Y-VENT VERSION ALFA INSTRUCTIONS FOR USE

Version ALFA

Y-Vent Project
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1. Introduction

The Y-vent is not a medical device. It cannot be used as such. Please refer to your local jurisdiction to learn a legal frame work for the emergency usage. The unit can be used in two basic configurations: 1) NO PEEP 2) PEEP. It provides physiological pressures if a proper pressure source is connected to the input port AND a compliant volume is connected to the patient port. The patient pressure can be adjusted by adjusting the supply pressure and the PEEP valve if used in PEEP configuration.

Risks

The device is a simple pneumatic oscillator triggered by pressure. It pumps air in to a set pressure threshold, reverses flow, pumps air out to a set pressure threshold and resets. It cannot: deliver a set volume of air, trigger alarms, display measurements, clear mucus, or perform many other critical functions of modern-day ventilators.

Basic Failure Modes

Y-Vent is reliable if the following requirements are satisfied:

1. Dimensional accuracy of the inlet and channel wedge is maintained
2. Seal of all chambers of the device is maintained
3. Air flow through the device is greater than leaks in patient circuit (preferably no leaks)

Y-Vent can fail in the following way:

- Violation of requirement 1 will change the pressure thresholds and pneumatic behavior of the circuit.
- Violation of requirement 1 may result in high frequency oscillation
- Violation of requirement 2 & 3 will result in no actuation

Theory of Operation

When pressure is applied to the input terminal of the Y-Vent, the air flow stream created by the narrowing in the geometry creates a vortex (Coanda effect) which attaches the stream to the patient output channel. When the flow stream encounters resistance on the output terminal (increased pressure in patient's lungs), the first vortex collapses and the

air flow stream redirects to the second output channel (again creating the Coanda effect vortex). In this fluidic configuration, air flows from the patient output channel to the output terminal in addition to from the input terminal to the second terminal. This allows for exhale of gas. Once pressure in the patient's lungs reaches the threshold pressure, the second vortex collapses and restarts the cycle. Our design uses a different approach to create the Coanda vortex effect, but functionally they are the same.

2.Y-vent basic features

Fully 3D-printed

Main Body

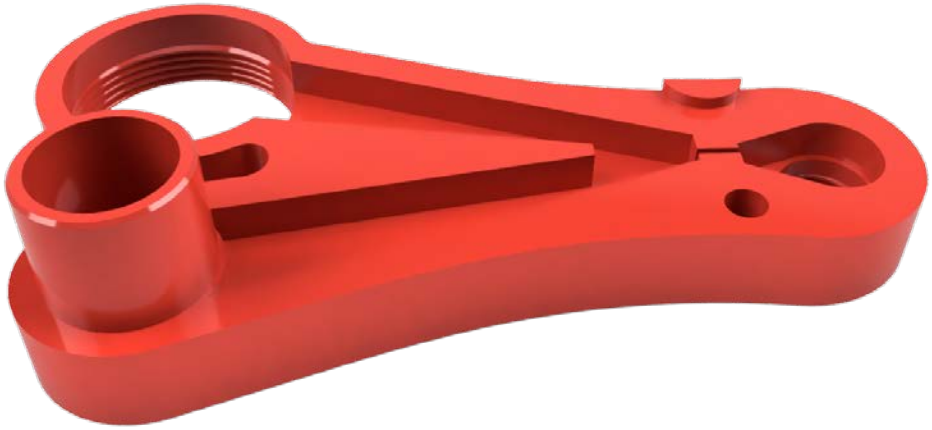

Figure 1. 3D printable main body

The main functional component of the Y-Vent consists of main input port for 0.3-2 psi regulated pressure, standard 22mm patient output port, and threaded PEEP/vent port. The threaded port mates with the PEEP module to provide a standard PEEP receptacle. The threaded port can also be used with a one way HEPA filter to reduce aeorosolization of viral and bacterial particles.

Cover Plate

Figure 2. 3D printable cover plate

Cover plate is used to seal all channels and provide basic use information of the device.

Note: Special care needs to be taken to glue the cover plate to the main body. This is the most common point of failure during assembly.

PEEP Module

Figure 3. 3D printable PEEP Module

The Y-vent can be fully printed. The list of printers which are suitable for this job is attached (Attachment A – list of printers). The printed version has a full Pressure Support Mode, PEEP valve port, Fall back Respiratory Rate, and 3D printed PEEP valve can be printed as a separate module (released separately from the main ventilator). It will NOT have the Respiratory Rate adjustment module and oxygen module which

requires additional components and instructions (will be published separately). The Balloon for the RR module needs to be acquired separately.

Estimated printing time is 4 hours, but this may vary depending on the printer.

No-moving-parts reliability

The Y-vent has no moving parts in the NO PEEP configuration, thus its reliability is limited only by the pressure source. As long as the pressure is supplied and a compliant volume connected to the output, the vent will cycle. Adding a PEEP valve will add moving parts (spring and membrane), thus the reliability may change.

