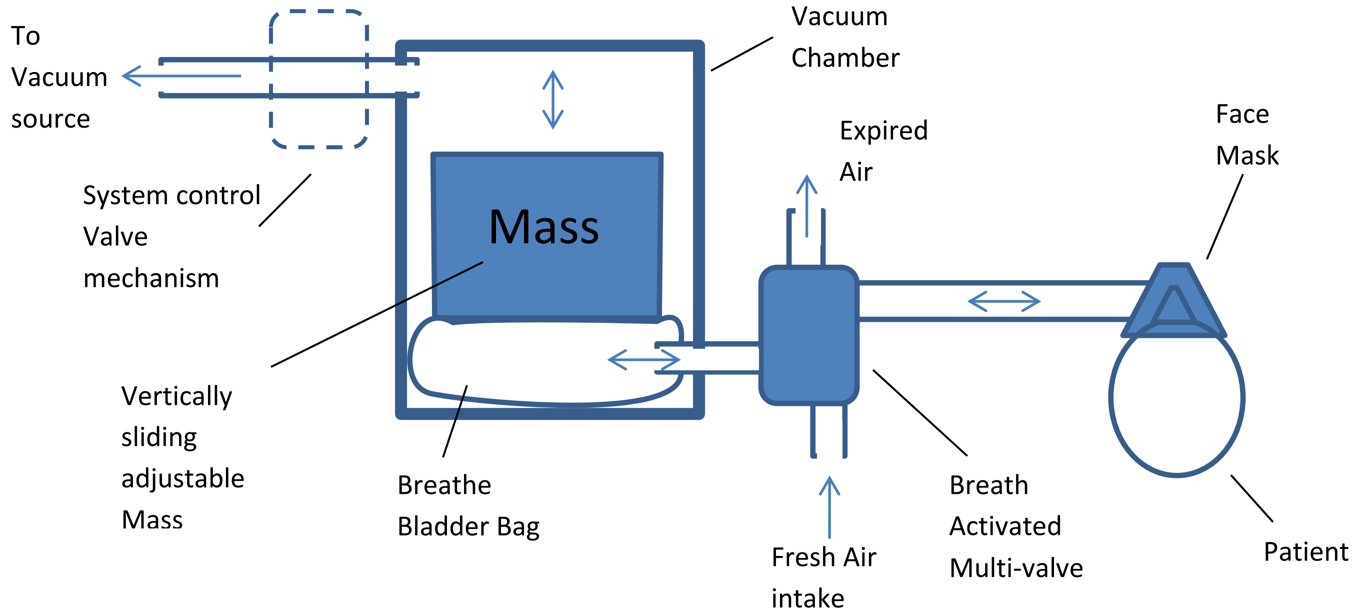
Requirements

- To deliver a specific volume of breathing air at a specific pressure followed by an adjustable duration for expiration, in a repeating cyclic manner.
- The volume of air delivered (tidal volume) per breath cycle should be preset, adjustable and quantified.
- The pressure of air delivered in each breath cycle should be preset, adjustable and quantified.
- The duration for expiration per breath cycle should be easily adjustable.
- The energy required for operation should be supplied solely by a source of vacuum, such as from a ducted vacuum system or household vacuum cleaner.

Challenges

- Creation of effective valve elements without the luxury of intricately molded silicon valve membranes, and/or precisely engineered metal spring components.
- Providing sealing without the luxury of precision dimensional tolerances for tight fitting self-sealing interconnecting components.
- Obtaining through household supply chains, items and materials used in transporting air which are benign or at least do not produce excessively hazardous or reactive emissions.
- Designing for safe failure modes.
- Providing sufficient usability without the use of intricate electronics and software.
- Providing effective means for monitoring of conditions and pressures without electronic sensing.

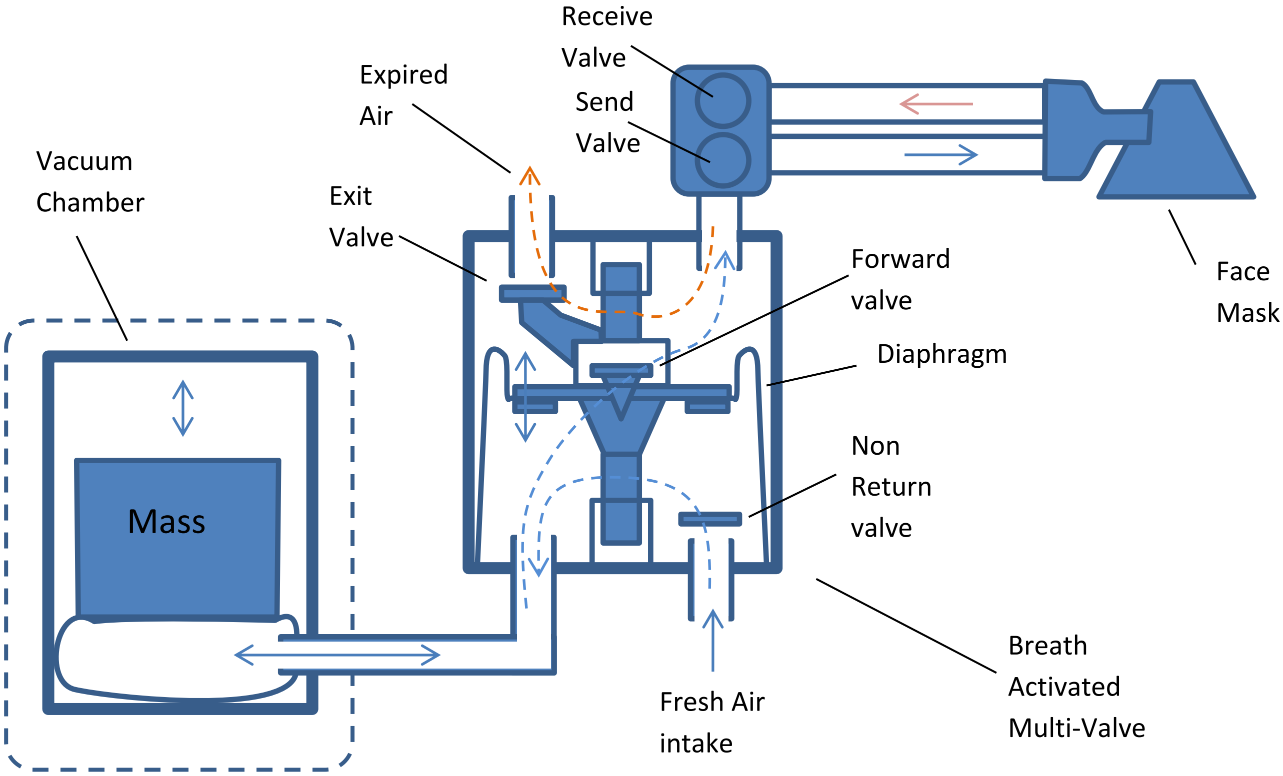
Concept overview



Operation principle

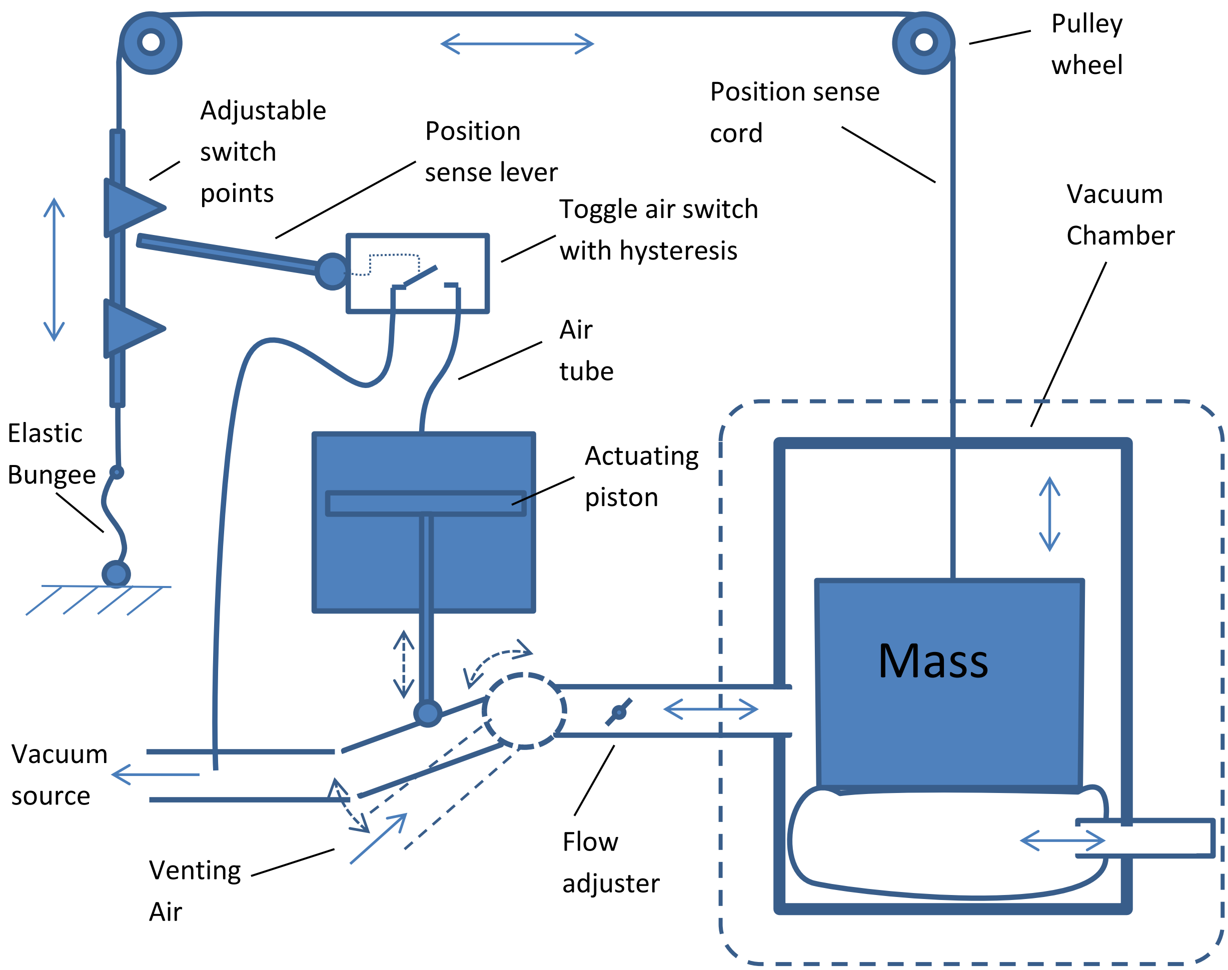
Vacuum Chamber, Bladder bag and Mass –

A vacuum chamber contains a bladder bag weighted down by a dedicated mass, and having an air duct which passes sealably through the vacuum chamber wall, and via dedicated valving to a respiration face mask, the mass substantially covers the bladder bag, and is slid-able vertically with low friction in the vacuum chamber. When vacuum is applied to the chamber, fresh air is drawn into the bladder lifting the mass. The vacuum source is then removed and the chamber vented to atmosphere. The weight of the mass and the distance moved in principle defines the pressure and volume which is delivered to the face mask. The pressure is determined by the Mass x Area of the mass in contact with the bladder bag, and the volume of delivery determined by the vertical displacement Height x Area of the mass on contact with the bladder bag.



