Production Methods for Custom Components

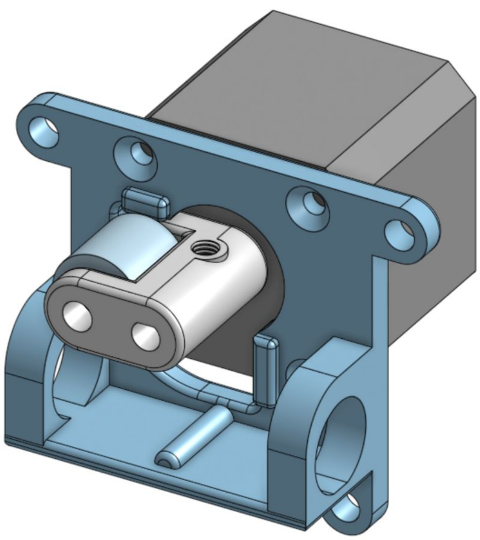
One of the foundational principles of the ventilator design was to avoid, where possible, custom components. However, for several parts, it was unavoidable to design a new component if price, availability, and functional performance requirements could not be achieved with already-available components. This document describes the few components that have been custom designed for this application. The manufacturing process for the prototypes is discussed, as well as plans and features for production at larger volumes, with an approximate scale-point of 1,000 units. For smaller orders of less than 100 units production, some of the prototype production methods may prove more cost- and time-effective.

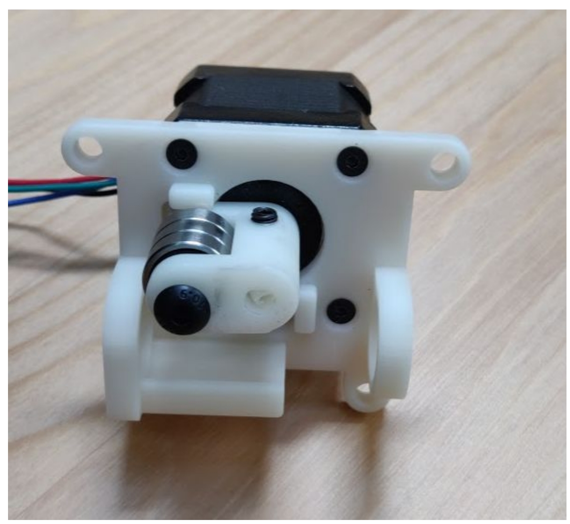
Pinch Valve

Design Basis

Two custom pinch valves are used to modulate flow through the ventilator: a valve on the inspiratory path works in conjunction with the blower to enable quick responses to required flow changes; an identical valve on the expiratory path closes periodically to minimize oxygen wastage due to excess bias flow during high pressure periods of the breathing cycle.

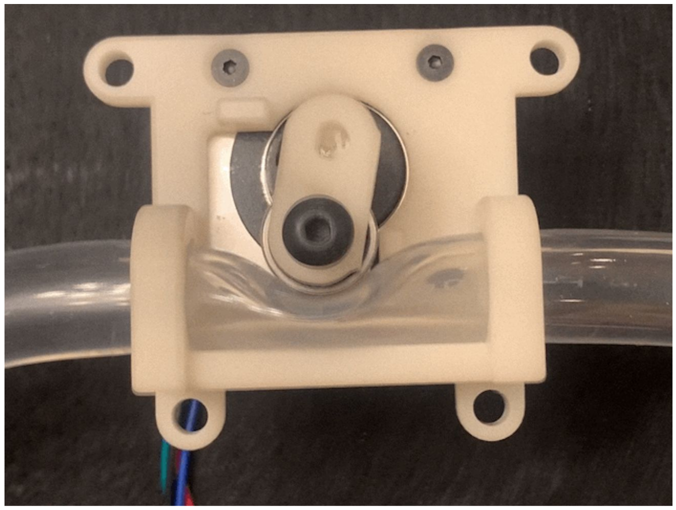
Flexible tubing-based pinch valves were selected based on the requirements for quick response time, and the ability to keep the gas pathway clean (a feature unique to pinch valves, as most other forms of actuated valves require passing the gas through the valve workings).





Pinch valve CAD model and an earlier prototype of the assembled (3d printed) version. Neither shows the section of flexible rubber tubing, which forms part of the ventilator pneumatic circuit.

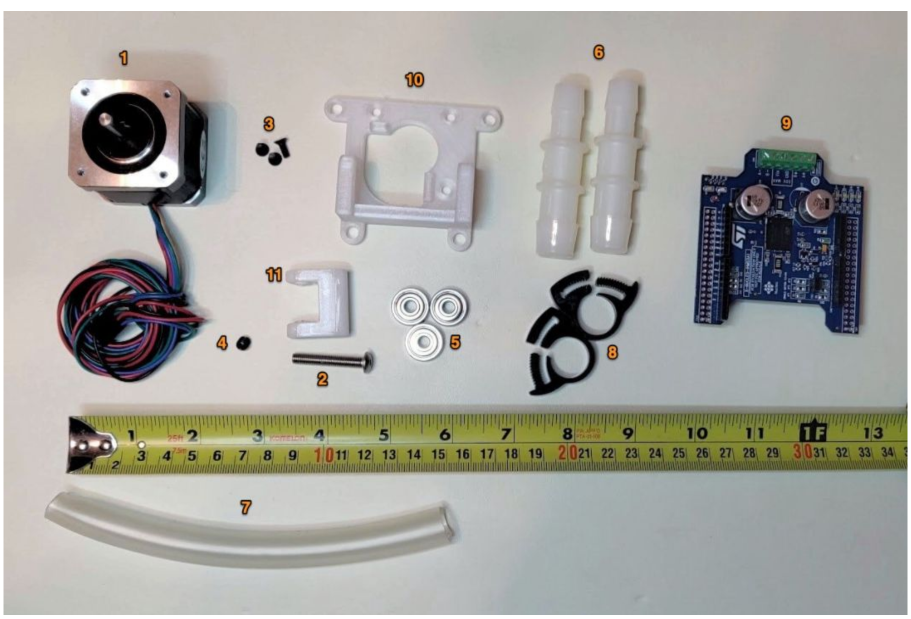
The soft rubber tubing selected is manufactured and rated for peristaltic pumps, which have similar loads consisting of cyclical stresses on the tubing walls. This tubing is ⅝” OD x ⅜” ID, somewhat smaller than the main ventilator circuit tubing standard in order to make it easier to completely seal the tube when the valve is closed. Roller bearings on the rotor eliminate frictional wear on the outer surface of the tubing. While this tubing is rugged enough for weeks of use in this application, it will likely need to be replaced periodically. Current testing is underway using a life leader prototype[1] to demonstrate the lifetime of the tubing and to quantify degradation in performance over time.



Earlier prototype of pinch valve compressing soft rubber tubing to seal the gas pathway

Prototype Fabrication

The valves are an assembly of two custom plastic parts with commonly available off-the-shelf hardware. The design of the custom plastic parts requires minor modification to be amenable to injection molding in ABS plastic, which is the intended at-scale production method. The parts for the prototype valve assembly are shown below:



[1] Currently the valve has performed 21 days (and counting) of accelerated wear testing described in 01-02 Progress Status Report, however, more testing will be needed to fully qualify the device.

Pinch valve components: two custom plastic parts (currently SLA printed in ABS-like resin), stepper motor and driver, 5x15mm roller bearings, hardware, and plumbing fittings

Further design documentation, including assembly instructions, can be found at the RespiraWorks: open source documentation page[2] for this part.

Fabrication at Scale

For the pinch valve fabrication at scale, the key difference would be to use the enclosure mounting plate as part of the assembly, removing the housing (item 10) in the BOM above. The tube supports would be replaced with routing clamps and the pinch plate would be a single injection molded ABS piece affixed to the mounting plate.

The rotor is slightly more complicated, and a few different iterations have been proposed. Likely the cheapest and fastest method to produce would be to procure aluminum 60601 bar stock with the correct outer dimensions. Blanks for each rotor would be cut and milled to final size. A group of 10-15 rotors would be placed in a vice with the central channel milled out. The set screw hole would be through-drilled and tapped. A third operation would be required to drill and tap the axel and bearing shaft holes.