Assembly time: less than 10 minutes

The assembly can be done with a double sided tape, glue gun and an x-Acto knife. Equivalent glue and knife options are listed in Attachment B (Attachment B- tools needed). Respiratory Rate (RR) adjustment mode will require a balloon. Please see RR module assembly instructions (will be published separately).

Cost - less than $12 (depends on the type of 3D printer)

The cost is basically the cost of the 3D printer filament, glue, and tape. Plus, the cost of the balloon (roughly an additional $10).

Contamination limiting and Disposable

The Y-vent is a covid-19 specific device. It was designed to limit the contamination by being disposable and working always with positive pressure, so the contamination cannot cross beyond the vent to the pressure supply and modules connected on the pressure supply line. We do not recommend any disinfecting procedures as it wasn't designed to withstand any disinfecting solutions or treatments. The unit should be safely disposed of after being disconnected from the patient and a new unit should be used. 3D printed units are not sterile!

Basic mode – Pressure Support

The basic mode of operation is called Pressure Support. During the inhale phase, it will slowly reach the preset level (End Inspiratory Pressure), and then it will reverse the ventilation phase. Similarly, during the exhalation phase, it will reach the preset End Expiratory Pressure level and after that, it will reverse the ventilation phase to inhale. If the patient is breathing on his own, the vent will follow patient's breathing pattern unless it falls beyond the Fall Back Respiratory Rate. If the patient doesn't breathe, the

unit will breathe for him maintaining the preset respiratory rate (RR). Both pressures (End Expiratory and End Inspiratory) can be regulated by the supply pressure and the PEEP module. If the PEEP module is not installed, then the only adjustment available is the supply pressure level. The Y-vent can vary EIP between 5 and 50 cmH2O and the EEP between -5 and 0 or 5 and 20 cmH2O (in PEEP configuration). Pressures ranges may differ depending on the manufacturing quality, overall leakages, and stability of the pressure supply.

PEEP (Positive End Expiratory Pressure)

The PEEP capability is provided by the PEEP module. The PEEP module is printed together with the main configuration and can be connected to a PEEP valve, which converts the unit to its PEEP configuration. Regular medical PEEP valves can be used, or a 3D printed version. Rotating the cap of the PEEP valve clockwise will increase the PEEP, and rotating it counterclockwise will decrease the PEEP. Refer to the markings on the PEEP valve to adjust it to the desired level. The 3D printed version has no markings and needs to be calibrated by the user. If the PEEP valve is 3D printed, then the opening pressures will change with the printer, filament, and slicer settings. ALWAYS CALIBRATE YOUR 3D PRINTED PEEP VALVE.

Adjustable EIP and EIP

EIP and EEP will differ for the NO PEEP and PEEP configurations. Please refer to appropriate characteristics (Section 6).

Adjustable RR

Because of the fact that the Y-vent will always try to achieve the preset pressures operating with relatively constant flow, the Respiratory Rate will depend on the volume and compliance of the breathing loop, including patient's lungs.

If needed, the Respiratory Rate can be adjusted by connecting the Respiratory Rate module and a balloon. The balloon will slow down the respiratory rate to its minimum. If fine adjustment is desired, a volume limiting clamp can be used, please see the RR module manual.

When the PEEP valve malfunctions in the open position, the Y-Vent will start working in NO PEEP configuration. This will cause the pressure characteristics to change. Always check visually if the PEEP valve is working.

IF THE PEEP VALVE MALFUNCTIONS, THE PEEP WILL NOT BE MAINTAINED

Supply pressure 60l/min(max) at 30 – 200 cmH2O

Pressure supply needs to provide medical grade air, please refer to your local procedures. This air will be pumped to the patient's lungs. Make sure that the air has required quality. Tested regulators are listed in Attachment C.

Connects to a trach tube or mask

The Y-vent works best with the Endotracheal tube (ETT), but can be also used with a mask. If the mask is used, it needs to be sealed off properly. Leaking mask may lead to suboptimal performance or even malfunction due to inability to reach the preset EIP or EEP. With unconscious patients, when the trachea is blocked, a mask may cause irregular cycles.