Breath Activated Multi-Valve –

Pressurized air from the Breathe Bladder Bag causes a diaphragm in the multi-valve to move and close the outlet port for expired air, and subsequently opening the passage connecting the mask, delivering air to the patient. On expulsion of air from the bladder bag, the diaphragm in the multi-valve retreats opening the expired-air port, allowing the patient to exhale. On vacuum being applied to the chamber, the bladder bag draws fresh air in through the multi valve via a one-way/non-return valve to atmosphere, recharging the bladder/mass combination.



System Control Valve Mechanism –

A continuous vacuum source such as from a household vacuum cleaner or ducted vacuum system feeds the System Control Valve Mechanism. When the mass in the chamber is in the low position, the vacuum control valve enables vacuum to the chamber, causing the bladder bag to charge and the mass to rise. When the mass reaches a preset height determining the intended charge volume the valve mechanism disables vacuum to the chamber and opens the chamber to atmosphere, allowing the bladder bag to deflate under the downward force of the mass delivering air to the patient until the mass has dropped to its lowest point which is detected by the System Control Valve Mechanism which again enables vacuum to the chamber the cycle then repeating. The System Control Valve Mechanism includes an adjustment to control to flow of evacuating air from the vacuum chamber, thereby changing the rate and time between cycles and hence the breathing rate.

Description

Fundamental characteristics –

The inherent nature of the concept in providing a defined volume of air per charge at a predefined pressure nominally contains the maximum pressure delivery to a value determined by the mass acting on the area in contact with the bladder bag. The intention is to operate the bag through an inflation range in which the moving part of the bag is nominally that in contact with the mass, resulting in the delivered volume being nominally the movement of the mass multiplied by the area in contact with the bag, and the pressure is nominally constant determined by the mass divided by the a area in contact with the bag. In practice however, the bladder bag-mass concept presented here, in order to operate reliably in a simple DIY application, requires the mass to have a smaller area in contact with the bag than the containing area of the containing vacuum chamber, such that that the upper surface of the bladder bag acts somewhat akin to a rolling diaphragm, hence there are edge effects which make the simple calculation a basic approximation in the lower positions being the more linear region, with the deliverable pressure becoming higher as the bag inflates into its balloon range where the area in contact with the mass reduces at a nonlinear rate. This may be advantageous if a higher initial pressure of the inspiration phase is required, or a downside requiring vigilance in observing maximum pressure.

Overall control is provided by the System Control Valve Mechanism which, in its simplest form enables vacuum and then vents the vacuum chamber to atmosphere depending on the position of the mass. When the mass position drops below a minimum height, the vacuum is enabled, causing the mass to rise as fresh air is entrained into the bladder bag, when the mass reaches a predefined height the vacuum is disabled and the mass forces air out of the bladder bag toward the patient.

The initial implementation of the System control valve mechanism employs a self-powered vacuum valve. The height range of the mass is sensed by a control lever which connects or disconnects a pilot flow of vacuum to a vacuum operated piston which in turn opens or closes the bulk flow of vacuum while also alternately providing venting to the vacuum chamber when vacuum is disabled. The inter-connect between the lever and the vacuum pilot tube which powers the controlling piston, also includes an intermediate lever, which is spring loaded against an over-centered geometry to provide hysteresis which ensures a binary on/off state. The spring loading is provided by a household rubber band, avoiding the need for specially manufactured metal springing.

The initial implementation senses the position of the mass using a cord/string passing upward and out of the vacuum chamber and redirected through a pulleys and connected to a slider bar in the vicinity of the system control valve mechanism, the slider bar having a pair of reloadable trigger blocks which each communicate with the control lever in the extreme upper and lower limits of the mass’s vertical displacement to trigger switching of the state and a change in direction of movement of the mass.

Breath delivery and valving -

The cyclic output from the Breathe Bladder Bag in the vacuum chamber is connected via tubing to the distal end mask via the Breath Activated Multi-Valve. The Breath Activated Multi-Valve is fabricated completely from household items and a series of 3D printed components.

The Breath Activated Multi-Valve could alternatively or preferably be comprised of or replaced by the AMBU Resuscitation Bag, in which case the Breathe Bladder Bag is connected to the rear of the AMBU Resuscitation Bag and the associated mask attached directly to the patient. The AMBU bag supplies a path for fresh air to be entrained in the bladder bag during the charge phase, and non-return valving for feeding the pressurized air toward the distal end at the patient where included valving closes off the patient expiring airway and progressively opens the path to the patient in response to pressurized air moving toward the patient. To achieve this, the AMBU Resuscitation Bag contains an intricately shaped membrane component with delicate elasticity which is subject to precision manufacturing. The AMBU device alto contains a pressure relief valve which contains a precision built spring component. There are a series of non-return valves which also contain membranes fabricated from delicate flexible materials.

Where an AMBU Resuscitation Bag is unable to be obtained, the DIY approach requires an alternative. In this prototype, the Breath Activated Multi-Valve component is comprised of 3D printed parts, and a household food grade quality plastic freezer bag. In the absence of intricately shaped elastic membranes, the principle for achieving a return springing effect is provided in this case by the force of gravity. The readily available food grade plastic feezer bag serves as a diaphragm for responding to incoming air flow, translating air flow to sealed unrestricted movement of an element which closes the expired air port ahead of then opening the path to the distal or patient end. Valving is successfully or at least adequately performed by hard discs covering port openings, the discs being encaged to maintain position, and biased in the default state by the force of gravity. There are a performance compromises resulting from the approach of utilizing gravity in lieu of component material elasticity to achieve valve return bias in that the device requires a fixed orientation with respect to the vertical axis. Another tradeoff is the size of the prototype device prior to size optimization, which being larger than required on the one hand reduces the sensitivity to build tolerances, however increases the space for containing dead air, or air which needs to be displaced or wasted during the valve switching process. The valve needing a fixed vertical orientation as well as being large, then does not lend itself to being deployed close to the distal/patient end, which subsequently necessitates dual carriage separate send and receive tubing to the patient to minimize the reuse of patient expired air. The dual carriage approach has other advantages such as enabling the expired air pressure to be controlled and monitored by apparatus located at the ventilator unit, as opposed to adding bulk at the distal/patient end. Also the deployment of any HEPA filtering to the expired air to protect operations personnel from pathogens in expired air can also be deployed at the ventilator unit.

Breathe Tubing -

As a DIY project, the prototype was fitted with thin walled light weight flexible polyethylene tubing sourced from a hardware store normally purposed for grey water. Polyethylene tubing as opposed to PVC garden hose type tubing was found to produce greatly reduced levels of plastic odor.

Design

Vacuum chamber

Objectives:

1. Create a vertical air tight chamber with for a bucket to fit neatly and slide vertically with minimal friction.
2. The area to be smaller than the Breathe Bladder Bag such that the bag pushes against the containing side walls to lessen the pressure impact to the bag.
3. The chamber utilizing only 2 panels of melamine 1200x295x16mm particle board with all cuts being performed by the hardware store.
4. Note, the hardware store will only cut to length, not trim the sides hence the ad hoc appearance.

A height of ~600mm was chosen. (Half the length of the Malemine panels)

In practice it was found that ~400mm in height would suffice, depending on the type of weight used.

