Supplementary Information for MADVent: A low-cost ventilator for patients with COVID-19

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Supplementary Information for MADVent: A low-cost ventilator for patients with COVID-19 — Calculations

1 Torque Estimation

Referring to Supplementary Fig. 1, there is a force, $F_b = p_b \times A_b + F_s$, on the lever due to contact with a pressurized bag, where p_b is the pressure in the bag, A_b is the contact area between the bag and the lever, and F_s is the inherent force of the self-inflating bag.

We assume the pressure in the bag is 40 cm H₂O, the largest pressure anticipated to be used during normal operation. The contact area in the most compressed state can be approximated by the radius of the circular portions of the lever and the distance between these two, $A_b = 6.5 \times 3 = 19.5 \text{ cm}^2$. The force produced by the self-inflating bag estimated by applying an increasing amount of static weight to the bag until the force of gravity on the weight overcomes F_s , ≈ 10 N. The torque required about the hinge is estimated by $T_{arm} = A'F_b$, presuming the force is perpendicular to the arm. But given that the string is not always perpendicular to the arm depending on the angle of rotation, the force produced due to motor rotation is given by $\frac{F_b}{cos(\beta)}$, where β is the angle between the lanyard and the normal direction to the arm and F is the perpendicular component of tension from the string. Using the law of of cosines and referring to Fig.1 B, the relationship between θ , the angle between the lever and the base, and β can be solved by the equation:

$$\frac{2AB\sin^2(\theta)\cos(\theta+\beta)}{\cos(\beta)} + (B - A\cos(\theta))^2 = A^2\sin^2(\theta) + \frac{B^2\sin^2(\theta)}{\cos^2(\beta)}$$
(1)

A and B in the above equation are known lengths, and the system operates over $37^{\circ} \le \theta \le 78^{\circ}$ based on the geometry of the device. This equation allows us to solve for $\cos(\beta)$ and hence, find the torque required to compress the bag.

$$T_{\text{motor}} = \frac{aF_b}{\cos(\beta)} \tag{2}$$

The above expression produces a torque ranging from 140 mN - m to 180 mN - m as represented in Supplementary Fig. 2. The expression does not take into account the changing contact area of the bag or the increasing force during short inspiration times. The force for a particular inspiration time can vary by as much as a factor of 3, given the range of inspiration times that the system allows. An additional factor in the system that can limit the torque delivered to the bag include the torsion spring, which always acts to restore the arm to its original position. Consequently, a factor of safety of 2 was taken into account while choosing a motor, which produces an estimate for the required motor torque to be 1.8 N-m. This is the rated torque of the selected motor.

2 Volume derivation

When the motor rotates by an angle ϕ in Supplemental Fig. 1, the distance between the tip of the lever arm and the motor shaft, *L*, is reduced by the amount $a\phi$. The rotation furthermore reduces both the length, *d*, between the center of the bag and the center of the circular portion of the lever, and the angle θ . The tidal volume is the cross-sectional area A_i multiplied by a length scale, b_d , dependent upon the bag's length in a somewhat complex manner as detailed below.

The equation for the area of intersection, A_i of two circles of equal radius, r whose centers are separated by a distance, d is

$$A_i(d) = 2r^2 \arccos \frac{d}{2r} - \frac{d}{2}\sqrt{4r^2 - d^2}.$$
(3)

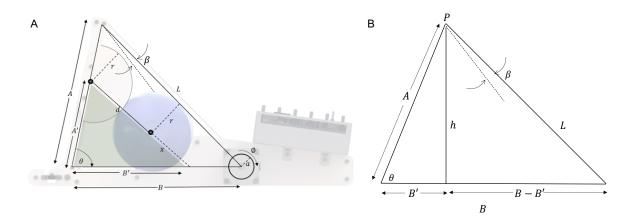


Figure 1: The side view of the MADVent ventilator, to scale, including geometry sufficient to determine the relationship between the angle of rotation of the spool and the delivered tidal volume(A) and estimated torque to compress the bag(B) (V_{tidal}).