Oxygen supply possible

Oxygen can be supplied via an oxygen module. FURTHER RECOMMENDATIONS WILL FOLLOW

3. Clinical considerations (Preliminary)

Inspection before usage

After assembling the unit, a visual inspection should be performed. The unit can be roughly tested for leaks by blowing slightly positive pressure to the input port (e.g. 20 cmH2O), closing the patient and vent ports with fingers and listening to hissing sounds. If no leaks detected, the test lung (e.g. Maquet test lung 190 – with opened covers) should be connected to the patient port with a pressure transducer. Test the unit for min and max supply pressures in NO PEEP configuration. Refer to the Pressure tables to see if the values are comparable within 2cmH2O, if not, create your own tables using the Y-vent tables as a template. Connect a PEEP valve and test for 5, 10, 15, 20 cmH2O of PEEP, compare to Y-vent characteristics. If your results are within +/- 2cmH2O, you can use Y-vent tables, if not, create your own tables using Y-vent tables as a template. Please note that not all PEEP values can be achieved with low input pressures. Refer to Y-vent characteristics. If no pressure transducer is available, a manometer can be used to observe EEP and EIP. If neither is available, a makeshift manometer can be produced from a transparent tubing filled with water (see video: https://www.youtube.com/watch?v=XUeu1THIvc0) .

NEVER USE Y-VENT WITHOUT TESTING

Pressure support with patient breathing If the patient is breathing, make sure that the pressure settings are comfortable for him. Settings which are too high may cause discomfort when changing from inhale to exhale.

Weaning seems to be the best way to use the Y-vent if regular ventilators are desperately needed for more difficult cases. The patient should be intubated and the switch from the regular respirator to the Y-vent would be performed after the Y-vent is setup and EEP and EIP are adjusted on a test lung.

Apnea With a passive patient, Y-vent will fall back to a fixed RR. The Y-vent is a very reliable device if 1) the supply pressure is properly set and stable 2) the output loop is sealed off.

MAKE SURE THAT THERE ARE NO LEAKAGES IN THE BREATING LOOP SINCE THIS MAY CAUSE THE VENTILATOR TO STOP.

Oxygen titration FURTHER RECOMMENDATIONS WILL FOLLOW

4. Trouble shooting

Y-vent not cycling

Possible causes: 1) Unit is not glued properly (internal or external leakages). Fix: Re-assemble 2) The patient loop has leakages, Fix: Seal off leakages/replace the loop, make sure the ETT connector works properly 3) The patient port is blocked. Fix: Remove the blockage.

Vibrations (the unit is vibrating with high frequency)

Possible causes: 1) Unit is not glued properly (internal or external leakages). Fix: Re-assemble, 2) The patient loop has leakages. Fix: Seal off leakages/replace the loop, make sure the ETT connector works properly 3) The hose in the patient loop is kinked, ETT blocked. Fix: Remove kinks, revise intubation.

RR too high, need to reduce

Possible causes: 1) Small lungs and or tidal volume. Fix: Use RR adjustment module, or increase the volume of the breathing loop by using longer hose, or reduce supply pressure (warning: it will change EEP and EIP).

RR too low, need to increase

Fix: Reduce the breathing loop volume. Decrease supply pressure. (warning: it will change EEP and EIP).

5. Manufacturing and Assembly

- Tools needed - see Attachment B
- Files needed for 3D printing can be obtained at http://3dprintedventilator.com/ OR https://github.com/MSwoboda/Y-Vent

Explanation

Y-Vent has been designed to be entirely 3D printed. However, CAD and STL file folders include both 3D printable versions and a rough version adapted for CNC milling and injection molding (threads removed, holes sized for tapping, overhangs removed).

The design has been printed and tested using Markforged Onyx One and Prusa i3 Mk3 printers.

3D printed versions can be assembled using double sided tape (video: https://www.youtube.com/watch?v=hZ9rezzCuwM) or silicone glue.

Both methods are presented below.

Medical Grade Silicone Adhesive Method

This method creates a robust seal between the main body and cover using a medical grade silicone rubber. This is the preferred method of sealing the part.

Tools

- Spatula
- Q-Tip
- Medical-grade Silicone Adhesive
- Paper towel
- Glue gun

Instructions

1. Remove supports from 3D printed parts and prepare tools.

Figure 4. Tools and parts needed for the first step of Y-vent assembly

Add blob of adhesive to the smooth side of cover (side without writing). The amount of adhesive should be enough to create a thin (0.2-1mm) layer.

Figure 5. Glue application

3. Distribute adhesive evenly with spatula. This should create a uniform layer with no pits. Fill any gaps with more adhesive and smooth out with spatula.

Figure 6. Glue distribution

4. Lock the cover on output port and align with protrusion on the main body.

Figure 7. Parts alignment

5. Clean any adhesive leaking out with a paper towel.

Figure 8. Excess glue removal

6. Apply pressure to the part and leave to try until adhesive is set. Time and pressure will depend on adhesive type. Note the setting and curing time.

Figure 9. Cure under pressure

Double Sided Tape Method

(video: https://www.youtube.com/watch?v=hZ9rezzCuwM)

Tools

- Scissors
- Scalpel or sharp knife
- Strong Double-Sided Tape
- Hot air gun (optional)

Instructions

1. Apply a single strip of double-sided tape to cover the input port and one arm of the Y-Vent. A single strip should cover the input port, narrowing at the input port, and wedge dividing the Y-Vent into two channels.