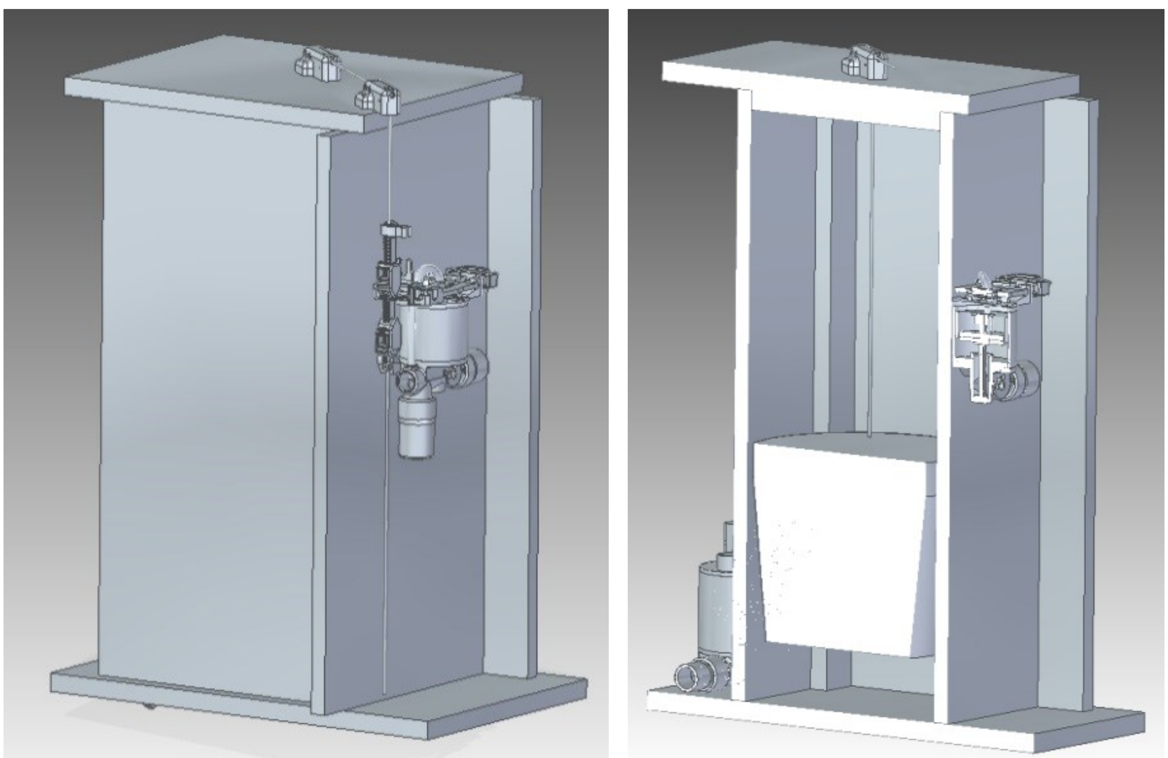


Fig – Ventilator - Oblique and cutaway view

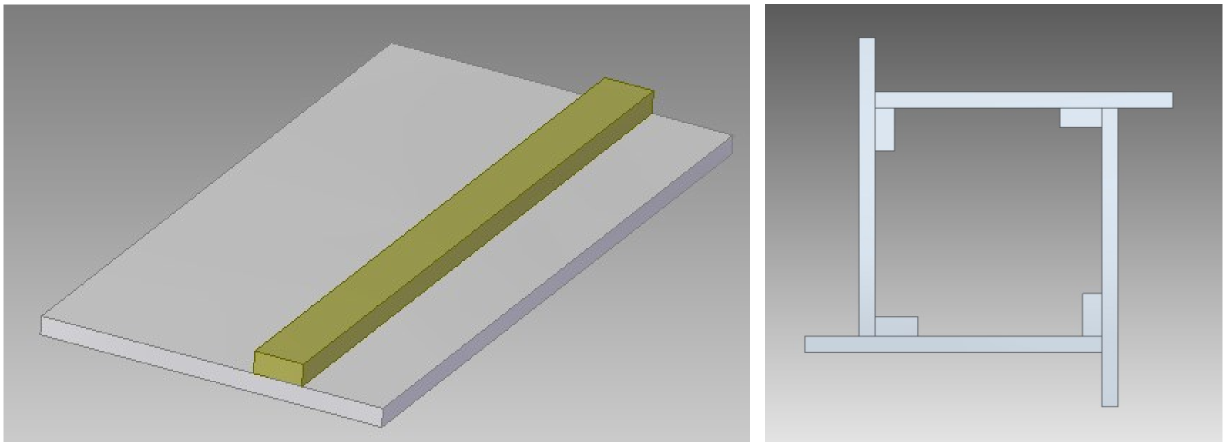


Fig – Vacuum Chamber – Wall Panel, Wall panels x4 joined

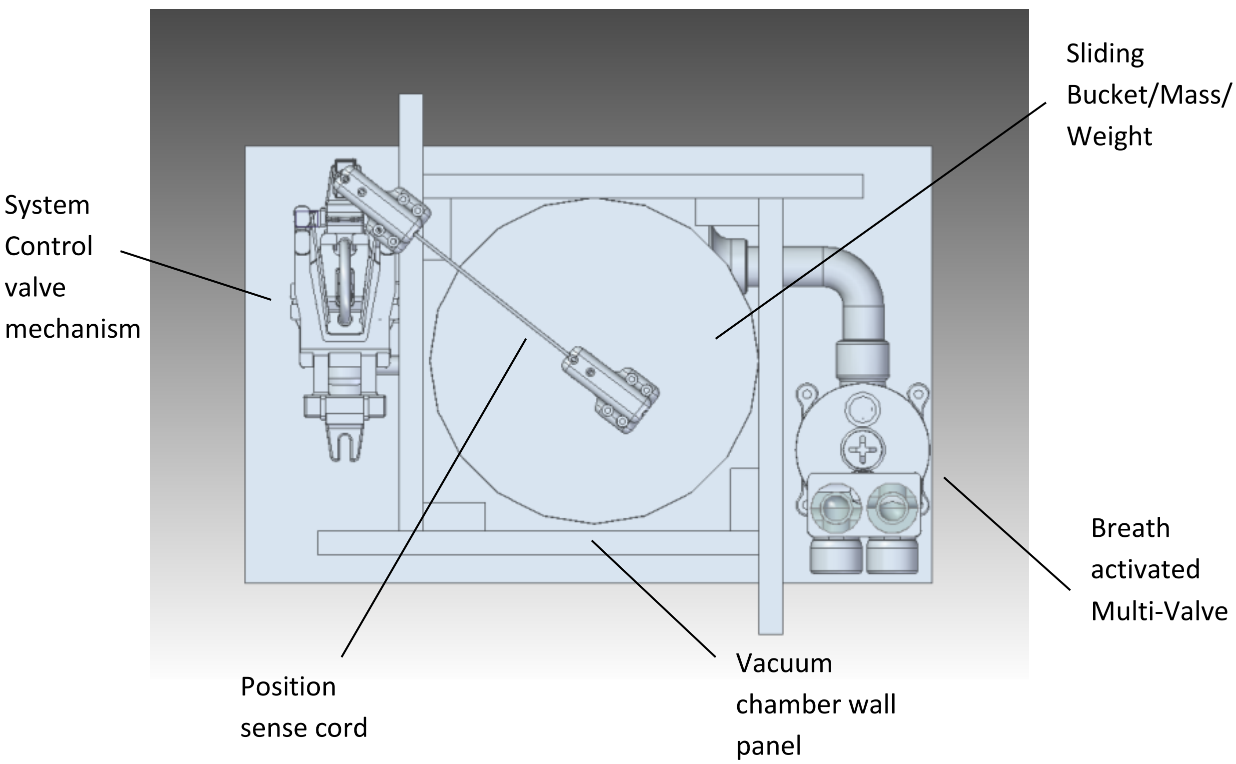


Fig – Ventilator – Top View - Open

Breath Activated Multi-Valve

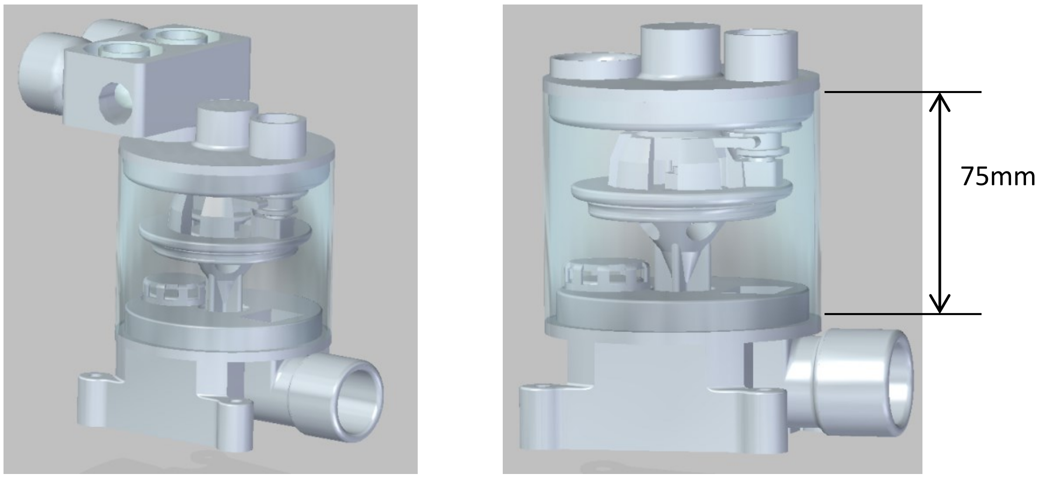
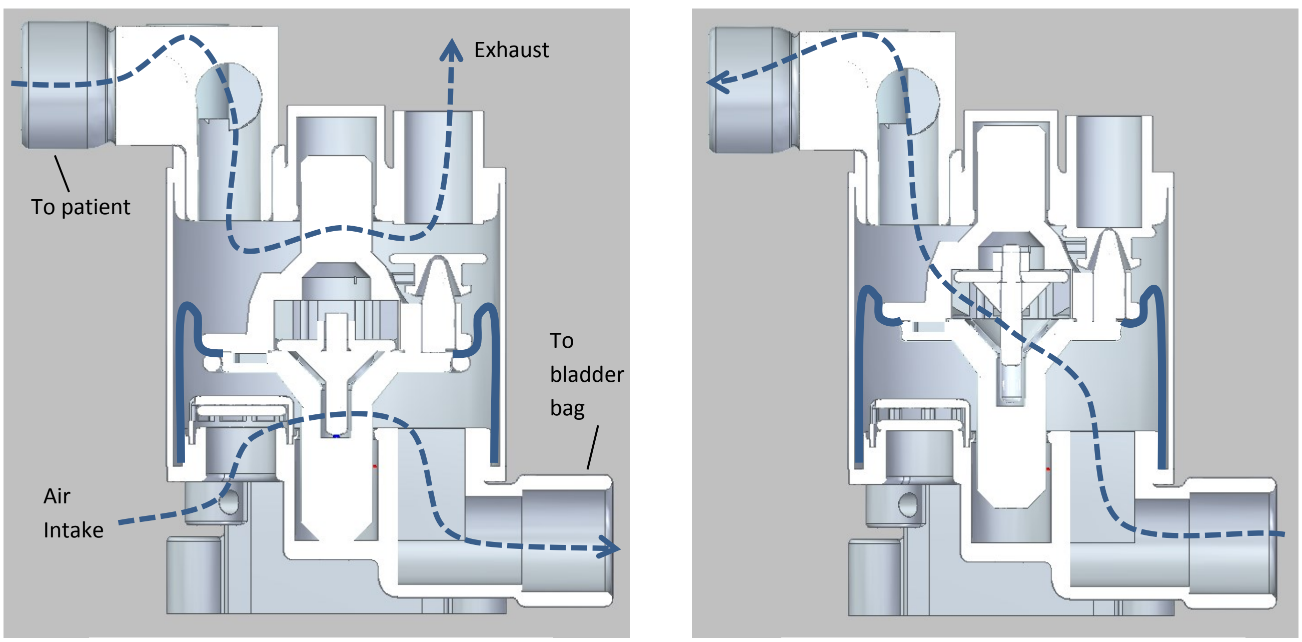