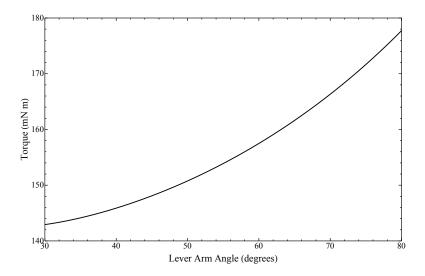


Figure 2: Motor torque as a function of θ , the angle between the lever arm and the base of the ventilator.

The law of cosines determines the length of string between lever and motor shaft,

$$l(\theta) = \sqrt{A^2 + B^2 - 2AB\cos\theta}.$$
(4)

Knowledge of the coordinates of the centers of the circular objects leads to an expression for the center separation distance,

$$d(\theta) = \sqrt{(x - y\cos\theta)^2 + (r - y\sin\theta)^2}.$$
(5)

The arc-length formula gives the amount by which *l* decreases when the motor shaft rotates by ϕ ,

$$\alpha(\phi) = a\phi. \tag{6}$$

The total length of the lanyard is assumed to be constant,

$$L = l - \alpha, \tag{7}$$

where *l* is the portion wound around the spool and α is the portion between the shaft and the lever.

Rearranging eqn. 7, we can solve for l and set the result equal to eqn. 4. Solving for θ and substituting into eqn. 5 and then eqn. 3 produces $A_i(\phi)$, the area of intersection as a function of the motor rotation. To find the volume change in compression, $V_{\text{tidal}}(\phi)$, we then multiply the area $A_i(\phi)$ by a constant b_d related to the length of the bag,

$$V_{\text{tidal}}(\phi) = b_d \left(2r^2 \cos^{-1} \left(\frac{\sqrt{\left(r - A'\sqrt{1 - \frac{\left(-(L - (a\phi))^2 + A^2 + B^2\right)^2}{4A^2B^2}}\right)^2 + \left(B' - \frac{A'\left(-(L - (a\phi))^2 + A^2 + B^2\right)}{2AB}\right)^2}{2r} \right)^2}{2r} \right)^2 - \frac{1}{2}\sqrt{-\left(r - A'\sqrt{1 - \frac{\left(-(L - (a\phi))^2 + A^2 + B^2\right)^2}{4A^2B^2}}\right)^2 - \left(B' - \frac{A'\left(-(L - (a\phi))^2 + A^2 + B^2\right)}{2AB}\right)^2 + 4r^2}}{\sqrt{\left(r - A'\sqrt{1 - \frac{\left(-(L - (a\phi))^2 + A^2 + B^2\right)^2}{4A^2B^2}}\right)^2 + \left(B' - \frac{A'\left(-(L - (a\phi))^2 + A^2 + B^2\right)}{2AB}\right)^2}{2AB}}\right)^2} \right)^2 \right).$$
(8)

The bag length-dependent factor, b_d , is obtained by noting the maximum total volume expelled from the bag when fully compressed within the prototype, 1175 m ℓ , and calculating the equivalent length of a cylinder with this volume and a radius equal to that of the bag. To improve the result, the maximum volume determined in this way should further be adjusted for the lanyard's elastic stretch during operation, accomplished by finding the *y*-intercept of the experimentally obtained tidal volume to rotor angle data, giving 1225 m ℓ . Setting this volume equal to the equation for the volume of a cylinder, $1225 = (b_d)(\pi r^2)$, in which the length of the equivalent cylinder is b_d , we find $b_l = 9.23$ cm. All other constants are directly measured from the prototype as provided in Supplementary Fig. 1.

3 ISO Test Results

Table 1 corresponds to the clinically relevant portion of Table 201.105 from ISO 80602-2-12 [1] for pressure-controlled mechanical ventilators. The resulting tidal volumes, as measured by the lung simulator, are reported for a range of inspiratory pressure, PEEP, compliance, rate, and airway resistance values. These volume values do not match the expected values outlined by ISO 80602-2-12 Table 201.105 [1]. We instead find good agreement between the

Rate (bpm)	Inspiratory Pressure (cmH ₂ O)	PEEP (cmH ₂ O)	Compliance $\left(\frac{L}{cmH_2O}\right)$	$\begin{array}{c} Airway\\ Resistance \left(\frac{cmH_2Os}{L}\right) \end{array}$	Tidal Volume ^(mL)
20	10	5	0.05	5	236
12	15	10	0.05	20	212
20	25	5	0.02	5	384
20	25	10	0.02	20	292
20	15	5	0.02	20	166
12	25	10	0.02	50	187
20	30	5	0.01	50	203
20	25	10	0.01	10	167