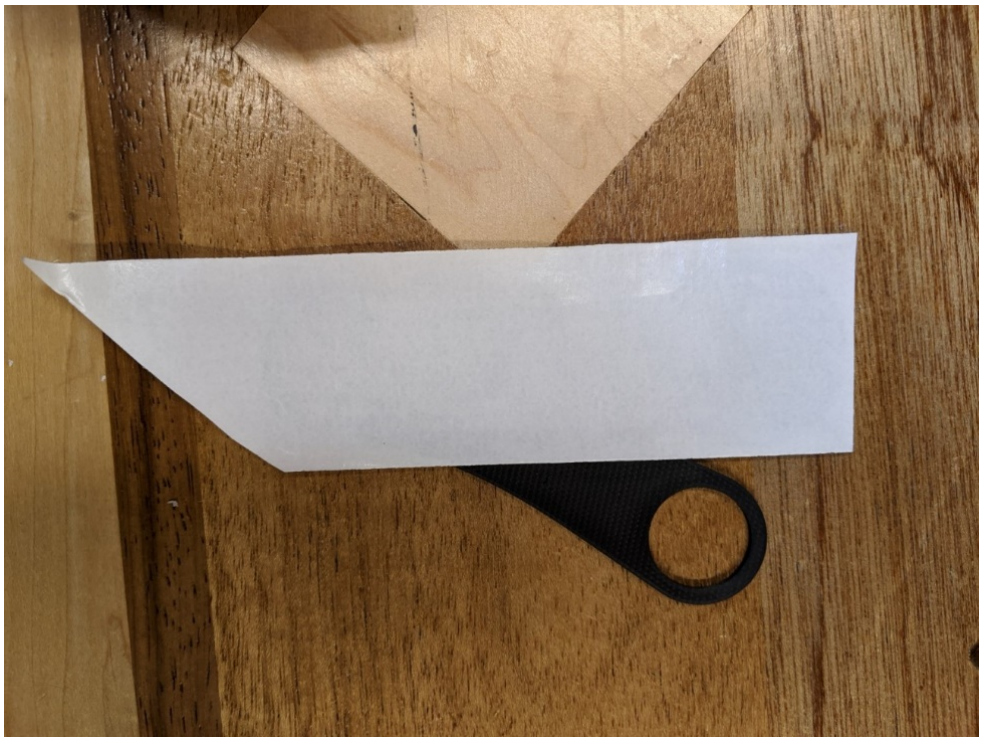

Figure 10. Double sided tape application, step 1

2. Apply second strip to the remaining part of the cover. The two strips should create a small (less than 0.5 mm overlap) to provide optimal sealing.

Figure 11. Double sided tape application, step 2

3. Cut the tape with a scalpel or scissors to align with the edge of the cover.

Figure 12. Tape cutting

4. Lock the cover on the output port and align with protrusion on the main body. Remove any protruding tape with a scalpel. The protruding tape can also be removed with a hot air gun (**Note:** Apply a small amount of heat to only melt the tape and not the plastic of the Y-Vent).

Figure 13. Parts alignment

5. Apply pressure to the part.

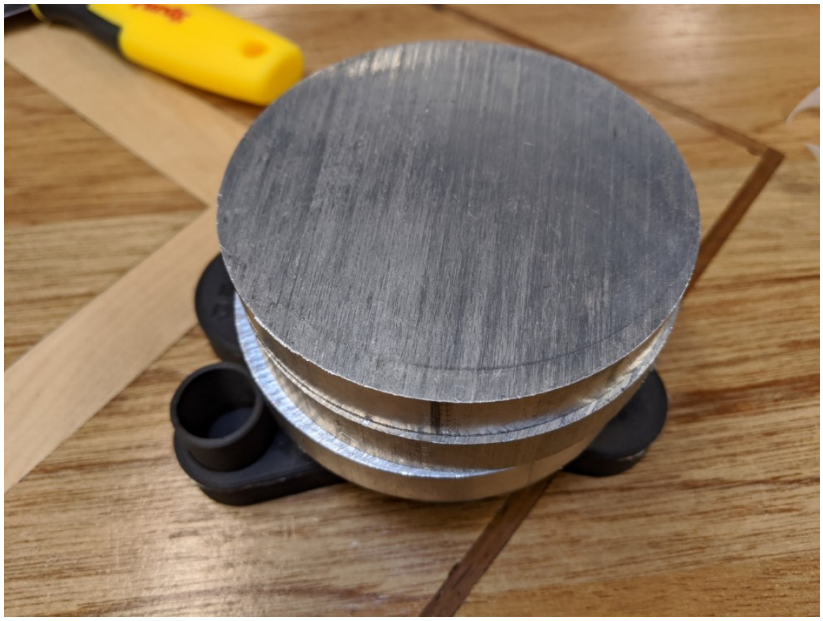

Figure 14 Cure under pressure

Input Port Mount

The Y-Vent has a standard 1/4 NPT thread on the input port, which can fit a wide variety of connectors (like push to connect, barb). Select the connector most appropriate for your environment (testing, clinical). When inserting the connector, apply a small amount of glue to the threads to seal it.