Fig – Breath Activated Multi-Valve – Oblique View and Side view



Bladder bag intake/recharge, and patient expiration

Bladder bag output and send to patient mask

Fig – Breath Activated Multi-Valve – Flow - Cutaway Side Views

Send-Receive Valve module

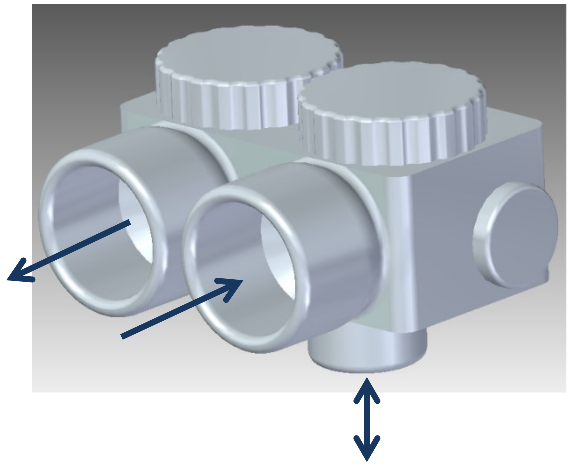


Fig – Send-Receive valve assembly

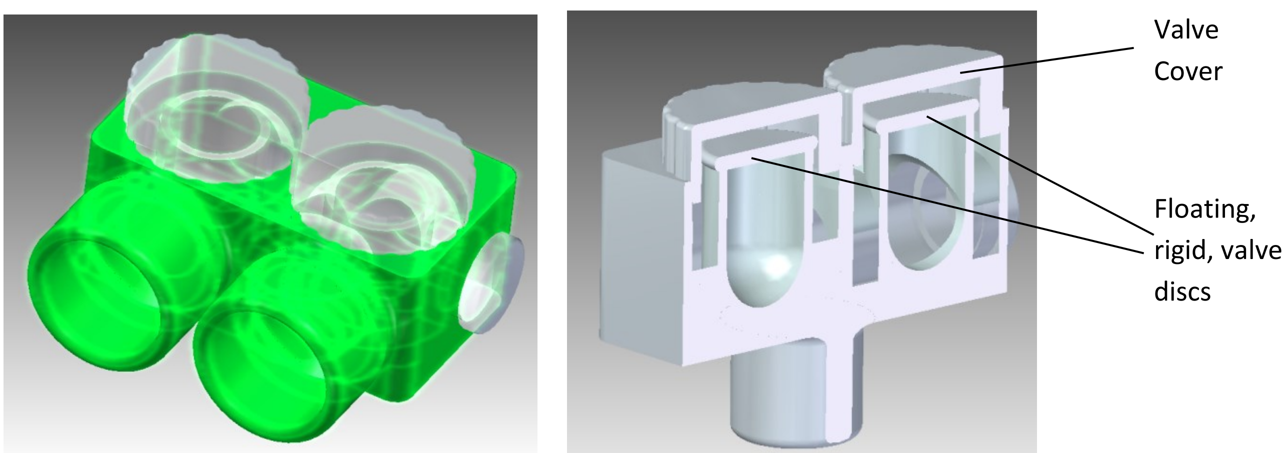


Fig – Send-Receive – Opaque and Cutaway

Breathe Send-Receive and Mask attach

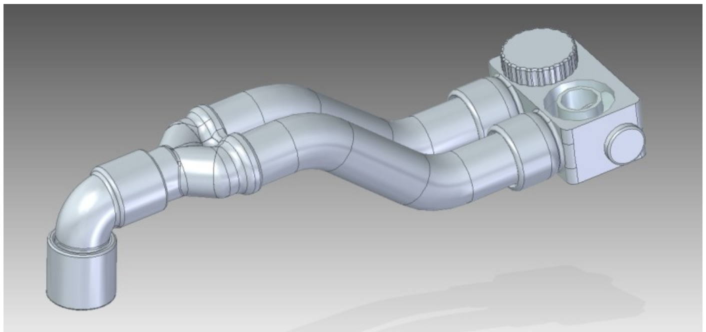


Fig – Breathe tube Mask attach, and Send-Receive assembly

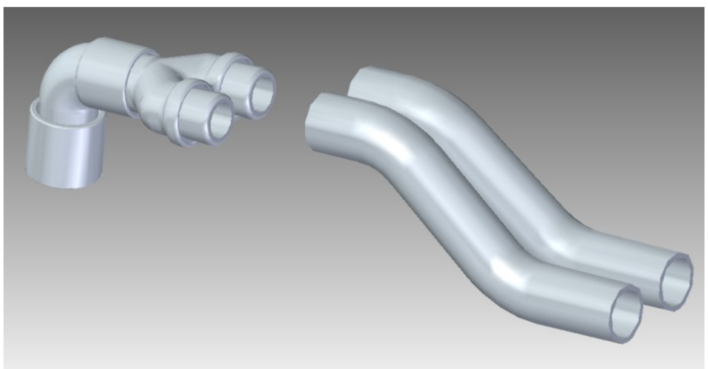


Fig – 3M mask attach, elbow, Y piece, tubing

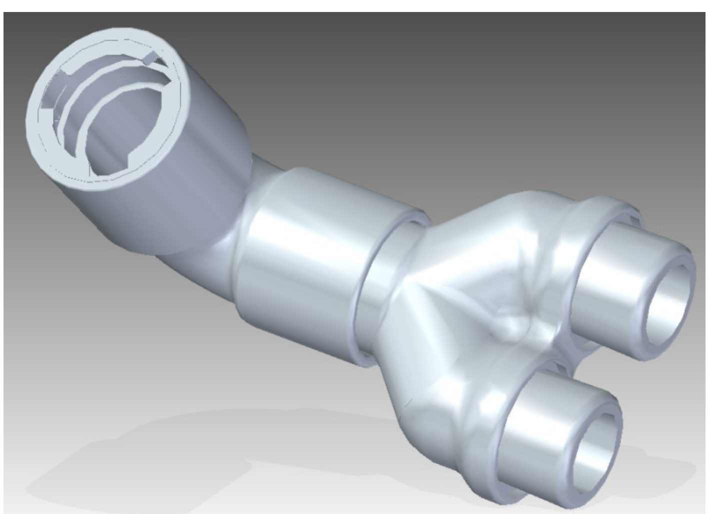


Fig – 3M mask attached elbow and Y piece

System Control Valve Mechanism

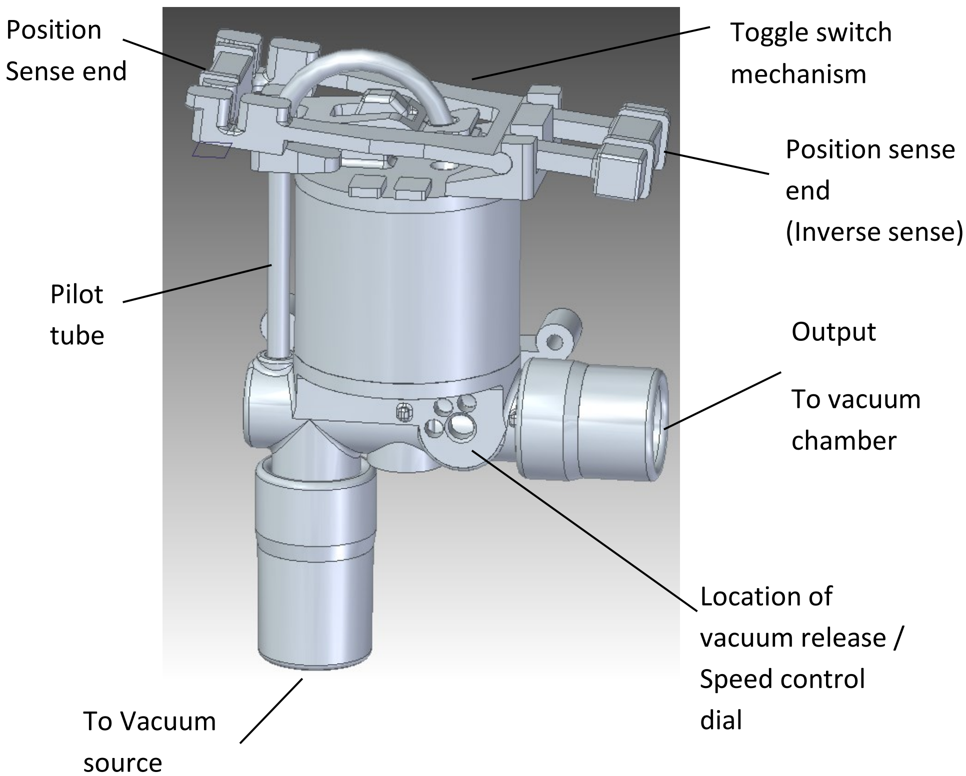


Fig – Vacuum toggle valve assembly - Side view

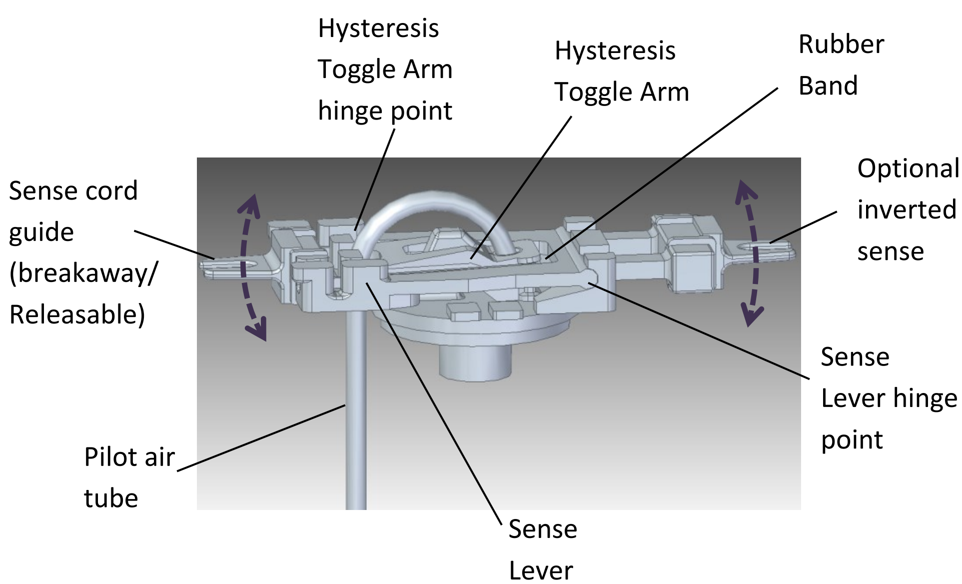
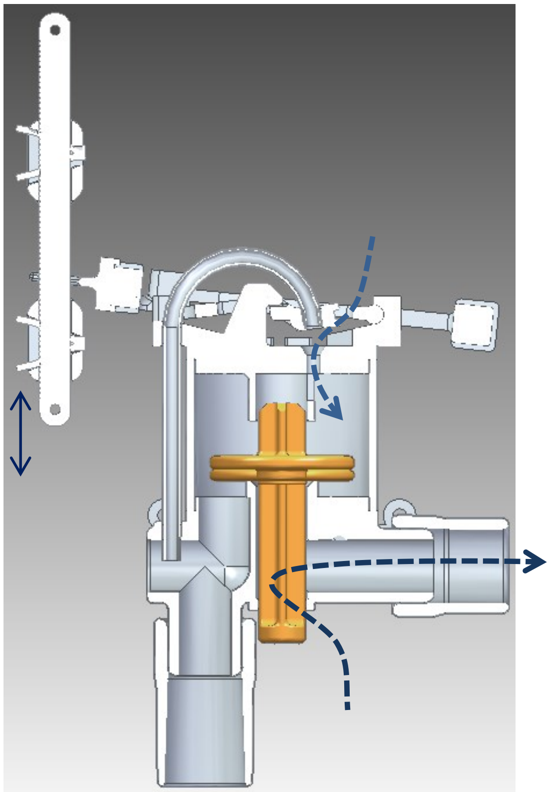
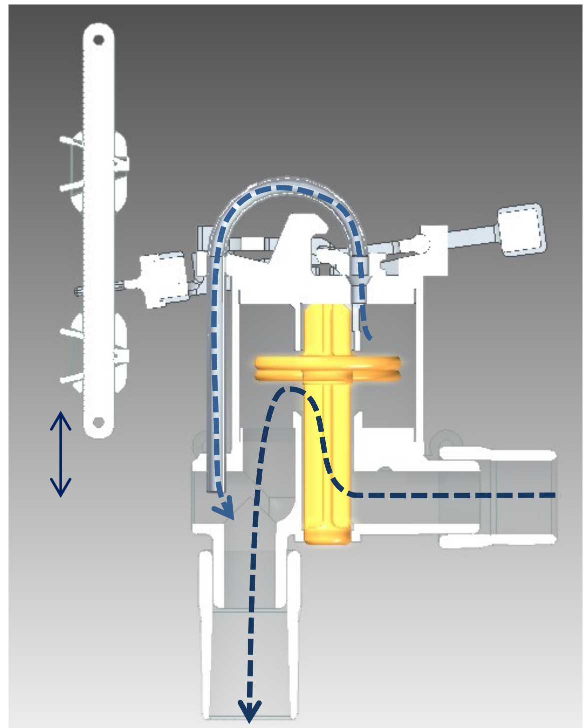


Fig –Toggle switch mechanism

A household rubber band applies tension between the sense lever and the over-centering toggle arm, resulting in a bi-stable on-off mechanism with hysteresis. The rubber band serves to also provide the retaining force to maintain the two components in their respective pivot hinge recesses.



Venting, Vacuum Disabled



Vacuum Enabled

Fig – System Control Valve - Section side view

Sense Cord - pulleys and adjustable switch-points

Fig – Cord ratchet movable set-points

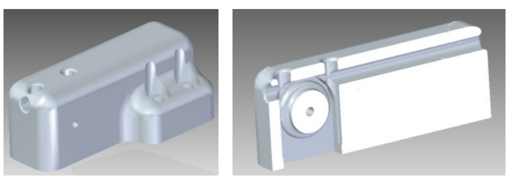


Fig – Pulley Block, and cutaway view

Build Files

BOM

https://github.com/kaiem/COVID-19_Ventilator_DIY_Prototype/tree/master/BOM

STL (3D model Files)

https://github.com/kaiem/COVID-19_Ventilator_DIY_Prototype/tree/master/STL

Not included - STL for 3D printed 90mm Storm pipe (75mm long) and 65 DPVC (55mm long).