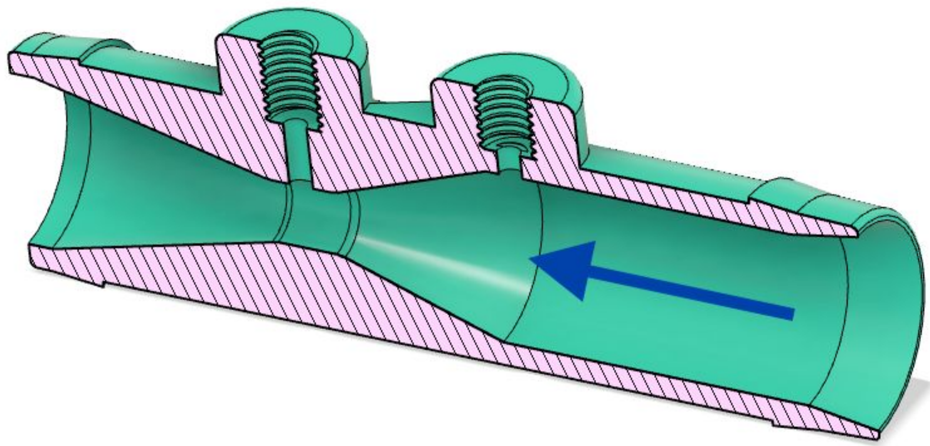
The boss on the rotors to isolate the inner race of the bearing would be replaced with a small shim washer.

Venturi

Design Basis

Two venturi flow sensors are used to measure flow into and out of the patient's lungs by measuring a change in pressure as the flow accelerates through the throat. Relative to other pressure sensor types, a venturi flow meter produces the largest signal pressure at the smallest pressure loss. This allows significantly cheaper and more widely available pressure sensors to be used, because a signal at peak flow can be 5 to 15 times larger than the flow resistance. For a resistance type flow sensor, the ratio is 1:1. The change in pressure is measured between the two ports, and this is correlated to the flow rate through the orifice.

[2] https://github.com/RespiraWorks/SystemDesign/tree/master/research-development/project-pinch-valve

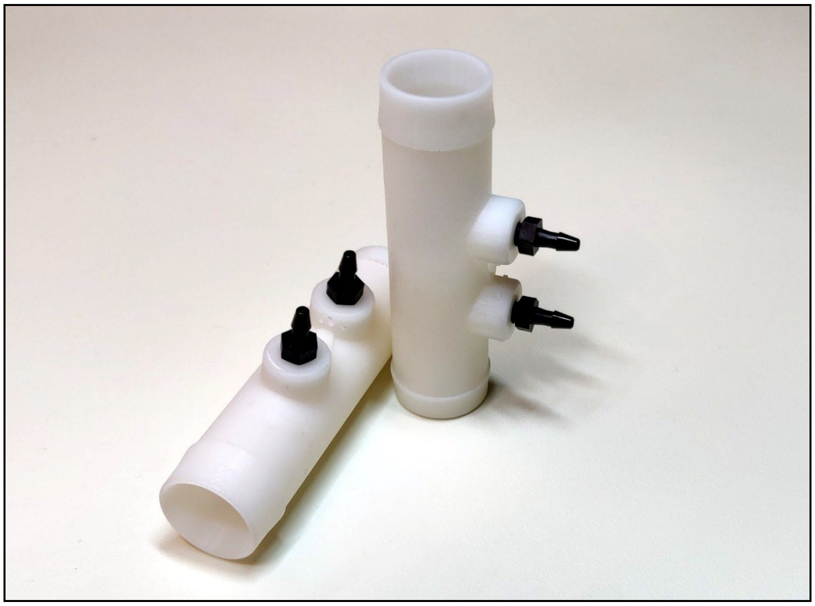


Cross-section view through venturi flow sensor. Blue arrow indicates flow direction.

Prototype Fabrication

Currently the prototype parts are 3D printed using an SLA printer in ABS-like resin. Ultimately this design requires some modification to make it amenable to injection molding, which is the intended method for at-scale production. Venturis like these are commonly injection molded, so there is precedent for successful injection molding of parts with the required internal profile. However, the team did not identify any off-the-shelf parts that met the orifice sizing requirements dictated by the ventilatory flow rates required, leading to a custom design for this part. This part incorporates molded-in hose barbs, which are compatible with either ¾” ID or 19mm ID flexible tubing depending on supply chain availability.

The pressure sensor selected (MPXV5004DP) used with this venturi has 2.5 mm or 3/32" barbs (note: this is not sufficiently close in size to use more common 3mm or 1/8" tubing and fittings). The venturi currently uses printed threads to accept an adapter (black, below) from #10-32 to 3/32" barb. This interface may change when the part is re-designed for injection molding.



Prototype venturi sensors, 3D printed in ABS-like resin,
with pressure sensor hose barb adapters installed.

Further design documentation, including flow rate correlation and characterization of sensor accuracy, can be found at the RespiraWorks [open source documentation page][3] for this part.

Fabrication at Scale

The basis for the design came from previous experience using adapted fertilizer injection venturis as flow measurement devices. The original part is shown below.

Injection molded ABS fertilizer venturi

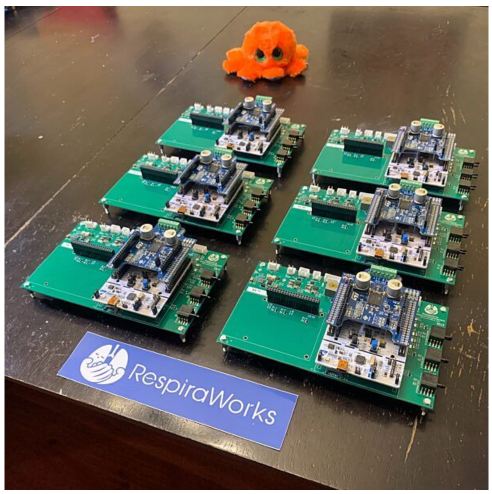
[3] https://github.com/RespiraWorks/SystemDesign/tree/master/research-development/project-venturi

There is no fundamental reason why the exact same design cannot be used for this application, especially if these are being produced at scale. However, the dimensions of this part are not quite right to optimize for the flow regime of patient inspiration. The commonly available ½-NPT fertilizer venturi has an entrance diameter of 12.7mm and a throat diameter of 4.1 mm. After experimentation with the prototype venturi, the final dimensions were selected as an entrance diameter of 15.05 mm and a throat diameter of 5.5 mm. These are significantly different from a flow measurement standpoint, but not particularly different from a manufacturing standpoint.

The fabrication for the above process is to produce two mirror half-molds with partial thread blanks for the three threads and alignment pins in the molds. Glue is applied to the mold halves, with the pins used to precisely align the components. After the glue sets, additional flashing and the alignment pins are machined off, and the threads are cleaned up with a cutting die. By using common thread fittings (½ NPT on other end, and ¼ NPT on the pressure tap) readily available adapters can be attached. For the upstream pressure tap, a ½ NPT tee is used, with the flow entering the tee from upstream, and a barb adapter used to connect to the 3/32 tubing. For the throat tap, a ¼ NPT female to 3/32 barb adapter is required.

Control Board (Printed Circuit Board)

Due to the coupled nature of the controls, electrical, and mechanical components and their design the RespiraWorks ventilator contains a custom fabricated printed circuit board (PCB) to connect the microcontroller, interface processor, and sensor interfaces. The use of a custom PCB greatly reduces the chance for electrical assembly and fabrication errors and is far more amenable to a quality fabrication process than hand-soldered components. We do not intend for this component to be hand-assembled, and engineering turnkey fabrication instructions have been generated as part of the submission; no assembly instructions are provided here.



The RespiraWorks Ventilator Mainboard PCB is a custom component that integrates the Cycle Controller, UI Computer, sensors, actuator drives, power supplies, filtering, and protection components. The PCB is designed by RespiraWorks and is open-source, with a dedicated repository available at https://github.com/RespiraWorks/pcbreathe.