Note: Make sure the connector's edge does not protrude over the floor of the Y-Vent channels.

Note: Make sure that any adhesive applied to the threads does not leak into the input chamber, especially the narrowing after the input port.

Figure 15 Fully assembled Y-vent in PEEP configuration

6. Y-vent verification. Pressure/Flow characteristics

Pressure flow testing

Connect your Y-vent to the pneumatic system as shown in figure 1. Use sensors listed in Attachment B. If pressure sensors are not available, use a makeshift U-tube manometer (video: https://www.youtube.com/watch?v=XUeu1THIvc0).

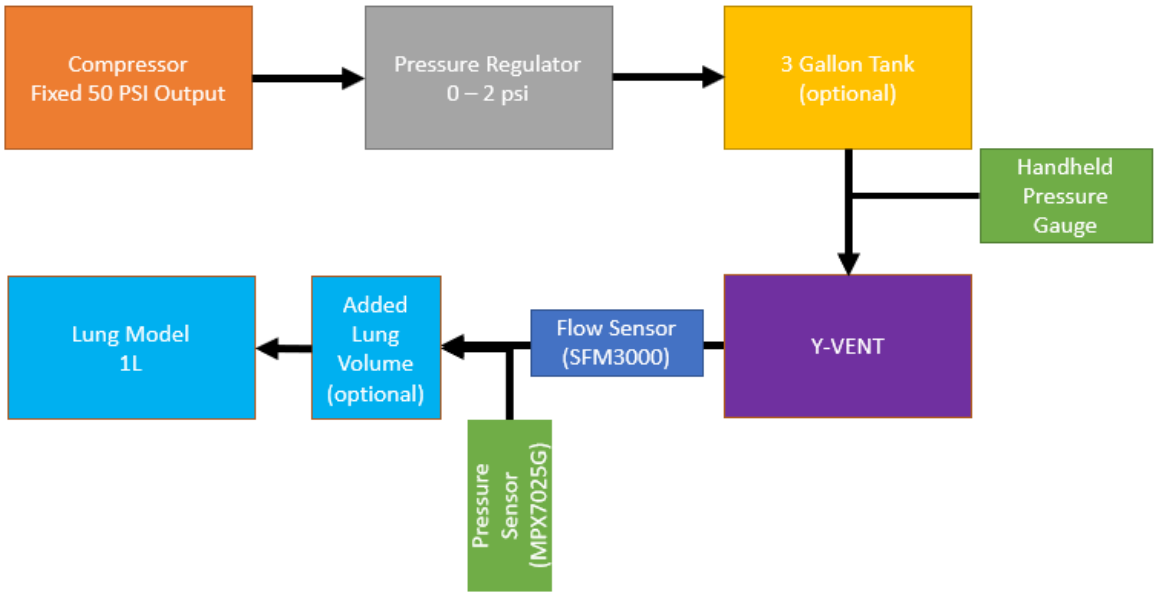

Figure 16. Flow/Pressure testing setup

Make sure that you pressure source is in agreement with the requirements (see section 2 Supply Pressure).

Testing Procedure (Y-vent setup: https://www.youtube.com/watch?v=HLaus3BIPC4)

1. Assemble setup as shown in figure 1 DO NOT CONNECT 50 PSI source to the pressure regulator
2. Check connections for leakages
3. Mount/Adjust PEEP valve to desired level
4. CONNECT 50 PSI source to the pressure regulator
5. Adjust input pressure to desired value (we suggest tests at 40, 60, 80, 100, 120 cmH2O)
6. Measure flow GOTO 5 repeat until 120 cmH2O
7. END

Collect Flow pressure data as shown in section 7. Use tables as a guide during operations.

The characteristics printed below are obtained on the ALFA version printed on Markforged ONYX series printer. The unit was working with a patient loop of ~ 1.5 L (with 1 L test lung). The testing setup is the same as shown in Figure 16, but an additional flow sensor is placed before the Y-Vent to measure air flow supply (F-supply).