GCode (3D Printer files)

https://github.com/kaiem/COVID-19_Ventilator_DIY_Prototype/tree/master/gcode

Printer GCode files were created for 3D printer plate size 200x200x180mm high, machine type setting, “RepRap Sprinter/Marlin”.

GCode files created from STL files using Cura 18.01

https://download.lulzbot.com/Software/Cura/Packages/Cura_18.03/

Assembly

Vacuum Chamber

Fig- Vacuum Chamber

Fig - Vacuum Chamber – Bucket entry

Fig - Vacuum Chamber – Bucket Inserted

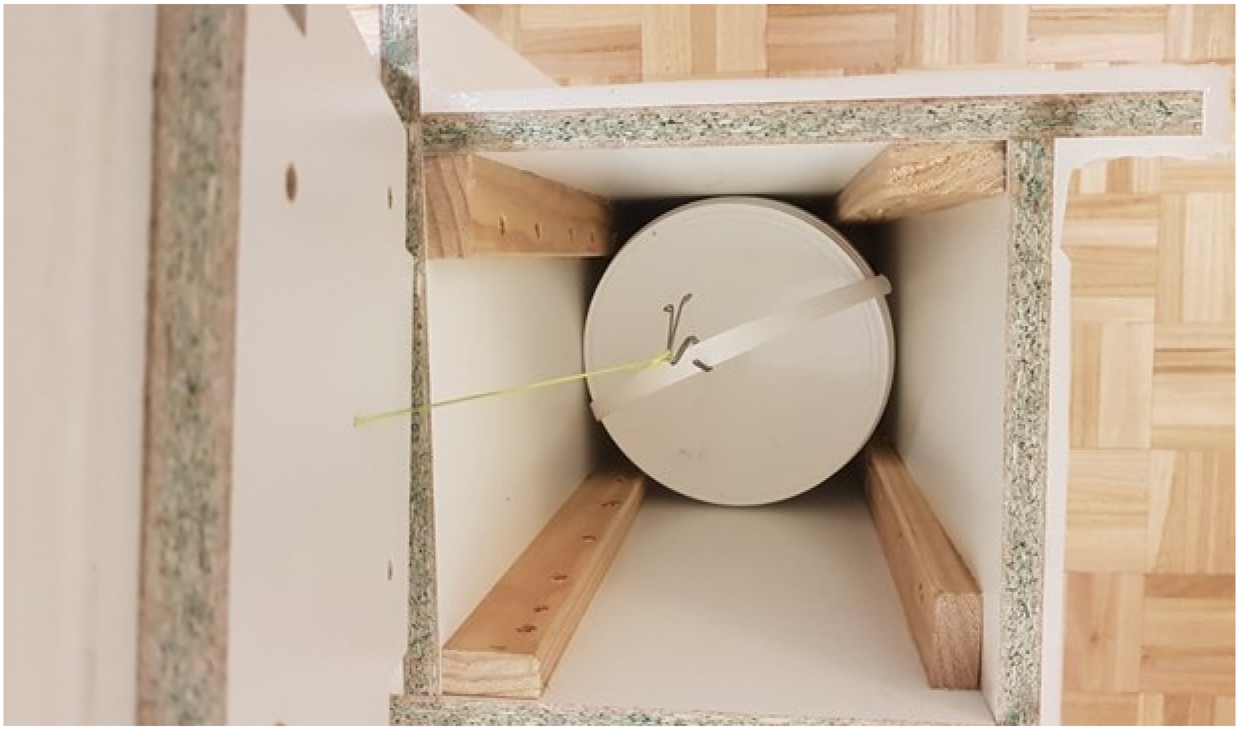


Fig - Vacuum Chamber – Sense Cord attached

Breathe Bladder Bag

Fig – Breathe Bladder Bag – Bag prep -> Pipe Inserted from inside

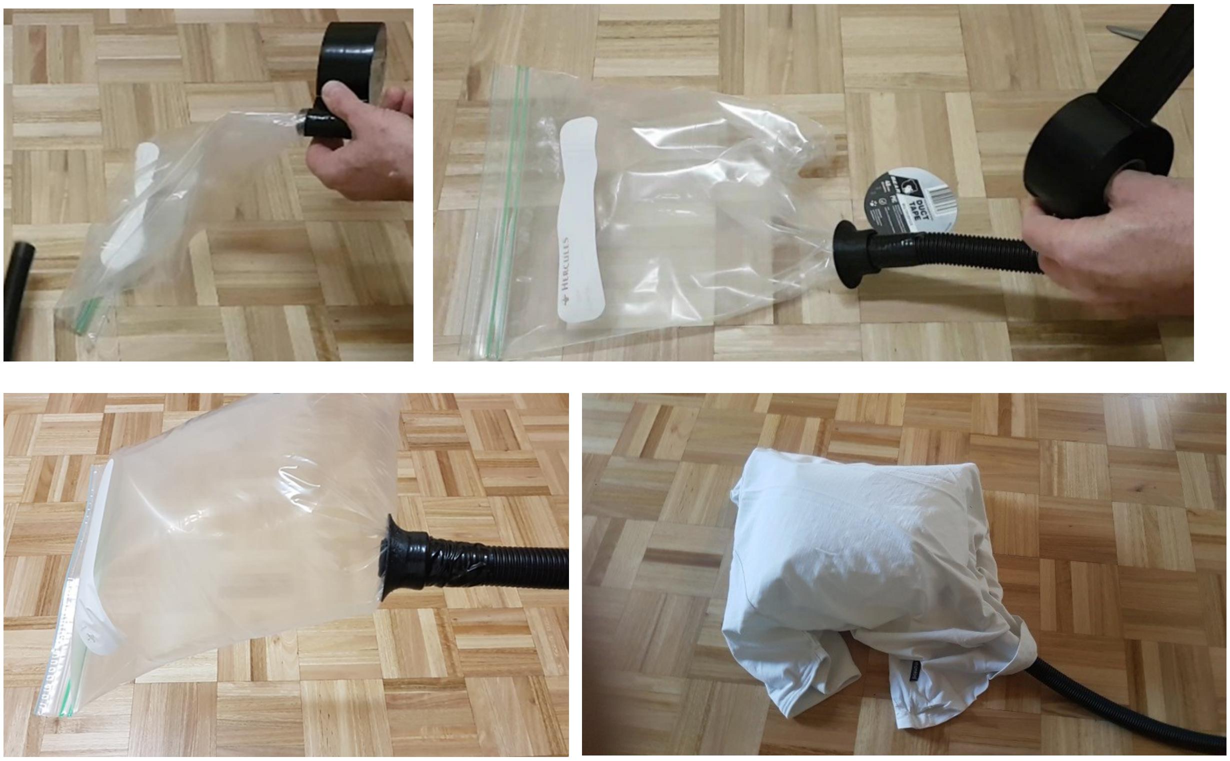


Fig – Breathe Bladder Bag – Pipe attach -> Relief Horn attach -> Loose Fabric Cover

Breath Activated Multi-Valve

Fig – Breath Activated Multi-Valve – Raw Parts (with 3D Support material)

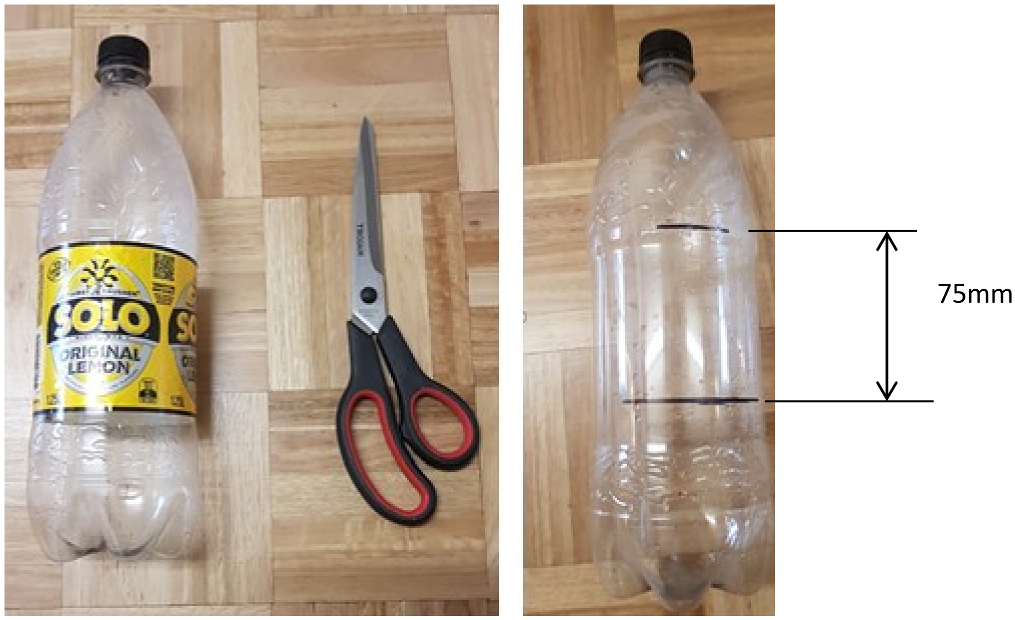


Fig – Breath Activated Multi-Valve – Soft drink bottle

Fig – Breath Activated Multi-Valve –Flatten valve surfaces by Sanding

Fig – Breath Activated Multi-Valve – Flatten valve surfaces by Sanding

Note: An M8 Nut is attached to the top stem of the forward valve, not shown. The M8 Nut provides mass which serves to provide restriction to the forward flow to ensure that the diaphragm lifts the valve assembly and closes off the expiry air port. The means of attachment of the nut is not finalized with the prototype using PVC tape to build out the stem before screwing the nut on and trimming the excess.