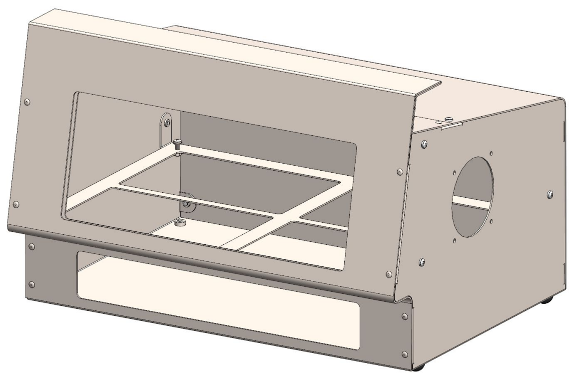
The complete turn-key manufacturing files for Rev 1.0 have been included as part of this submission package. This package includes PCB artwork files, NC drill data, fabrication and assembly drawings, Bill of Materials, and machine-assembly centroid (pick-and-place) files. Any standard PCB fabrication and assembly vendor will be able to manufacture these boards using the file package available at the referenced link[4], or submitted as a zip as part of this application (01-08B RespiraWorks PCB (Manufacturing).zip). The design was created in Altium, and the full design package for Rev 1.0 is submitted as a part of this application (01-08B RespiraWorks PCB (Manufacturing).zip) be found at the referenced link[5].

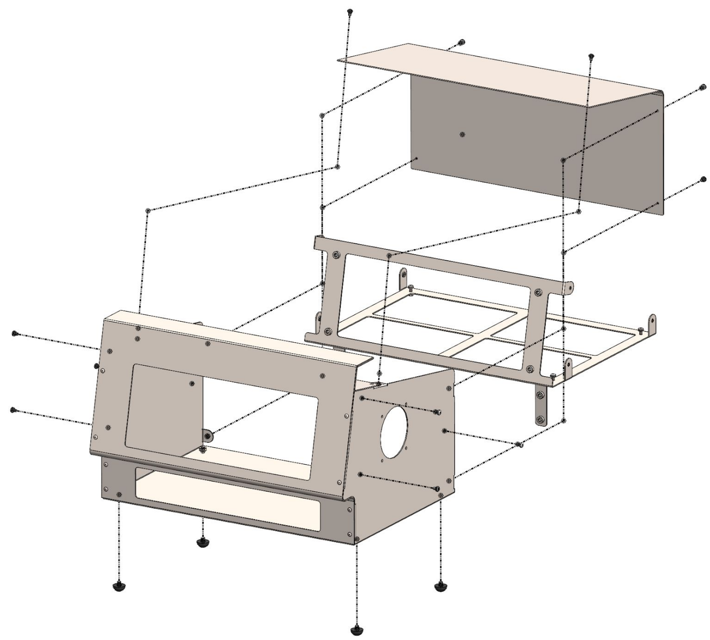
[4] https://github.com/RespiraWorks/pcbreathe/blob/master/NIGHTLY/20200424v2-RELEASE-CANDIDATE-2/20200424v2-RespiraWorks-Ventilator-Rev1.0-RC2-PKG-TURNKEY.zip
[5] https://github.com/RespiraWorks/pcbreathe/blob/master/NIGHTLY/20200424v2-RELEASE-CANDIDATE-2/20200424v2-RespiraWorks-Ventilator-Rev1.0-RC2-PKG-DESIGN.zip

A detailed guide to setup of the PCB is included as part of the assembly instructions (03-02 Respiraworks Assembly Instructions.pdf) and is available at our GitHub repository[6].

[6] https://github.com/RespiraWorks/pcbreathe/blob/master/README.md

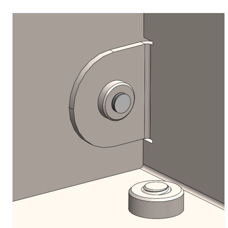
Enclosure





The ventilator enclosure is made up of three folded, 1.52mm thick, stainless steel sheets; the main enclosure, the rear closure panel and the internal equipment bracket.

The main enclosure is folded from a single sheet and fastened together using ⅛” diameter, stainless steel blind rivets (McMaster 97525A420). There are rubber bumper feet (McMaster 9541K82) on the bottom of the enclosure that are threaded into M6 PEM nuts (Bisco CLS-M6-1). The rubber bumpers can be removed to allow the enclosure to be mounted to a medical cart. M4 PEM nuts are installed, on tabs, on the main enclosure to allow the rear closure panel to be fastened to the main enclosure.



The rear closure panel is folded from a single sheet. The rear closure panel is fastened to the main enclosure using (6) M4 x 0.7 x 6mm long, phillips, pan head, 18-8 stainless steel screws.

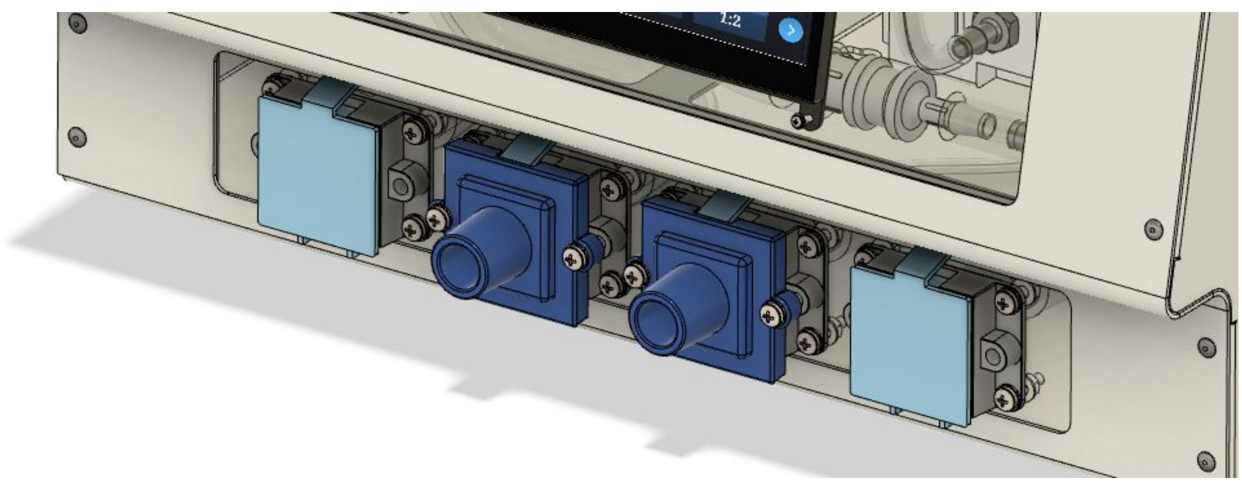
The internal equipment bracket is folded from a single sheet. The bracket is designed to be simple and lightweight. Acrylic sheets are either fastened to or hung from the bracket to allow for design adjustments while utilizing the same bracket. The internal equipment bracket is attached to the main enclosure using (6) M4 x 0.7 x 6mm long, phillips, pan head, 18-8 stainless steel screws.

Fabrication drawings for the enclosure are provided in Appendix 1.