Table 1: Test results according to ISO 80601-2-12:2020(E) Table 201.105. All tests were performed using a one second inspiratory time.

volume reported by the lung simulator and the volume calculated using inspiratory pressure and compliance at lower airway resistances (eqn. 9).

$$V_{\text{tidal}} = C(\text{PIP} - \text{PEEP}) \tag{9}$$

References

[1] Organization, I. S. Medical electrical equipment — part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators. https://www.iso.org/standard/72069.html (2020).

Supplementary Information for MADVent: A low-cost ventilator for patients with COVID-19 — List of Parts

Component	Manufacturer	Part Number	Unit Price	Quantity	Total Price
Microcontroller	Arduino	Mega	\$16.00	1	\$16.00
Stepper Motor	Trinamic Motion Control GmbH	QSH5718-76-28-189	\$28.69	1	\$28.69
Motor controller	STMMicroelectronics	L293D	\$3.91	2	\$7.82
Wall power adapter	N/A	N/A	\$10.00	1	\$10.00
Bread board	Sparkfun	PRT-12070	\$4.95	1	\$4.95
Bag valve respirator	Ambu	Spur II	\$15.79	1	\$15.79
PEEP Valve	Ambu	Peep Valve	\$10.00	1	\$10.00
Rotational Potentiometer	TT Electronics	P160KN2-4QC20B10K	\$0.79	6	\$4.74
Rotary encoder	Bourns Inc	ECW1J-C24-BC0024L	\$5.02	1	\$5.02
LED	Lumex Opto/Components Inc.	SSF-LXH104ID	\$0.81	2	\$1.62
Buzzer	CUI Devices	CEM-1203(42)	\$0.74	1	\$0.74
Pressure sensor	Bosch	BMP180	\$9.95	2	\$19.90
Viral filter	Hudson RCI	N/A	\$1.00	1	\$1.00
Wire	Braided Nylon	2057T77	\$0.15	1	\$0.15
Velcro	N/A	N/A			\$0.00
Acrylic/Delrin/Aluminum	ePlastics for Delrin	ACTLNAT0.250X24X48	\$40.00	1	\$40.00
Shoulder Screw	McMaster Carr	92981A107	\$3.31	1	\$3.31
Spacer	McMaster Carr	94669A014	\$1.41	10	\$14.10
Torsion Spring	McMaster Carr	9271K459	\$1.48	1	\$1.48
Nut	McMaster Carr	90591A255	\$0.02	14	\$0.28
Screw 30 mm	McMaster Carr	91292A130	\$0.11	3	\$0.34
Screw 65 mm	McMaster Carr	91292A317	\$0.37	8	\$2.92
Screw 20 mm	McMaster Carr	91292A121	\$0.09	3	\$0.27
Spacer	McMaster Carr	91292A121	\$1.94	10	\$19.40
Spacer	McMaster Carr	91292A121	\$0.12	2	\$0.23
Nut	McMaster Carr	90591A260	\$0.03	1	\$0.03
Set screw	McMaster Carr	92015A104	\$0.17	1	\$0.17
LCD Screen	Sparkfun Electronics	LCD-14074	\$25.00	1	\$25.00
				TOTAL	\$233.95

PEUA200567 MADVent Mark V List of Parts, Complete v1.0 1 May 2020

Supplementary Information for MADVent: A low-cost ventilator for patients with COVID-19 — ISO 80601-2-80 Validation Tests