Legend: Supply Flow F-Supply, EIP End Inspiratory Pressure, EEP End Expiratory Pressure, F min highest flow during exhale, F max highest flow during inhale, RR Respiratory Rate. Error +/- 2 cmH2O

PEEP configuration characteristics (Pressure/Flow)

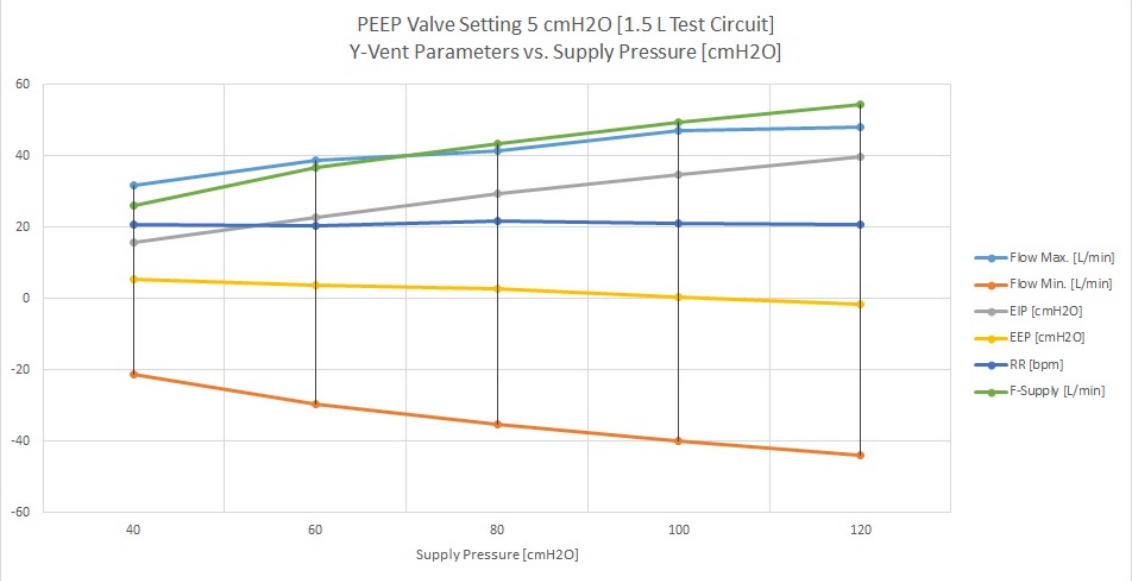