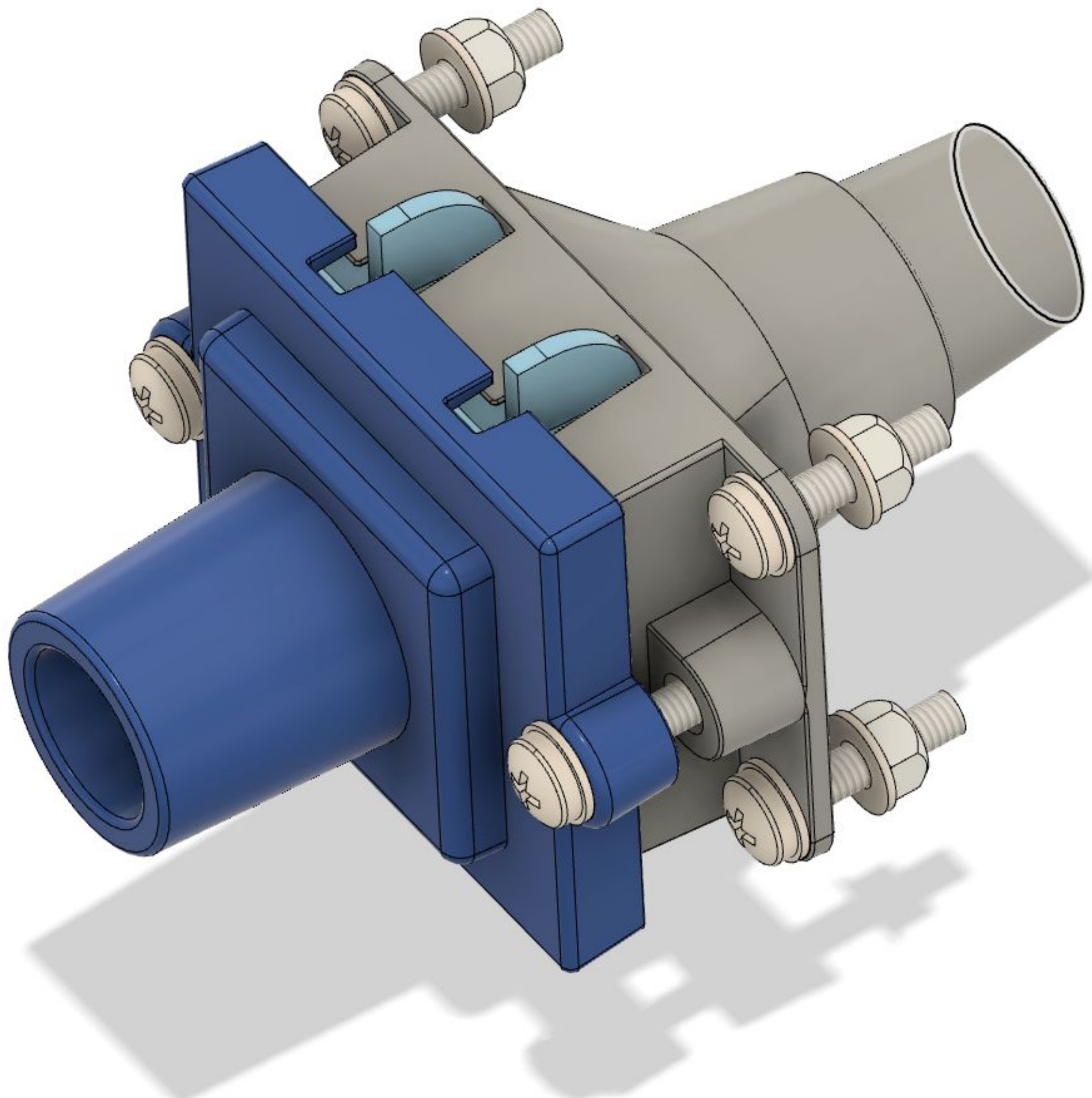
In-Line Filter Housing

The ventilator uses four mass-manufactured replaceable HEPA filter cartridges to isolate the patient from the device, and to isolate the device gas path from the environment. These filters were selected based on research described in the design overview document. Currently this form factor HEPA filter is available in quantities exceeding 10,000. A set of custom panel-mount components houses this filter cartridge and serves as the connector for the inspiratory and expiratory ends of the patient breathing circuit. A modified version of these connectors, utilizing the same filter, is used as an additional barrier on the inspiratory and expiratory pathway to the device.

Roomba Hepa Filters



CAD mockup of the 2 patient tubing connectors.

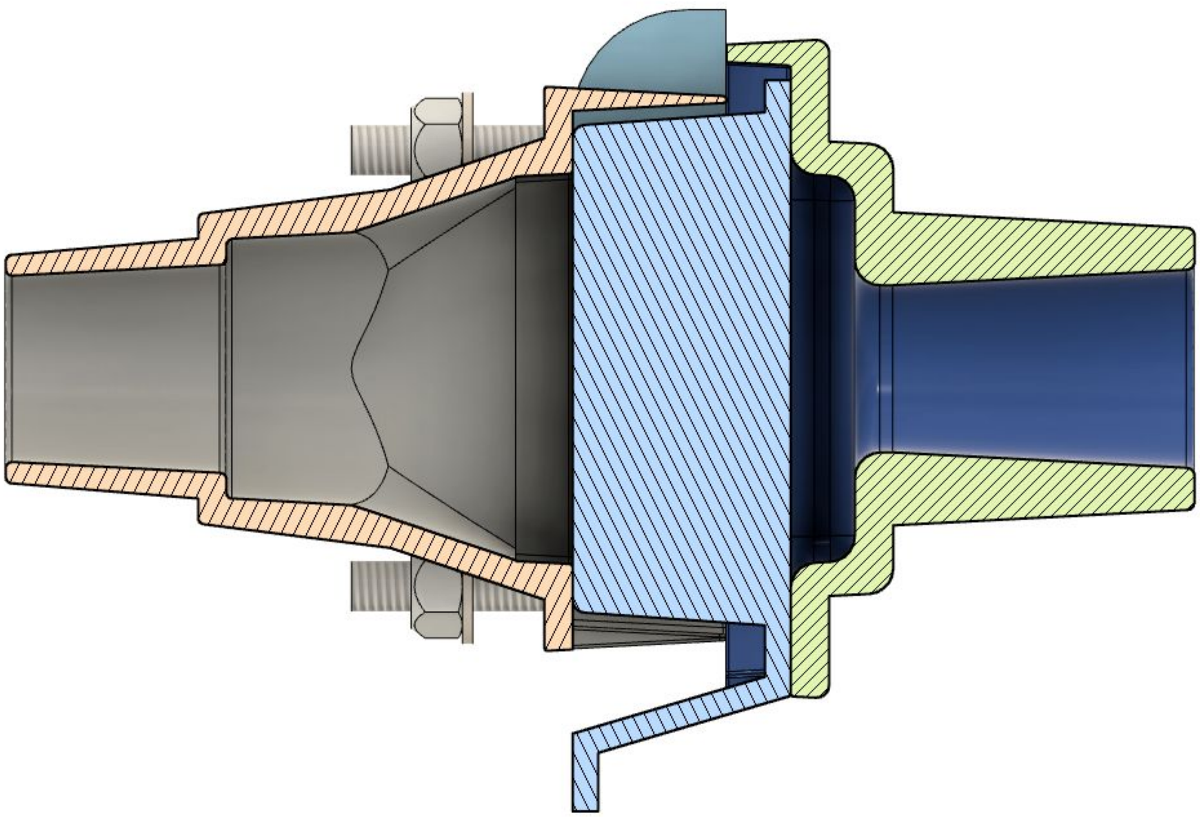


Tubing connector assembly, with side 22M tubing connector in dark blue, filter in light blue, and internal connector shown in gray.

While the prototype components are 3D printed using SLA resin, these parts are designed to be injection molded in ABS, and have undergone several iterations of feedback from a fabrication partner that specializes in injection molding. As such, they have a draft angle of 2 degrees and uniform wall thickness to simplify mold-making.

These parts are modular in design: the fixed component of the filter housing can accommodate several sizes of flexible tubing connections on the back side (options for ¾ in / 19mm ID, and 1 in / 25 mm ID). This allows the same part to be used for all four filter housings, decreasing part cost by economies of scale and simplifying the assembly procedure. The fixed panel-mount component includes two M4 press-in or heat-set threaded metal inserts to be used as a mounting point for the filter cartridge hold-down parts.