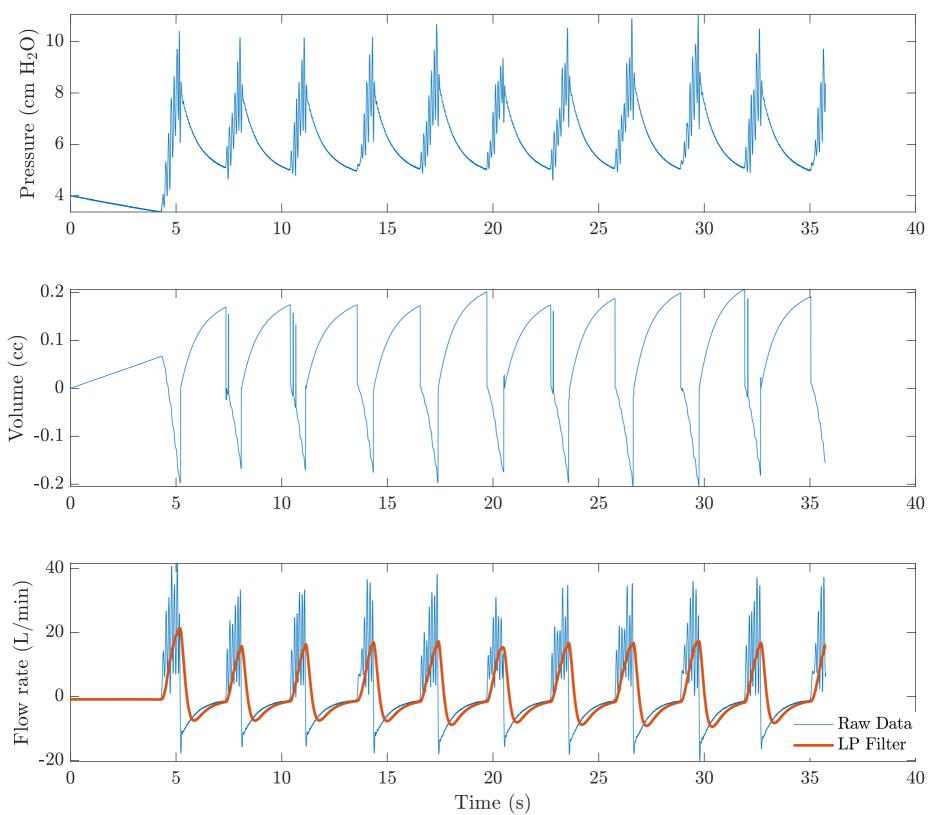
ISO Standard 80601-2-80:2018

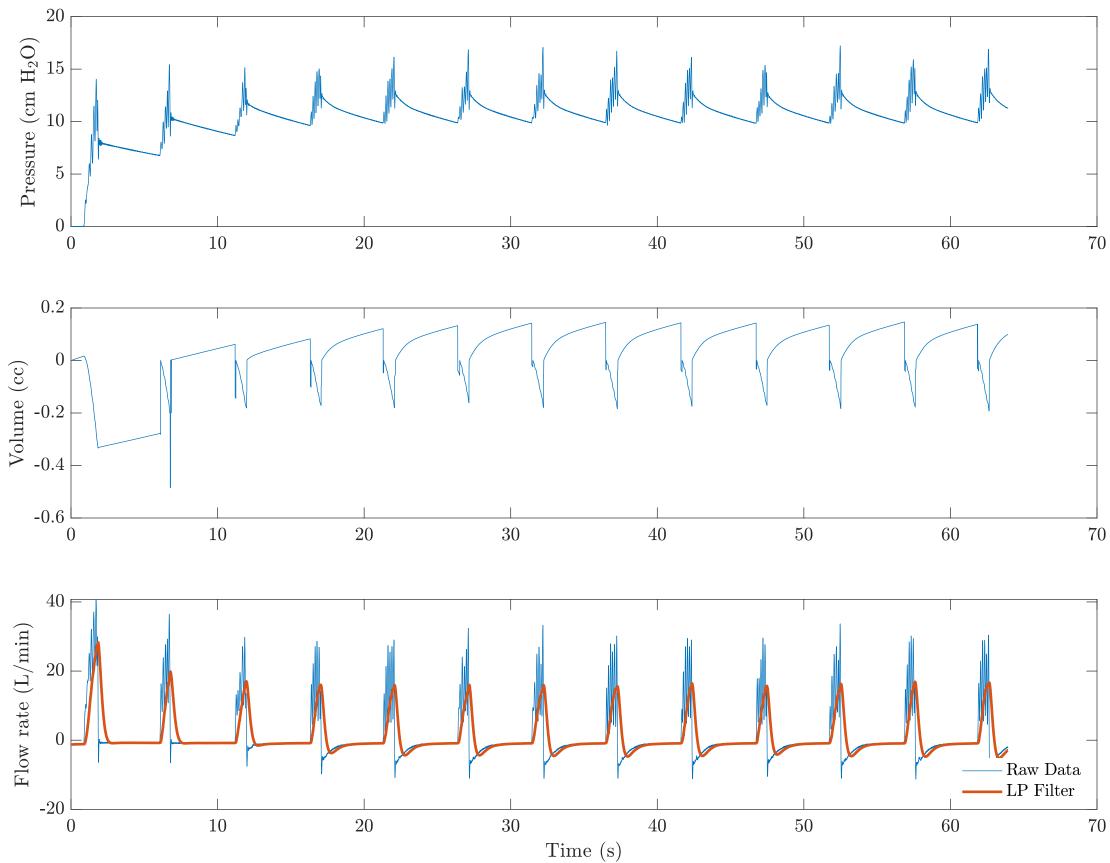
Table 201.105 — Pressure-controlled breath TYPE TEST settings