Fig – Breath Activated Multi-Valve – Parts cleaned

Fig – Breath Activated Multi-Valve – Create diaphragm from Freezer bag

Fig – Breath Activated Multi-Valve – Seal up with Electrical tape

3M Mask & Breathing Assembly

Fig – Mask & Breathing Tube connections

System Control Valve Mechanism

Fig – System Control Valve – Parts, Tools

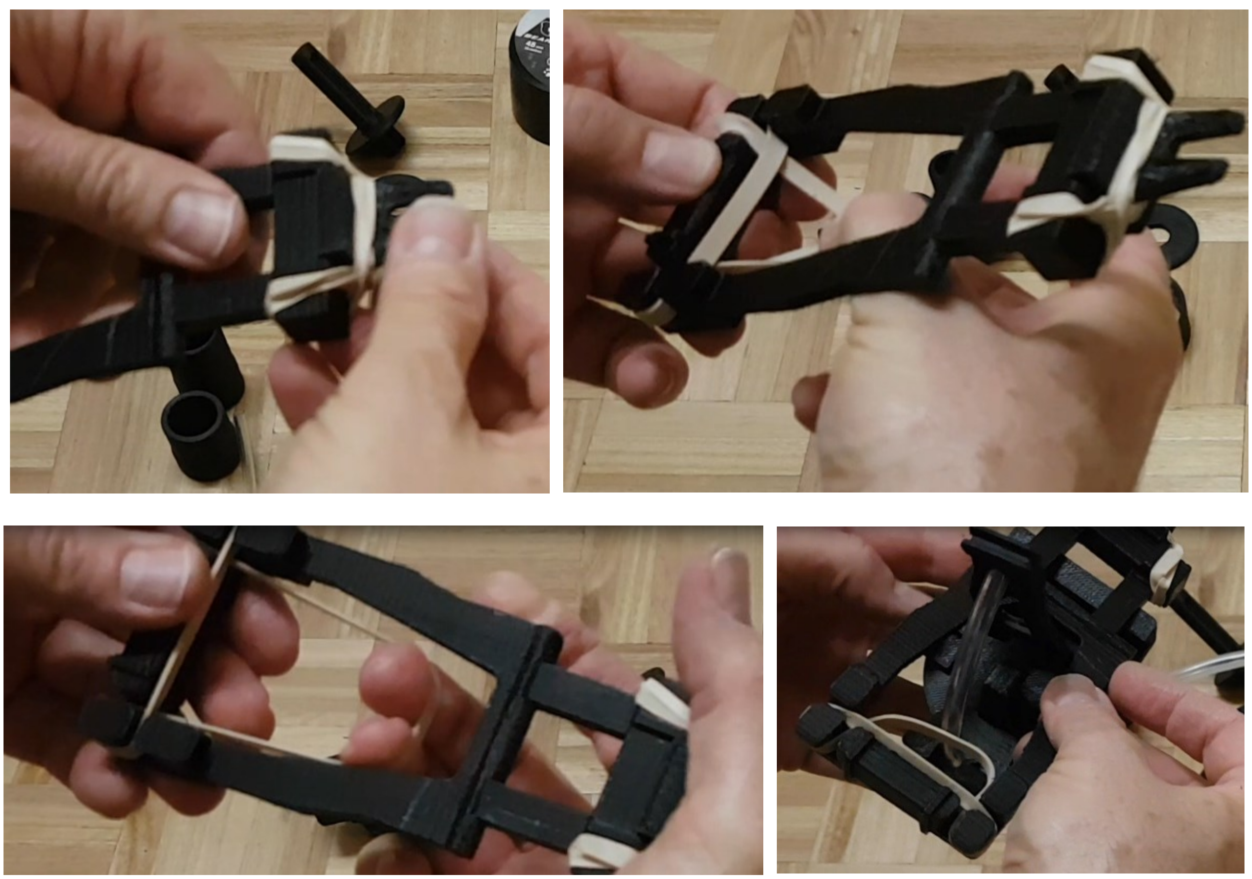


Fig – System Control Valve – Toggle Mechanism – Rubber Band

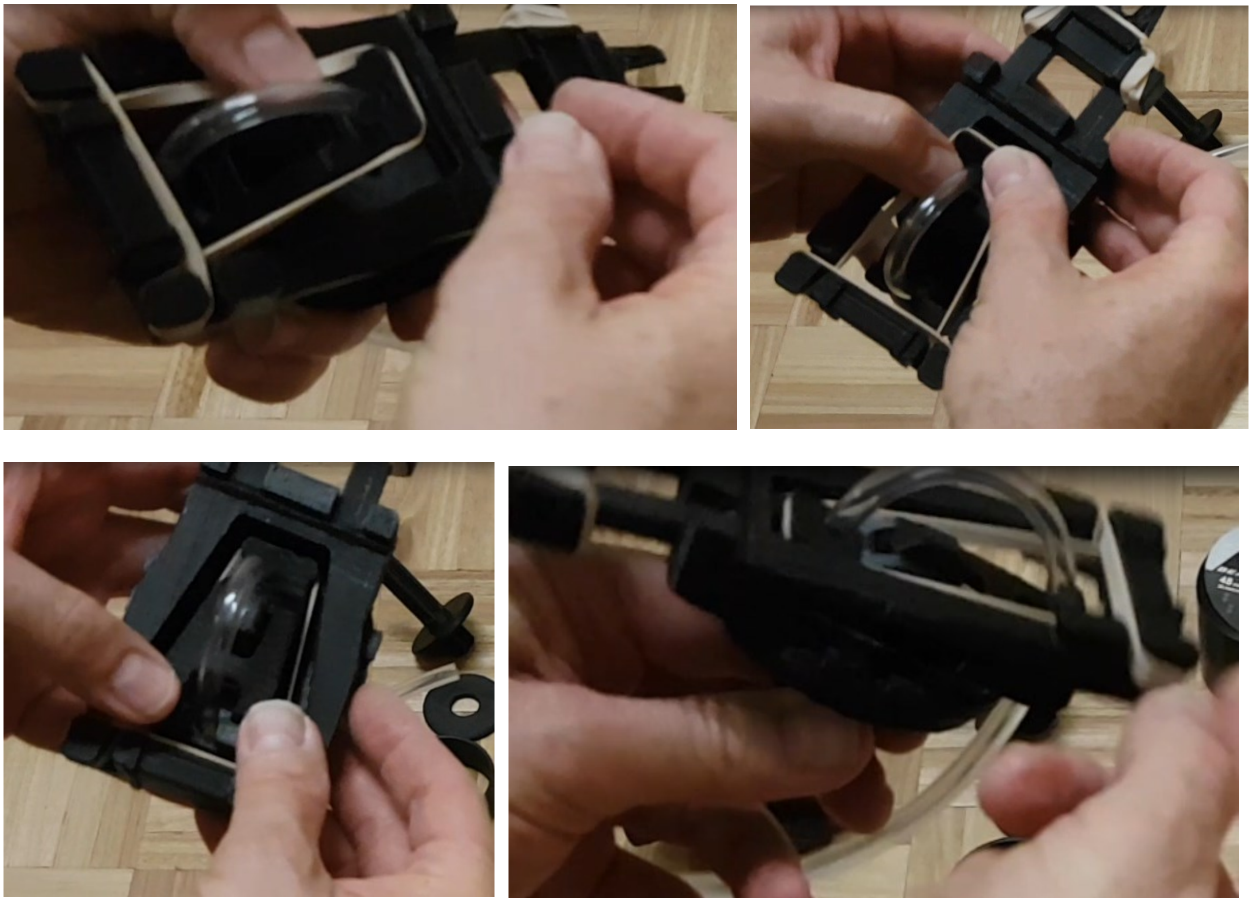


Fig – System Control Valve – Toggle Mechanism – Assembly & Test

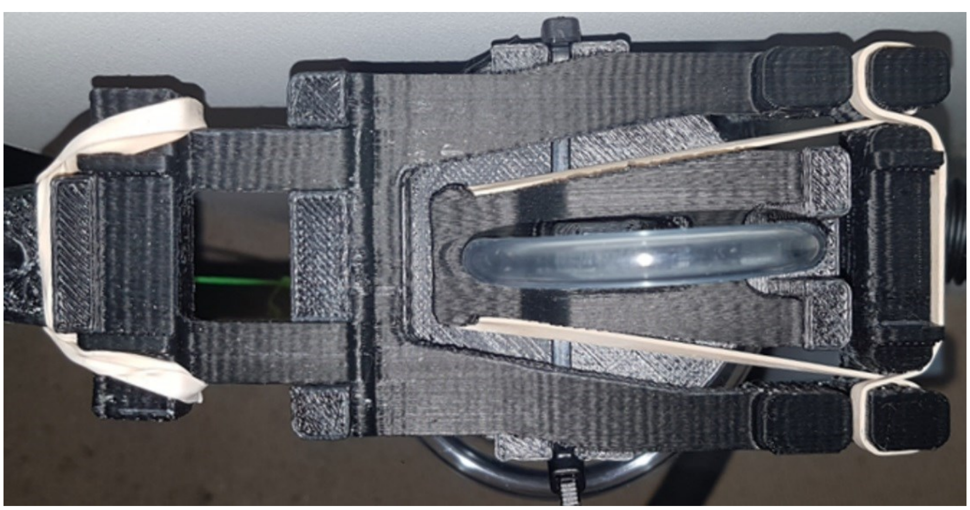


Fig – System Control Valve – Toggle Mechanism – Top View

Fig – System Control Valve – Plastic Diaphragm & Piston

Fig – System Control Valve – Cylinder assembly

Fig – System Control Valve – Cable Tie, Speed control knob

Sensing Cord Pulley and Sense Points

Fig – Sense Cord - Pulleys and Set-point

Fig – System Control Valve Mechanism, Sense Cord and Set-point

Fig – Ventilator, System Control Valve Mechanism, Sense Cord - Pulleys and Set-point

Fig – Ventilator, System Control Valve Mechanism, Sense Cord, Pulleys, Set-point, Elastic

Fig – Ventilator - Complete assembly

Build instructions

Step A1 - Use a 3D printer to create each of the listed component parts from.

The prototype was built with ABS plastic, using ESUN 1.75mm ABS filament.

The files can be downloaded here Build_Files

(Note: this takes considerable time and can be done in parallel other steps below).

Step A2 – Obtain the parts listed from hardware store

Step A3 – Obtain household items from food supermarket

Vacuum chamber

Step B1 – Construct the Vacuum chamber

Items: 1. Malemine panels, 2. Pine 18x40mm pieces, 3. Self tapping screws, 4. Aquadhere PVA glue, 5. Silicone caulking.

Glue and screw the pine pieces to x4 side panels, such that bucket has ~2-4mm clearance.

Join side panels to each other with glue and screws

Apply a chamfer to the edges of the pine using a hand plane

Attach base by glue and screws

Cut a neat fitting piece that slides into the top, and attach it under the lid piece such that it can repeatedly consistently locates the lid.

Apply a 1cm silicone bead to all external joins, and flatten to a gusset using a 45degree plastic spatula and allow 6 Hrs to set.

Use a long flexible bladed knife to cut through the silicone under the lid so that it can be removed and replaced at will while maintaining a vacuum seal. Note, cut as close as possible to the lid flat surface.

Step B2 – Drill holes in the Vacuum chamber;

Use a spade bit to drill 28mm hole at base for breathe pipe

Drill 3mm hole in lid for sensing cord

Breathe Bladder Bag

Step C1 – Clean up all 3D printed parts by removing the support material and removing and smoothing by scraping using side of chisel and sandpaper if required.

Step C2 – Attach pipe to Ziploc plastic food bag using duct tape;

Cut small hole at far end corner of bag and pass the pipe through the bag from large zip opening and push into the hole widening it as required. Leave ~5cm of pipe inside the bag and tape the outside of the bag to the pipe using Duct tape.

Slip the relief horn onto the pipe and slide along the pipe over the duct tape, such that it is in contact with the plastic bag and assists in applying pressure to the first layer of tape. Apply duct tape around the base of the horn so that it doesn't move back along on the pipe in response to pressure in the bag.

Wrap the Ziploc bag loosely inside a smooth rag such as a T-shirt or towel, one layer only

Thread the pipe through the bottom 28mm hole in the vacuum chamber from the inside, and lay the wrapped Ziploc bag neatly in the base. See discussion on treatment of the Ziploc bag. Pull the pipe from the outside while guiding from the inside to push the layered duct tape into the hole to produce a tightly sealed fit.