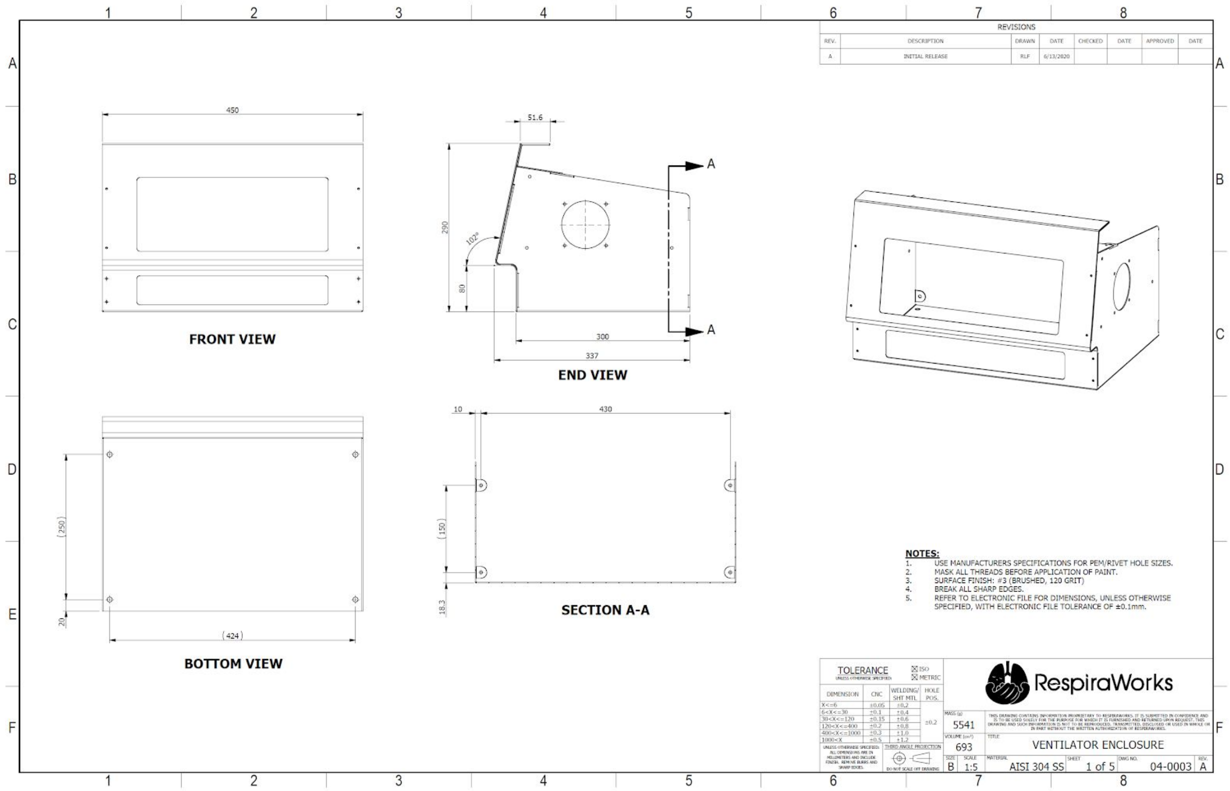
The replaceable filter cartridges are held in place by one of two component options - for the device inlet and outlet, a simple screw-down tab holds the filter in place; for the patient breathing circuit connectors, a 22mm cone (male) port is provided to interface with standard 22mm socket (female) breathing circuits. The patient breathing circuit connector cone is dimensioned according to ISO 5356-1 [7]. All screw-down components use M4 fasteners screwed into the threaded metal inserts on the panel-mount component.

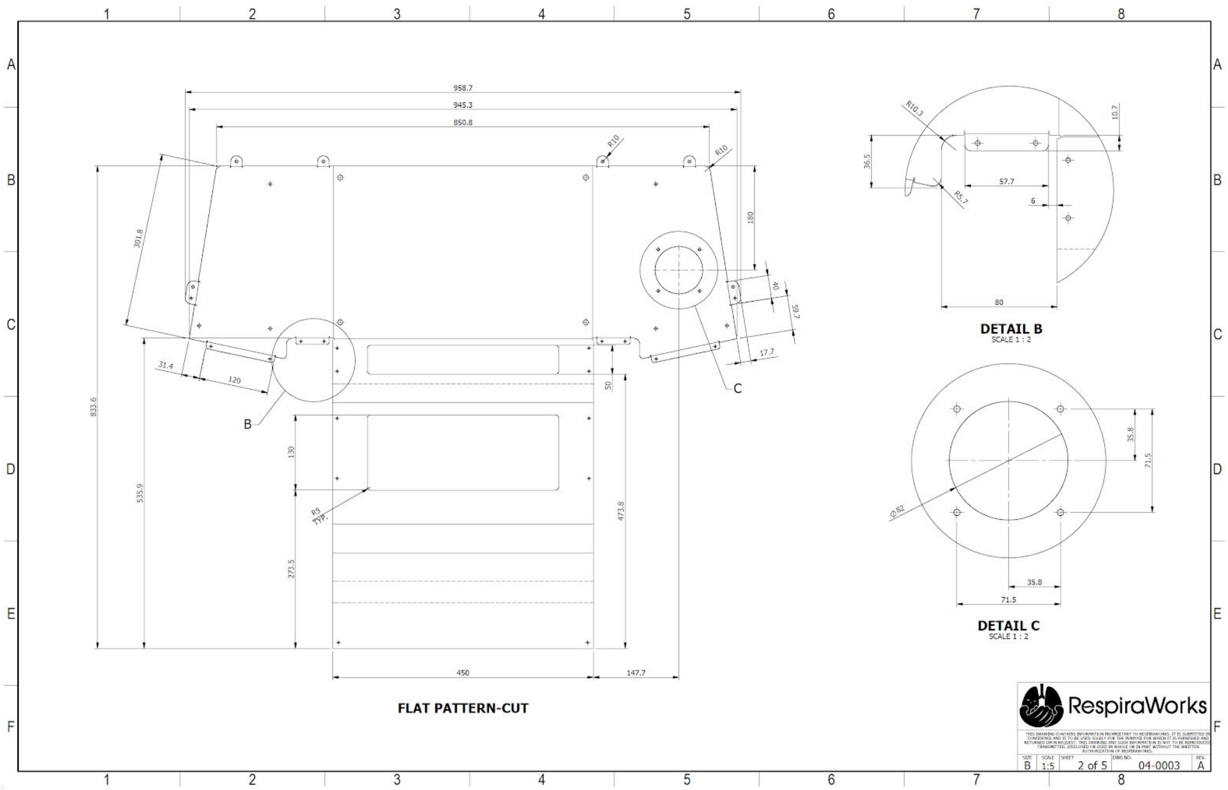


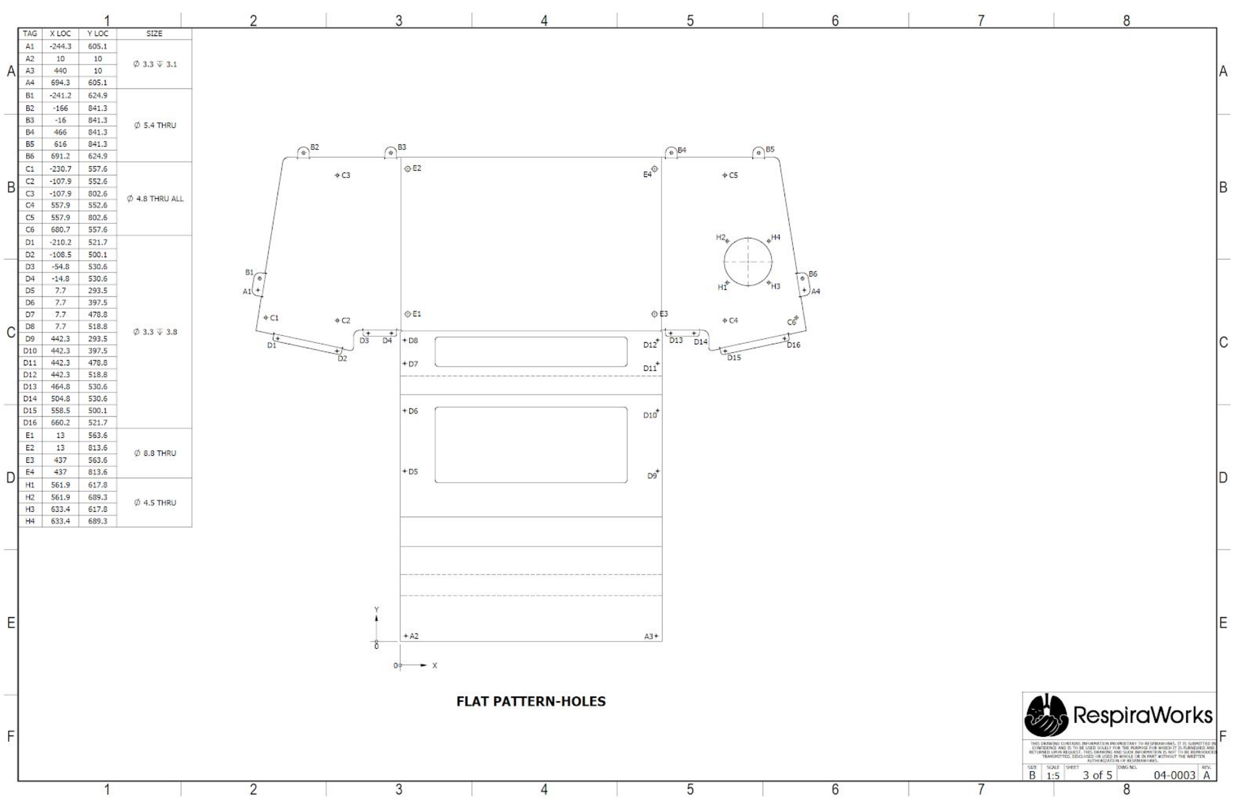
[7] https://www.iso.org/obp/ui#iso:std:iso:5356:-1:ed-4:v1:en