		Test lung parameters			VENTILATORY SUPPORT EQUIPMENT Settings			
Intended DELIVE Test number VOLUME ^a (ml)		Compliance (ml(hPa) ⁻¹) ± 10 %	Linear ^{[11][12][13]} resistance (hPa(l/s) ⁻¹) ±10 %	Leakage ^b (ml/min) ±10 %	ntilatory frequencyfr (breaths/min)	ispiratory time ^d (s)	Pressure ^e (hPa)	Peep (hPa)
1	500	50	5	0	20	1	10	5
2	500	50	20	0	12	1	15	10
3	500	20	5	0	20	1	25	5
4	500	20	20	0	20	1	25	10
5	500	50	5	5 000	20	1	25	5
6	500	50	20	10 000	12	1	25	10
7	300	20	20	0	20	1	15	5
8	300	20	50	0	12	1	25	10
9	300	10	50	0	20	1	30	5
10	300	20	20	3 000	20	1	25	5
11	300	20	50	6 000	12	1	25	10
12	200	10	20	0	20	1	25	10

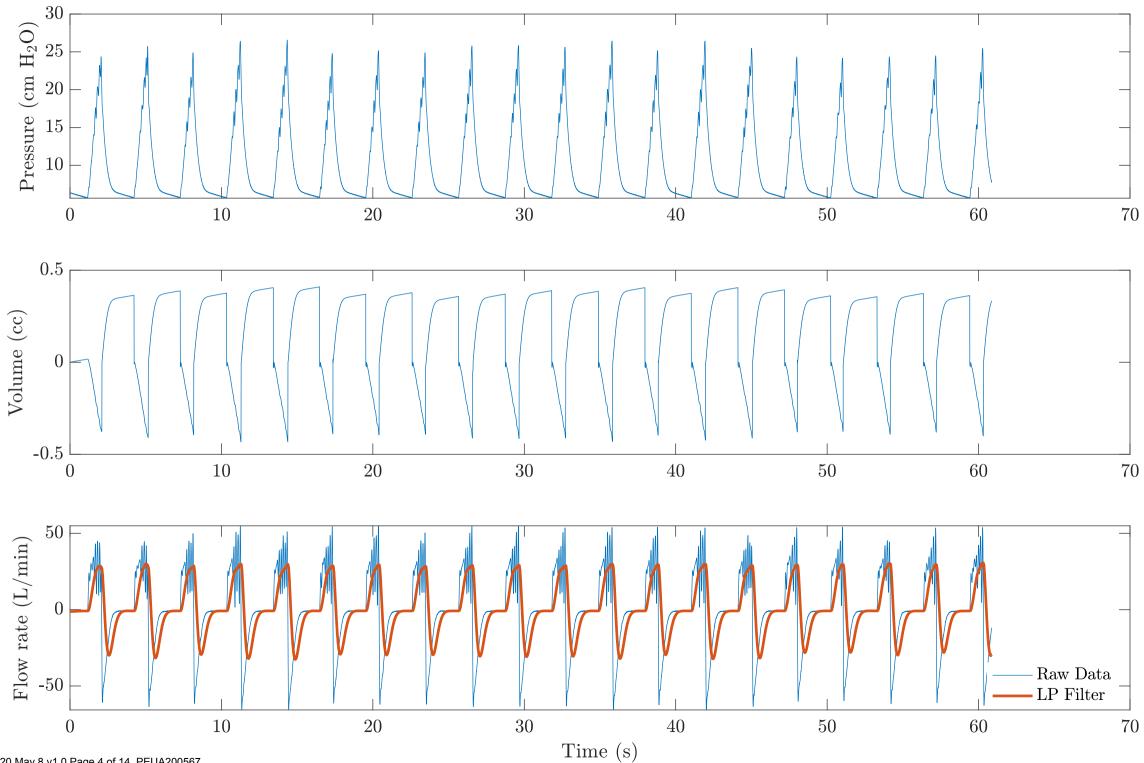
Tests on following pages are conducted per the settings in the list above.