Step C3 – Insert the 5L bucket into the cavity and confirm that it sits on the bag.

Add 5KG into the bucket, by filling with water or using an equivalent weight such as a gym weight disk, bricks or blocks.

Step C4 – Thread the sense cord through the hole in the top and attach to the bucket handle.

Breath Activated Multi-Valve

Step D1 – Cut a 75mm straight piece from a clear bottle such as a soft drink bottle.

(Discard the contents and avoid ingesting the fluid due to its hazardous sugar content).

Take advantage by including part of the flared/flanged section of this bottle if available.

Step D2 – Use a P180 sand paper on a flat surface to flatten all valve mating surfaces.

Step D3 – Wash and dry all components.

Optionally seal surfaces by brushing acetone (for ABS filament), prior to sanding valve flats, then wash and dry.

Step D4 – Assemble the forward valve by joining the valve disk and followed by applying some electrical tape to the top stem to build it out before screwing on an M8 nut (the M8 nut should be Stainless Steel, but galvanized or Zinc plated are possible if none other available).

Step D5 – Place the expired air valve in position on the upper diaphragm valve carrier and insert the post through the hole to locate the expired air valve in position between the two retracting guide arms.

Step D6 – Insert the forward valve into the lower part of the valve carrier assembly and join the upper and lower parts by rotating anticlockwise. Take care to observe the 3 part interconnect to ensure that after lock the shaft lines are inline on upper and lower sections. Note: the shaft has 4 vanes and the interconnect has only 3 so please choose the correct starting position.

Step D7 – Insert the non-return valve disc into the respective cover and snap fit into place on the base.

Step D8 – Cut a small hole through the center of a freezer bag, and push the bag over the bottom shaft stem. Place the ring over the plastic bag (ie resulting in 2 layers) and press locking the ring and bag in place. Cut away the section of the bag covering the air holes in the carrier assembly.

Step D9 – Place the diaphragm ring on the base, then place the valve carrier assembly shaft into its receptacle in the base, ensuring correct orientation.

Step D10 – Place the clear bottle section over the plastic and press down while lifting the carrier assembly off the base by 2cm to ensure sufficient slack in the plastic.

Step D11 – Check for freedom of motion up and down, the place the lid on correctly oriented, checking that inverting the unit allows the carrier assembly to flop down freely, and observe the correct closure of the expiry valve.

Step D12 – Trim the plastic bag leaving ~5mm, then apply 2-3 layers of PVC electrical tape to the base the to the lid.

Step D13 – Verify that blowing into the valve at the base forces the diaphragm upward, closes the expired air port and results in air emitting from the breathe port, and that the carrier drops back freely afterward.

Step D14 – Press fit the send and receive valve covers over the respective valve discs on the send receive assembly; then press fit the assembly into the top breathe port of the Multi-Valve.

3M Mask & Breathing Assembly

Step E1 – Cut two pieces of 22mm Polyethylene tube and apply 1.5 layer of PVC electrical tape around each of the ends, followed by press fitting into the Send-Receive ports at the multi-Valve at one end, and the Y piece at the other.

Step E2 – Press fit the Y piece to the elbow, applying 1,5layers of tape if necessary.

Step E3 – 3M Mask - Remove the non-return membrane from the 3M mask port to be connected to the ventilator, and apply PVC tape to cover the exit port of the mask.

Step E3 – 3M Mask – Attach the mask attach piece to the filter port f the mask, then press fit into the elbow. Attach the cover to the other unused filter port.

System Control Valve Mechanism

Step F1 – Attach the sense point guide locator to the sense toggle lever using rubber band as shown. Verify that it provides breakaway release under load.

Step F2 – Set up a rubber band on the sense toggle lever as shown

Step F3 – Push the end of 5mm Clear PVC tube through the retaining hole of the cylinder cover base, and into the hole of the over-center toggle arm, positioning to work with any natural curve in the clear PVC tube.

Step F4 – Locate the Push the sense toggle lever into its hinge recess, and place the rubber band around the end of the over-center toggle arm in the groove provided, ensuring the rubber band is central, square and not pulling sideways.

Step F5 – Press the front of the over-center toggle arm down so that it becomes retained under the hook. Then push with thumbs to locate the end in its respective hinge recess. Verify that the lever can move up providing free positive bi-stable operation. Adjust the tube position if necessary, and or clean out hinge cavities to alleviate any tightness as necessary.

Step F7 – Separate one sheet of a Ziploc plastic bag, cut a 5mm hole in the center, and press over the long shaft of the piston. Press the retaining ring over the plastic bag, then melt several burrs with a soldering to retain in place.

Step F8 – Lower the piston and bag into the diaphragm separation ring, then press the PVC pipe section over the ring entrapping the plastic, ensuring that there is slack in the plastic allowing the piston to move freely up and down by ~10mm.

Step F9 – Lower the PVC over the bottom cover, trim the plastic to ~4mm and use 3 layers of electrical tape to fix in position.

Step F10 – Apply the top cover and use electrical tape to fix in place, followed by applying a string of 3mm cable ties, passing between the locating blocks of the toggle mechanism to ensure no interference with the mechanism.

Step F11 – Locate the speed control knob, and use a soldering iron to burr the internal edges to retain in position while being free to rotate.

Final Assembly

Step G1 – Run the sense cord through the pulleys and fasten in place.

Step G2 – Attach the position set point bar to the sense cord, followed by attaching the lower end to bungee and fasten to the cabinet base.

Step G3 – Attach the System Control Valve Mechanism to the cabinet side wall with self-tapping screws.

Step G4 –Mount the Breath Activated Multi-Valve to the cabinet base using self-tapping screws, and attach the tube from the Breathe Bladder Bag.

Test Ventilator

Step H1 – Attach a vacuum hose to the System Control Valve. Verify that vacuum is applied the chamber and that air is delivered to the mask in a repeating breath cycle. Verify that the breath rate can be adjusted by the control knob on the System Control Valve.

Step H2 – Verify that after the breath delivery cycle, that it is possible to exhale through the mask, and that the expired air exits via the expired air port.

Advantages & Benefits

- Air charge is a separate circuit and does not pass through compressor, fan or blower equipment, advantageous where air pump equipment is not safety certified and/or free from oils and particulates.
- Low material item type count
- All items available from household hardware and supermarket stores, and only one material type required for 3D printing
- No electronics modules, specialist valves or components required
- Only mechanical build skills and household tools required to fabricate and assemble

Failure Mode Effects Analysis

Feature	Sub feature	Failure	Outcome	Severity	Likeliness
Vacuum chamber		Leaks vacuum	Reduced or no inspiration pressure	High	Moderate
Weight/Bucket		Distorts, becomes jammed	Reduced or no inspiration pressure	High	Moderate
Bladder bag		Leaks or bursts	Reduced or no inspiration pressure, reduced or no delivery volume	High	Moderate
			Continuous vacuum connection to multivalve, transferring to patient if non-return valve and forward valve are both stuck or diaphragm has burst and valve carrier is stuck	Extreme * **	Low
Air tubing		Pulls off or develops a leak	Reduced or no inspiration pressure, reduced or no delivery volume	High	Moderate
Breath Activated Multi-Valve					
	Non-return valve	Not sealing	Reduced or no inspiration pressure, reduced or no delivery volume	High	Moderate
		Stuck Open	No inspiration pressure, no delivery volume	High	Low
		Stuck Closed	Vacuum stresses diaphragm, diaphragm may burst	V. High*	Low
	Diaphragm	leak or burst	Positive pressure fails to close expiration valve, low or no inspiration pressure.	High	Moderate
			Vacuum passes into the	Extreme	Low

			breathe input-output chamber. Vacuum passes to patient if non-return and expiration valve are both also stuck	* **	
	Expiration valve	Not Sealing	Low or no inspiration pressure.	High	Moderate
		Stuck Closed	High resistance to patient expiration	V. High	Low
		Stuck Open	No inspiration pressure.	High	Low
	Forward valve	Not Sealing	Expiration port cannot close, reduced or low inspiration pressure	High	Moderate
		Stuck Closed	Air not passing to patient. Low or no inspiration pressure	High	Low
		Stuck Open	Expiration port cannot close, reduced or low inspiration pressure, next cycle recharge air mixed with expired air	High	Low
	Valve carrier	Stuck Upward	Expiration valve permanently closed, patient cannot exhale	Extreme	Low
		Stuck Downward	Expiration valve cannot close low or no inspiration pressure	High	Low
	Send-Valve	Not Sealing	Expired air passes into the send tube, reducing efficiency	Low	Low
		Stuck Closed	No inspired air pressure	High	Low
		Stuck Open	Expired air passes into the send tube, mixing exhaled air with inspired air	Moderate	Low
	Receive-Valve	Not Sealing	New air charge sent into expired air tube	Low	Low
		Stuck Closed	Patient cannot exhale	Extreme	Low
		Stuck Open	New air charge sent into expired air tube resulting in patient re-breathing some expired air in the tube.	Moderate	Low
	Air tube connections	Leaking or disconnected	Low or no inspired air pressure	High	Moderate
System control valve					
	Speed control knob	Stuck or dislodged	Breathing rate either excessive or too slow	High	Low
	Diaphragm and piston Assembly	Leak, burst or stuck	Slow or no change of state, slow or no inspiration cycle	High	Moderate

	Vacuum tube connections	Leaking or dislodged	Slow or no change of state, slow or no inspiration cycle	High	Moderate
	Toggle mechanism	Component dislodged or damaged	No change of state, No inspiration cycle	High	High
Position Sense					
	Cord attachment at Mass/bucket	Dislodge or jammed	Air charge volume changed, or no inspiration cycle	High	High
	Pulleys	Dislodge or jammed	Air charge volume changed, or no inspiration cycle	High	High
	Position sense points	Position slipped	Air charge volume changed, or no inspiration cycle	High	Moderate
	Tensioning Elastic/bungee		No inspiration cycle	High	Moderate
Mask & pipe assembly					
	Mask	Not sealing	Low inspiration pressure	High	Moderate
	Mask straps	Dislodge or release	Low or no inspiration pressure	High	Moderate
	Pipe and mask fittings	Leak or disconnected	Low or no inspiration pressure	High	Moderate
Vacuum source	Compromised or loss of power	Reduced or no vacuum	Slow or no inspiration cycling	High	Moderate

***Improve by moving the non-return valve outside of multivalve chamber**

**** Improve by adding inline one way valve between bladder and multi valve**

Notes:

If water is used as a weight, then water leaking into breathing circuit needs to be considered

Any implications arising from condensation in the breathe tubing have not been investigated or considered.

Discussion

Additional weight may be required, eg training weights, up to 10-15Kg. The weight was increased to 15 Kg, and the vacuum system was successful in a producing a cyclic output.

Water was used as the Mass/Weight in this prototype, however this may result in additional failure mode if water was to enter the breathe circuit due to failure.

Adjusting the output PIP (Peak Inspiration Pressure) requires the vacuum source to be temporary disabled, the lid opened and extra weight added. This process interrupts operation and pulls on the sense cord. It may be better to attach the cord to the edge of the bucket such that when the lid is opened it doesn't demand an increase in length. Various topologies such as mounting the System control valve on the lid may reduce the impact to the sense cord when opening the lid.