Appendix 1 - Fabrication Drawings

Enclosure fabrication drawings.







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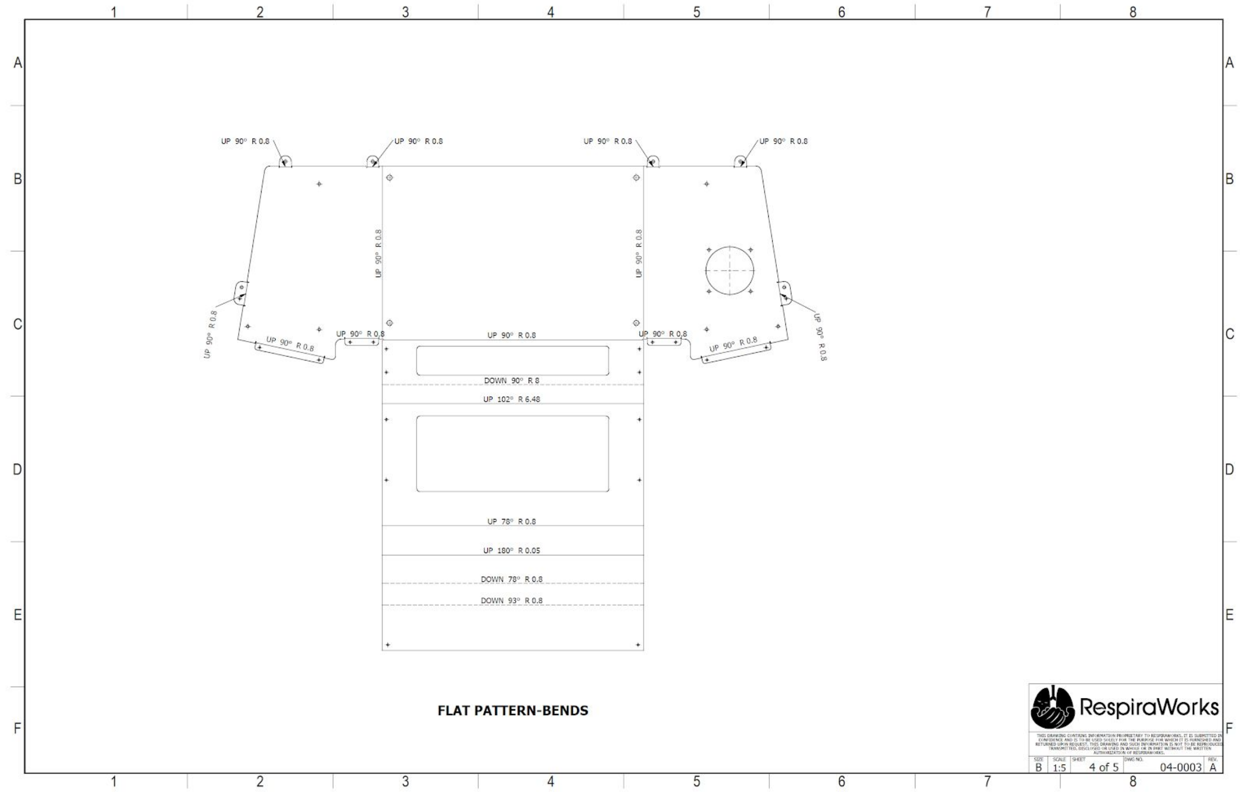
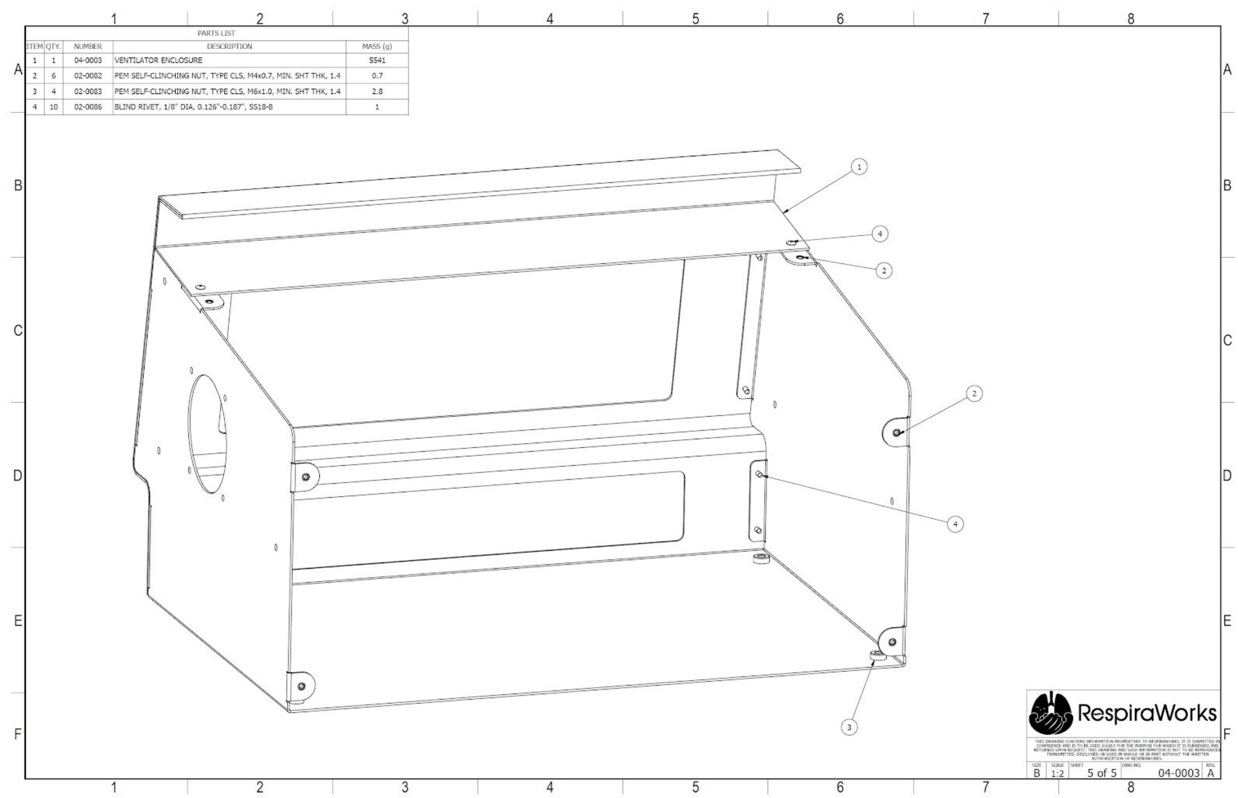
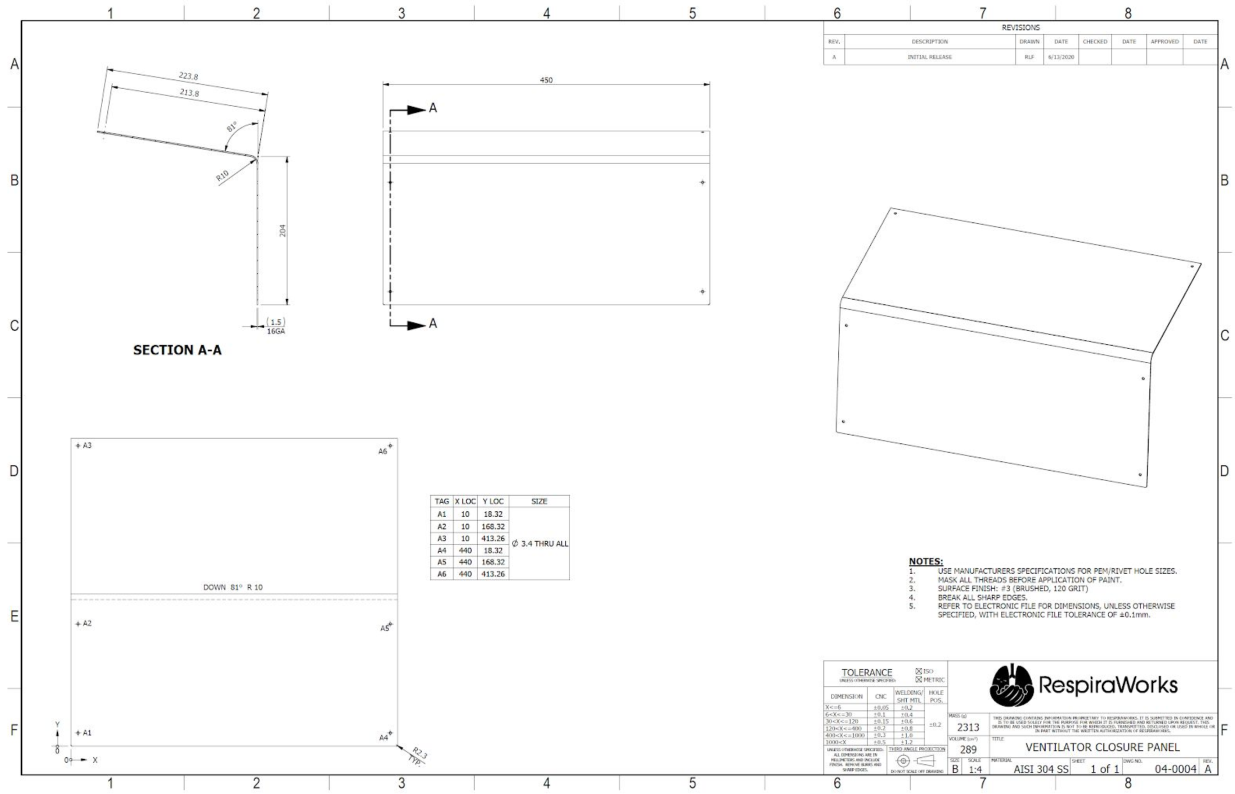
A2	10	10	
A3	440	10	
A4	694.3	605.1	
B1	-241.2	624.9	∅ 5.4 THRU
B2	-166	841.3	
B3	-16	841.3	
B4	466	841.3	
B5	616	841.3	
B6	691.2	624.9	
C1	-230.7	557.6	∅ 4.8 THRU ALL
C2	-107.9	552.6	
C3	-107.9	802.6	
C4	557.9	552.6	
C5	557.9	802.6	
C6	680.7	557.6	
D1	-210.2	521.7	∅ 3.3 ↧ 3.8
D2	-108.5	500.1	
D3	-54.8	530.6	
D4	-14.8	530.6	
D5	7.7	293.5	
D6	7.7	397.5	
D7	7.7	478.8	
D8	7.7	518.8	
D9	442.3	293.5	
D10	442.3	397.5	
D11	442.3	478.8	
D12	442.3	518.8	
D13	464.8	530.6	
D14	504.8	530.6	
D15	558.5	500.1	
D16	660.2	521.7	
E1	13	563.6	∅ 8.8 THRU
E2	13	813.6	
E3	437	563.6	
E4	437	813.6	
H1	561.9	617.8	∅ 4.5 THRU
H2	561.9	689.3	
H3	633.4	617.8	
H4	633.4	689.3	