Figure 17. Test results

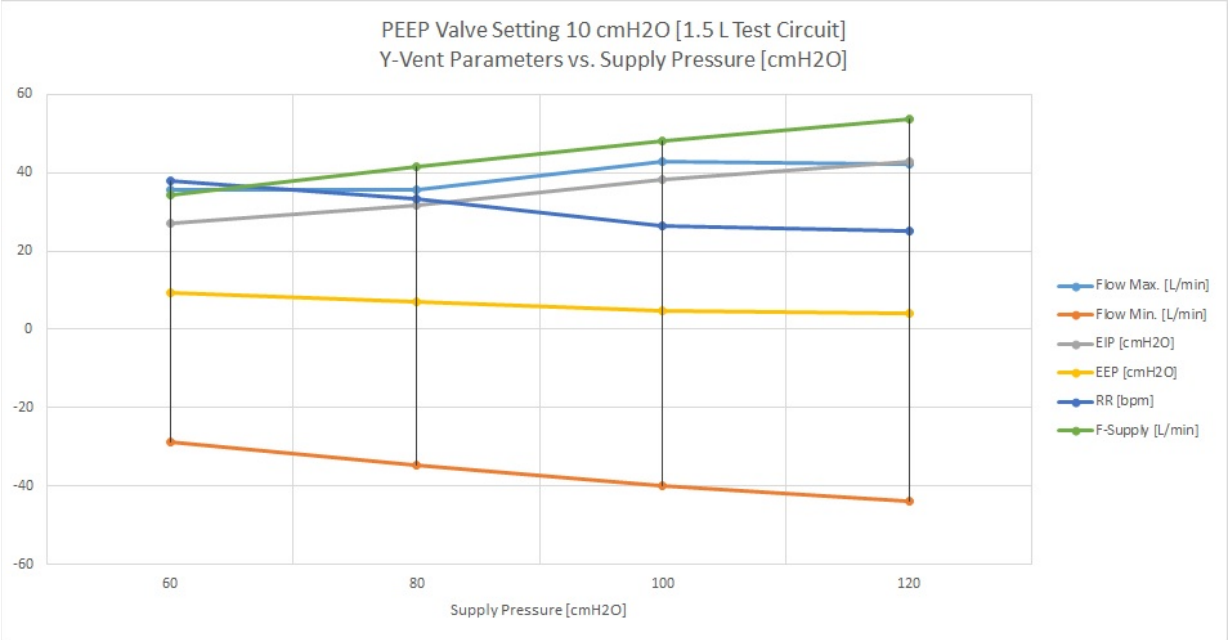

Figure 18. Test results

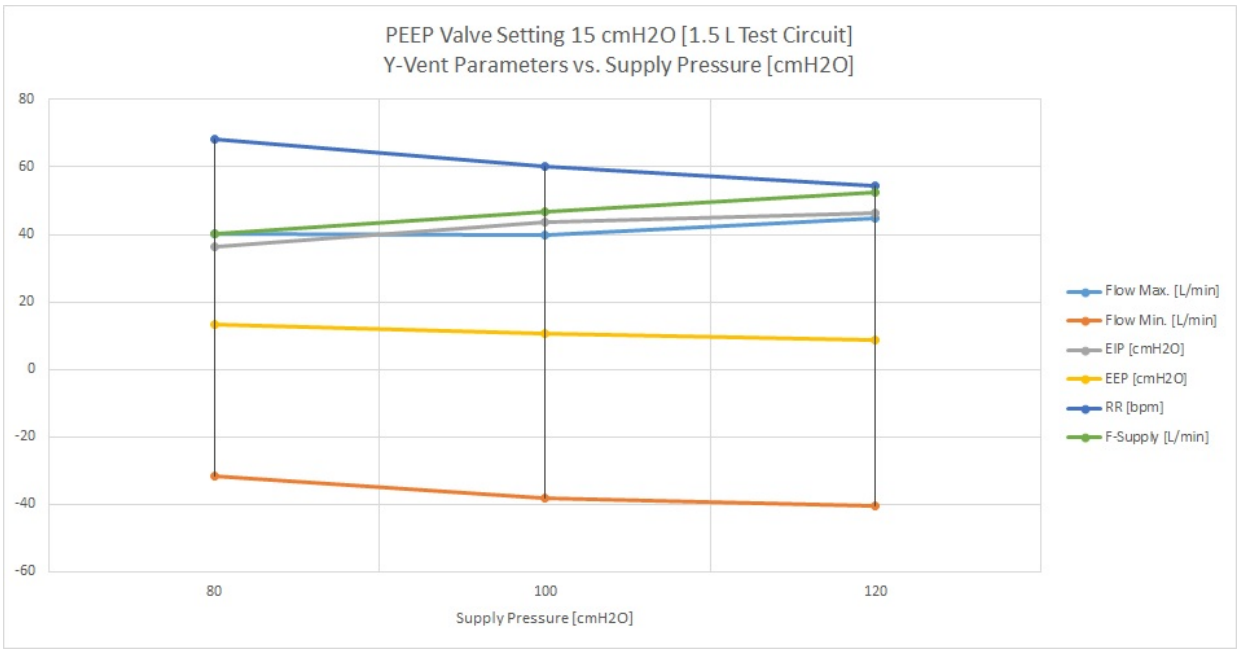

Figure 19. Test results

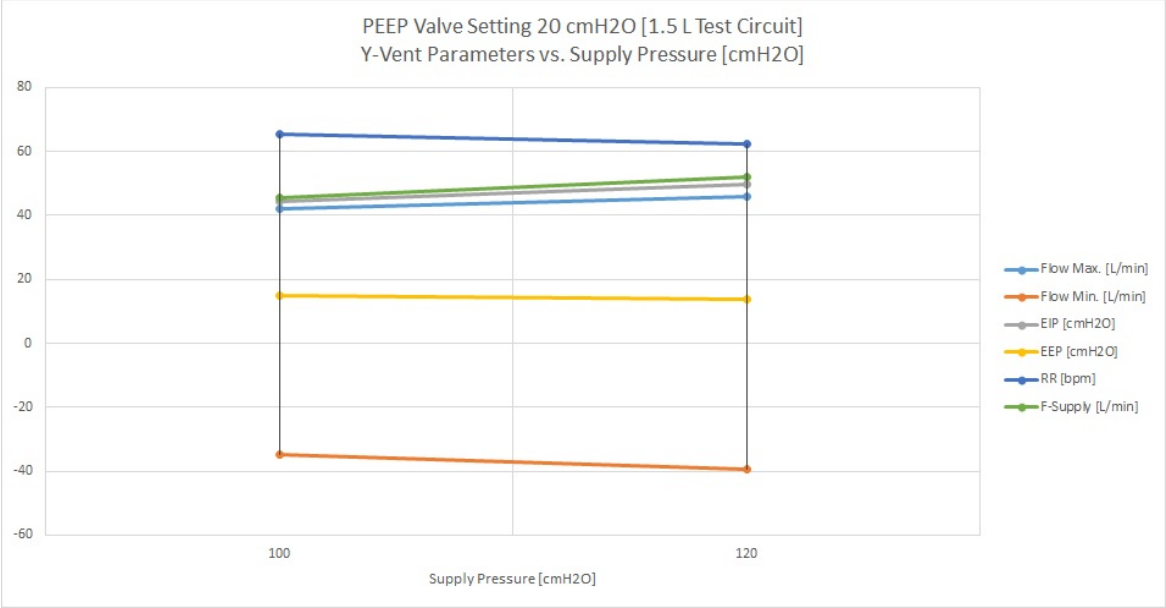

Figure 20. Test results

NO PEEP configuration characteristics (Pressure/Flow)