Adjusting the Tidal volume is by way of moving the upper sense point block, which requires pushing the trailing lock lever and the block in the direction of movement. This can require a two handed operation to support the cord inline strip while moving the sensing block. It is envisaged that a major improvement could be made by moving the adjustment mechanism to a non-moving location on the System Control Valve.

The Lower sense point block determines how empty the bag is before the vacuum is re-enabled. Moving the lower set-point higher results in the bag maintaining a higher volume. If the bag operates at a very high volume, the bag may be over inflated at the upper limit, where the bag balloons out resulting in a nonlinear pressure profile, which would also apply extra stress to the bag. Setting the lower limit too low would result in the unit never re-enabling the vacuum.

The Ziploc bag used as the Breathe Bladder bag while strong is vulnerable to any sharp edge when under pressure, hence a protective wrapping such as fabric is required to separate it from any sharp edges in the vacuum chamber. The relief horn serves to prevent the bag from kinking sharply back over the tape, peeling the tape backward. It is envisaged the relief horn may be improved by allowing the outer lip edge to further roll back on itself, and to also be asymmetrical allowing it to lay closer to the base of the vacuum chamber. Care should be taken to ensure the pipe and horn, do not encroach and pinch on the bucket (mass) bottom edge.

The Vacuum Chamber is bulky but could be greatly reduced in size if solid metal weights were used instead of water buckets. The displacement of the bucket/mass was found to be typically in the order of 10 +/-5cm.

The Breath Activated Multi-Valve forward valve component requires a weight to generate resistance and pressure for expanding the diaphragm. This component can oscillate at some intermediate flow rates, demanding some refinement to the shape governing the opening rate, making the opening less sharp and more progressive.

Vacuum cleaners are loud. It would be preferable to contain a loud vacuum system in a separate enclosure or room using an extra long hose. The low cost 22mm lightweight polyethylene hose may be suitable for extending the vacuum source.

Sterilizing components may be a challenging process. The Breath Activated Multi-Valve, send receive tubing, fitting and mask would be subject to needing sterilization, and possibly also the Breathe Bladder Bag.

3D printed parts, depending on the manufacturing density, resolution and machine used, are typically porous especially when printed with low density settings. The surfaces are rough and often contain irregularities from 3D printing artifacts which increase the surface area providing favorable conditions for harboring pathogens. The non-solid formation raises concerns about harboring pathogens beneath the surface. Extra care must be taken and possibly unit replacement may be the only successful way to provide a degree of sanitation.

3D printed parts printed on low density can be prone to being porous allowing air to pass through even though visually the item looks solid. For example, the bottom of the System Control Valve forming the base of the cylinder, needed to be coated in silicone to prevent loss of pilot vacuum in order for it to function.

The oxygen port simply retains the oxygen tube in the vicinity of the air intake, which would result in significant wasted oxygen form a continuous flow source. A bladder bag may be needed to act as an accumulator to contain the excess O2 for availability during the intake cycle.

Enhancements and Further work

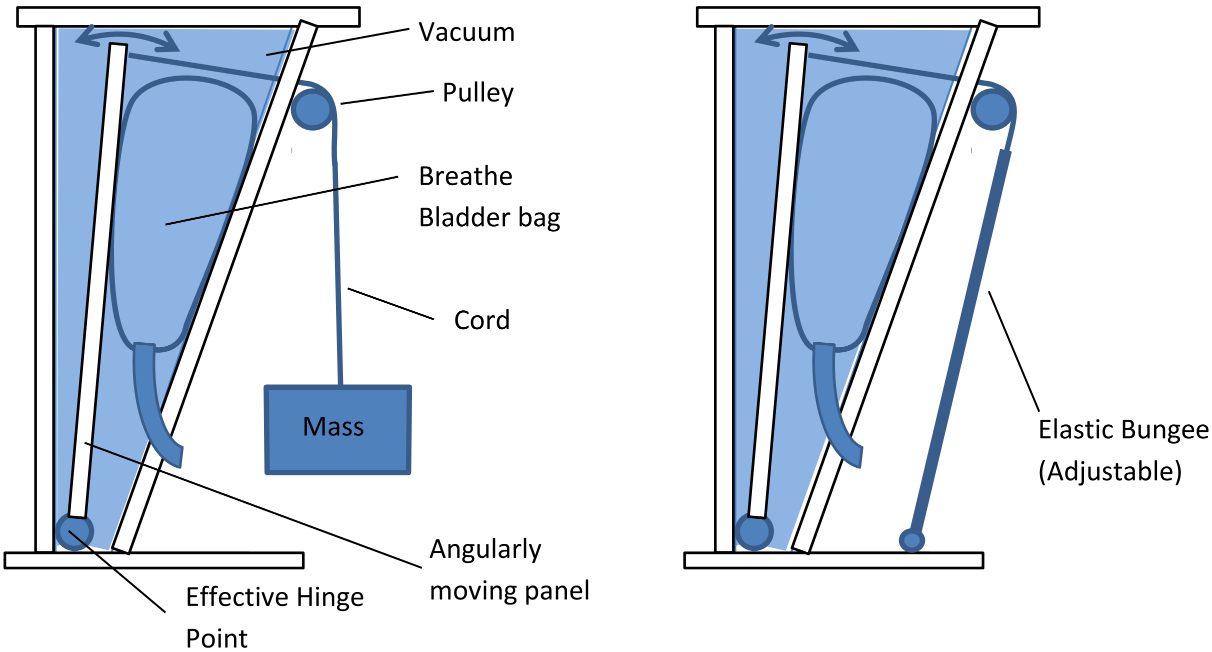
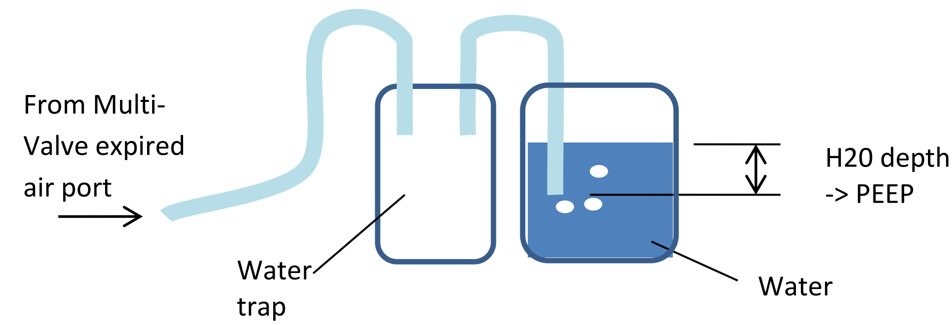


Fig – Alternate Vacuum Chamber Topologies – A) external mass, B) external Bungee

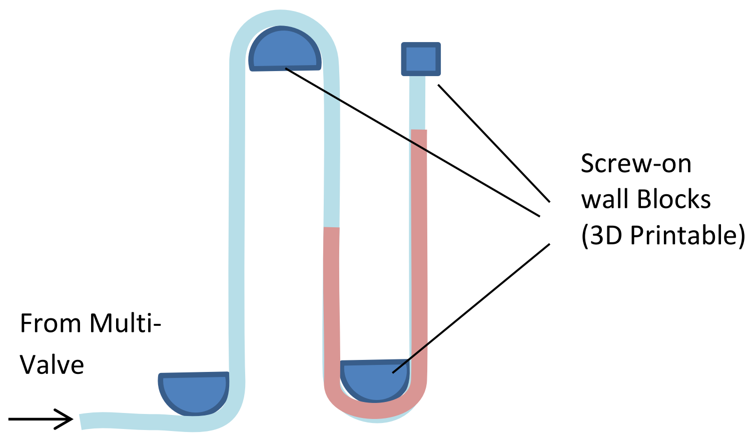
Alternate topologies to make the inspiration pressure more easily adjustable. Left hand diagram A, the mass is external to the chamber for ease of mass adjustment. Right hand diagram B, replaces the mass with elastic with a means to adjust the tension, the elastic being as long as practicable to minimize the difference in force between the start and end of the stroke. The movable internal panel shown for applying pressure to the Bladder Bag could be hinged at the base by the narrowness of the tapering enclosure, thereby not requiring any specific hinge component. This topology would also lend itself to providing simpler position sensing, such as by way of a stiff wire or rod passing directly through a neat hole in the chamber near the base attaching to the angularly the moving panel, and in communication with the System Control Valve Mechanism outside the chamber.

The control system could be enhanced to hold the air charge state until a breath intake or low pressure is sensed, thereby operating in an assisted breathing mode instead of a forced breathing mode.

It would be possible to augment the Toggle Mechanism of the System Control Valve to provide a stable state when the mass is in the charged position, and to sense an airway pressure drop (eg by piston and diaphragm) resulting from the patient breathing in, to activate the state change and thereby provide inspired air to the patient.



Provision for PEEP (Positive End Expiration Pressure) could be achieved by piping the expired air port of the Breath Activated Multi-Valve for bubbling into a water container at a predetermined adjustable depth (5-10cm of H20 is typically required).



Manometer - Pressure indication by manometer. This could utilize the already used 5mm clear PVC tubing, and be attached to the side of the vacuum chamber by way of 3D printed curved upper and lower retainers screwed to the side wall to produce the manometer "S" shape. Provision for manometer tube off-take could be added to the Breath Activated Multi-Valve.

Add a means to provide humidification.

Deploy HEPA filters to air intake and outlet. The Mask package listed in the BOM includes x2 HEPA filters which could be utilized by integrating into the system.

Add electronic sensing of air pressure, humidity, and mass air flow, to monitor and generate alarms as required.

Add augmentation by electronics to control the breathing rate.

Add augmentation by electronics to change operation to assisted breathing mode as opposed to forced breathing mode.

Conclusion

It was found that it is possible to create a rudimentary ventilator from readily available household items and 3D printed plastic components; however it is a much less trivial exercise than first expected. The challenges in not having access to high precision molded rubber-like flexible membrane parts for valving can be overcome albeit with an increase in complexity including a higher component count, and therefore reduced expected reliability. While the idea of using a weight on a bladder bag powered by an unregulated vacuum source in a separate air circuit was first thought and expected to give rise to an inherently safe system, in practice and after some FMEA analysis at least one potentially extreme adverse and hazardous condition was identified under component failure scenarios which could result in vacuum being transferred to the patient. Anyone embarking on utilizing this concept would be well advised to mitigate this outcome. Although the system looks simple, it is expected that a high level of familiarity, understanding and knowledge of the intricacies of this apparatus would be required in order to provide effective support to a patient, and as such may be deemed an un-user-friendly device. Additionally any non-ducted vacuum sources are typically particularly noisy, and would be best positioned in a separate room or enclosure.

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Licensing

Disclaimer

Presented here is a starting point for a proof of concept model, from which ideas or concepts disclosed are free for development and investigative purposes only.

No claims are made that any of the objectives or requirements as listed are desirable or if indeed they result in a solution which is suitable for human use, or if in fact the resulting prototype meets any objectives or requirements.

Anyone using this information agrees to waive any and all liability.

Warning

A ventilator can be a hazardous device and requires appropriately medically trained and certified personnel.

This is an unproven, untested prototype with much more work required to make this device useable or acceptable for use.