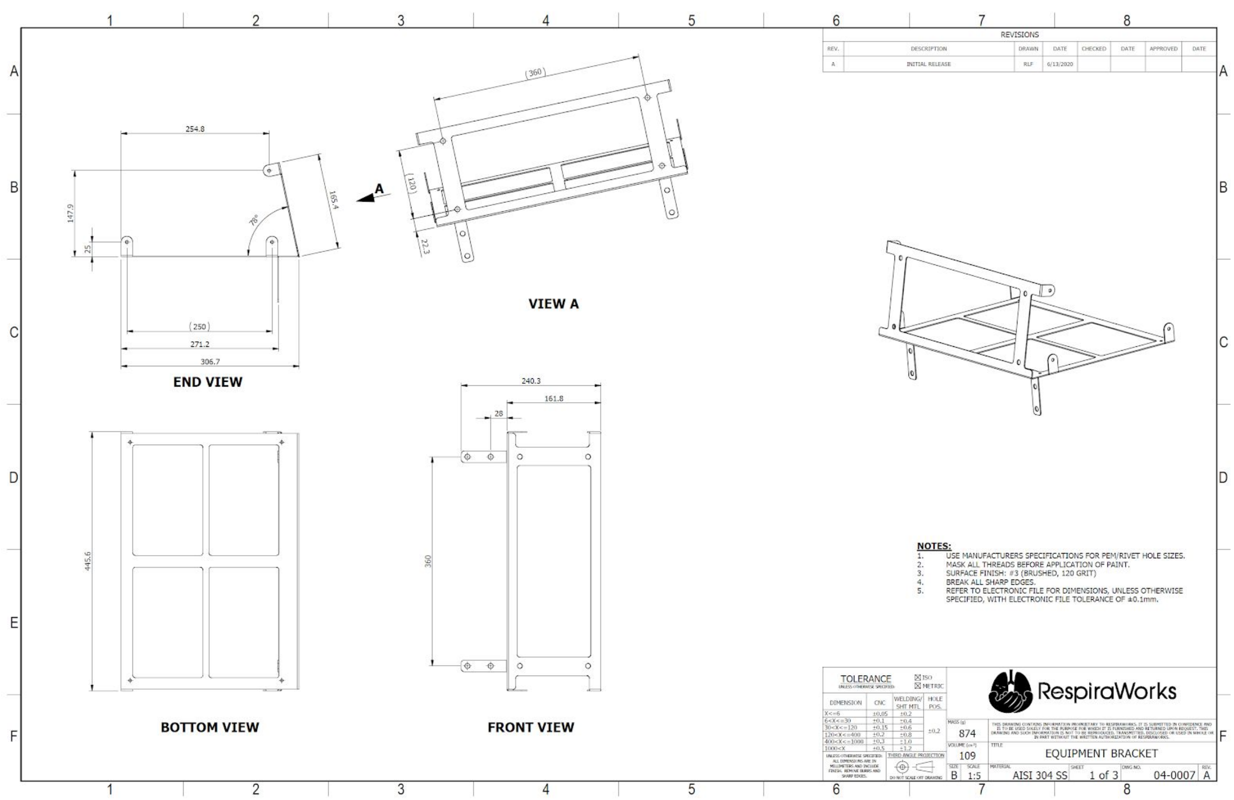


PARTS LIST

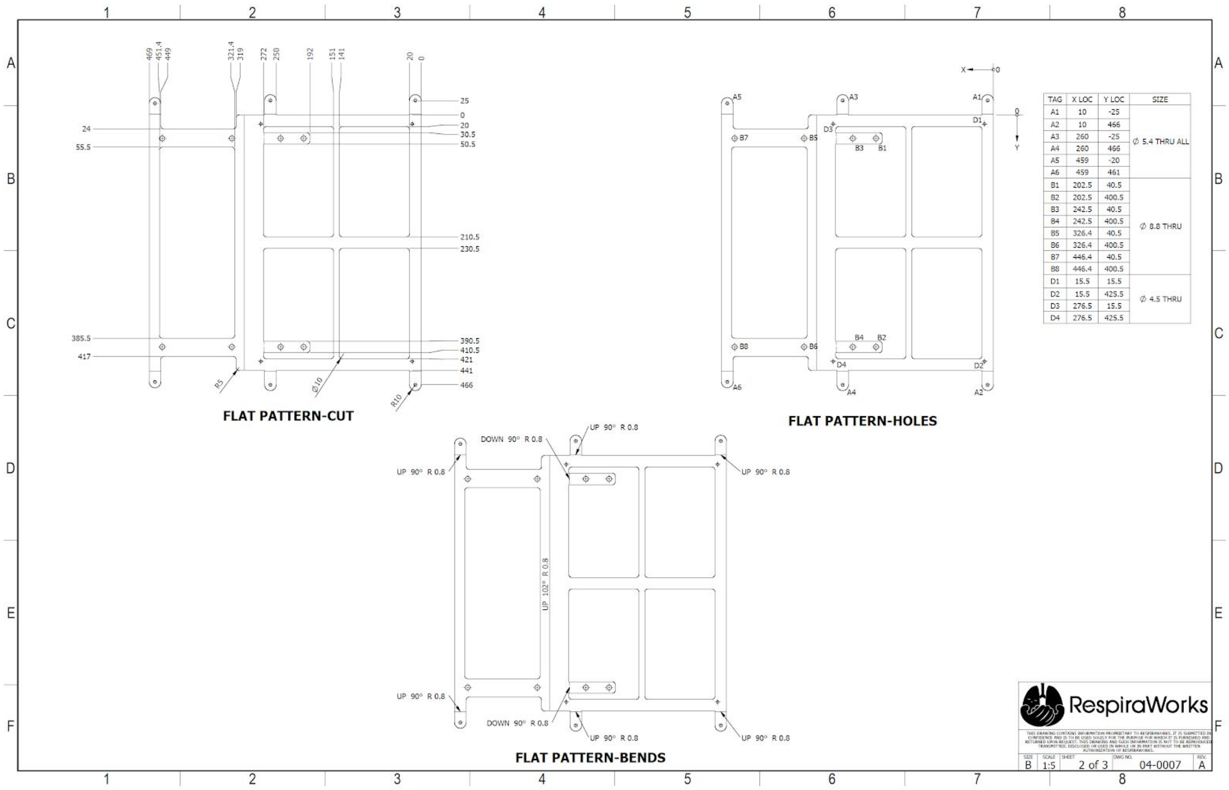
ITEM	QTY.	NUMBER	DESCRIPTION	MASS (g)
1	1	04-0003	VENTILATOR ENCLOSURE	5541
2	6	02-0082	PEM SELF-CLINCHING NUT, TYPE CLS, M4x0.7, MIN. SHT THK, 1.4	0.7
3	4	02-0083	PEM SELF-CLINCHING NUT, TYPE CLS, M6x1.0, MIN. SHT THK, 1.4	2.8
4	10	02-0086	BLIND RIVET, 1/8" DIA, 0.126"-0.187", SS18-8	1



SECTION A-A
223.8
213.8
81°
R10
204
1.5
16GA
450
A
DOWN 81° R 10
A1
A2
A3
A4
A5
A6
R2.3 TYP.
TAG | X LOC | Y LOC | SIZE
A1 | 10 | 18.32 | ∅ 3.4 THRU ALL
A2 | 10 | 168.32
A3 | 10 | 413.26
A4 | 440 | 18.32
A5 | 440 | 168.32
A6 | 440 | 413.26
REVISIONS
REV. | DESCRIPTION | DRAWN | DATE | CHECKED | DATE | APPROVED | DATE
A | INITIAL RELEASE | RLF | 6/13/2020
NOTES:
1. USE MANUFACTURERS SPECIFICATIONS FOR PEM/RIVET HOLE SIZES.
2. MASK ALL THREADS BEFORE APPLICATION OF PAINT.
3. SURFACE FINISH: #3 (BRUSHED, 120 GRIT)
4. BREAK ALL SHARP EDGES.
5. REFER TO ELECTRONIC FILE FOR DIMENSIONS, UNLESS OTHERWISE SPECIFIED, WITH ELECTRONIC FILE TOLERANCE OF ±0.1mm.
TOLERANCE
UNLESS OTHERWISE SPECIFIED
ISO
METRIC
DIMENSION | CNC | WELDING/SHT MTL | HOLE POS.
X<=6 | ±0.05 | ±0.2 | ±0.2
6<X<=30 | ±0.1 | ±0.4
30<X<=120 | ±0.15 | ±0.6
120<X<=400 | ±0.2 | ±0.8
400<X<=1000 | ±0.3 | ±1.0
1000<X | ±0.5 | ±1.2
UNLESS OTHERWISE SPECIFIED: ALL DIMENSIONS ARE IN MILLIMETERS AND INCLUDE FINISH. REMOVE BURRS AND SHARP EDGES.
THIRD ANGLE PROJECTION
DO NOT SCALE OFF DRAWING
RespiraWorks
MASS (g) 2313
VOLUME (cm³) 289