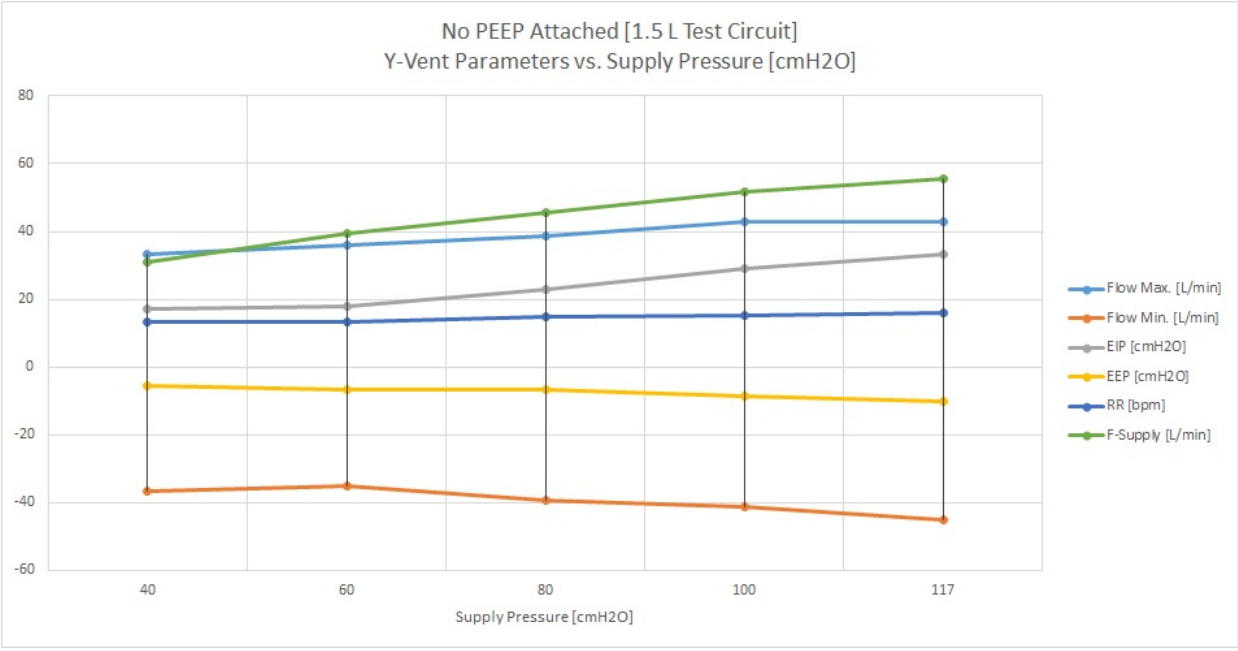

Figure 21. Test results

Note: PEEP settings do not directly translate to the true PEEP value. Calibrate before use. Most likely PEEP valve settings will need to be greater in order to achieve desired PEEP level.

Y-VENT PRINTED ON DIFFERENT PRINTERS USING DIFFERENT MATERIALS MAY PERFORM DIFFERENTLY

WARNING: ALWAYS CALIBRATE YOUR Y-VENT BEFORE USAGE!

Failure Reporting

We encourage everyone interested in the project to 3D print and try out the Y-Vent on your own. All you need is a 3D printer, lung model (could be a balloon, but ventilator test lungs work best), and a 0.3-2psi pressure source. If you'd like to add PEEP, a PEEP valve is necessary. Please post all problems you encounter in the Github's issues section along with a description of how the device was printed, the test setup, a detailed description of the problem, and possible solutions or send an email to contact@3dprintedventilator.com

http://3dprintedventilator.com/

Literature

[1] The Fluid Amplifier and its Application in Medical Devices

[2] Taxonomic Trees of Fluidic Oscillators

[3] Experimental Comparison between the Flow Field of Two Common Fluidic Oscillator Designs

Attachment A - List of tested 3D printers

1. Markforged Onyx series
2. Prusa i3 based

Attachment B – tools needed

Manufacturing

1. 3D printer
2. Double sided tape (verified brands: Shurtape, www.shurtape.com)
3. X-Acto knife
4. Glue gun (brand tested: Surebonder) the glue gun temperature should be lower than the 3D printer filament melting point. Watch for heat damage during gluing process.
5. For the silicone glue option use RTV 108 adhesive and spatula
6. Q-Tip
7. Paper towel

Verification

1. Pressure transducer with display capabilities. Range: -10 through 200 cmH2O

OR

Manometer Range: -10 through 200 cmH2O

OR

Transparent flexible tubing (2.5 m long) filled with water + ruler with centimeter scale

Flow meter range -200 through 200 l/min

Attachment C

Tested pressure sources:

Air regulators:

- Type 70 Pressure Regulator (Bellofram Corporation)