THIS DRAWING CONTAINS INFORMATION PROPRIETARY TO RESPIRAWORKS. IT IS SUBMITTED IN CONFIDENCE AND IS TO BE USED SOLELY FOR THE PURPOSE FOR WHICH IT IS FURNISHED AND RETURNED UPON REQUEST. THIS DRAWING AND SUCH INFORMATION IS NOT TO BE REPRODUCED, TRANSMITTED, DISCLOSED OR USED IN WHOLE OR IN PART WITHOUT THE WRITTEN AUTHORIZATION OF RESPIRAWORKS.
TITLE VENTILATOR CLOSURE PANEL
SIZE B
SCALE 1:4
MATERIAL AISI 304 SS
SHEET 1 of 1
DWG NO. 04-0004
REV. A



254.8
147.9
25
165.4
78°
(250)
271.2
306.7
END VIEW
(360)
(120)
22.3
A
VIEW A
445.6
BOTTOM VIEW
240.3
161.8
28
360
FRONT VIEW
REVISIONS
REV. | DESCRIPTION | DRAWN | DATE | CHECKED | DATE | APPROVED | DATE
A | INITIAL RELEASE | RLF | 6/13/2020
NOTES:
1. USE MANUFACTURERS SPECIFICATIONS FOR PEM/RIVET HOLE SIZES.
2. MASK ALL THREADS BEFORE APPLICATION OF PAINT.
3. SURFACE FINISH: #3 (BRUSHED, 120 GRIT)
4. BREAK ALL SHARP EDGES.
5. REFER TO ELECTRONIC FILE FOR DIMENSIONS, UNLESS OTHERWISE SPECIFIED, WITH ELECTRONIC FILE TOLERANCE OF ±0.1mm.
TOLERANCE
RespiraWorks
MASS (g) 874
VOLUME (cm³) 109
TITLE EQUIPMENT BRACKET
SIZE B
SCALE 1:5
MATERIAL AISI 304 SS
SHEET 1 of 3
DWG NO. 04-0007
REV. A



TAG	X LOC	Y LOC	SIZE
A1	10	-25	∅ 5.4 THRU ALL
A2	10	466	
A3	260	-25	
A4	260	466	
A5	459	-20	
A6	459	461	
B1	202.5	40.5	∅ 8.8 THRU
B2	202.5	400.5	
B3	242.5	40.5	
B4	242.5	400.5	
B5	326.4	40.5	
B6	326.4	400.5	
B7	446.4	40.5	
B8	446.4	400.5	
D1	15.5	15.5	∅ 4.5 THRU
D2	15.5	425.5	
D3	276.5	15.5	
D4	276.5	425.5	

PARTS LIST

ITEM	QTY.	NUMBER	DESCRIPTION	MASS (g)
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3	8	02-0083	PEM SELF-CLINCHING NUT, TYPE CLS, M6x1.0, MIN. SHT THK, 1.4	2.8