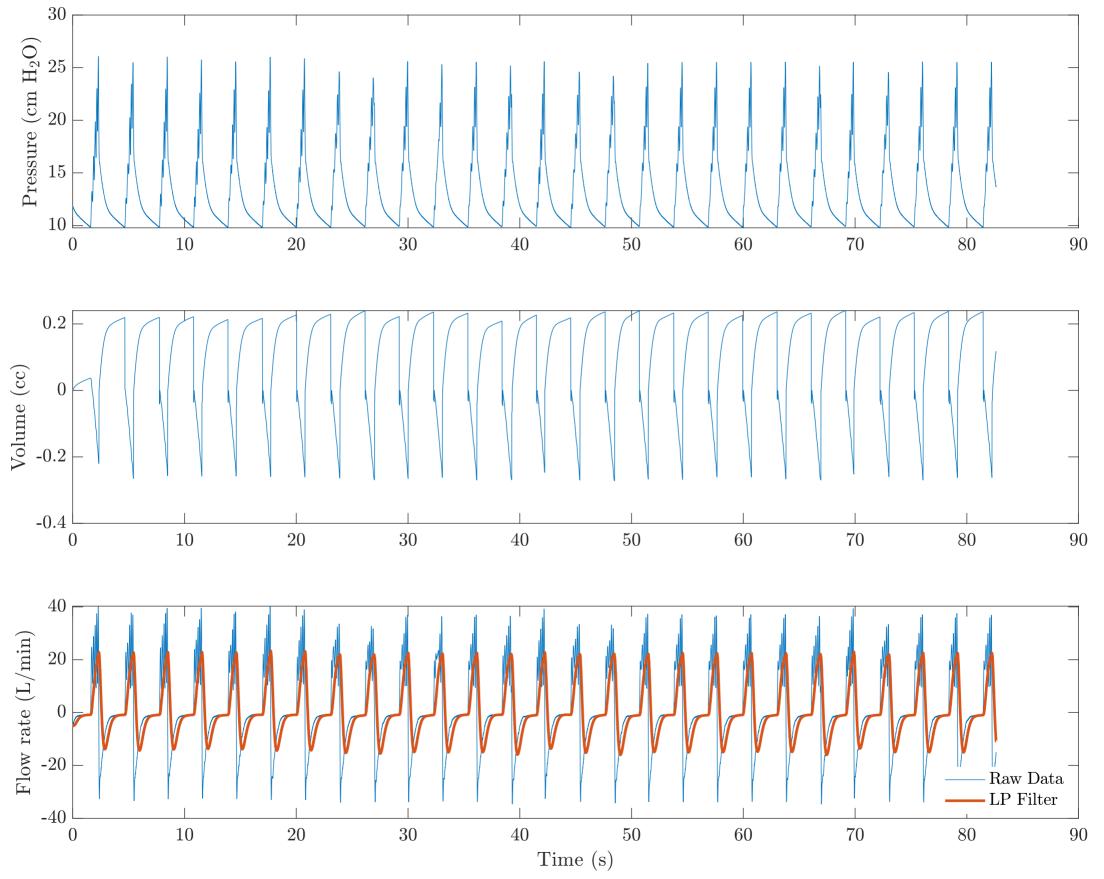




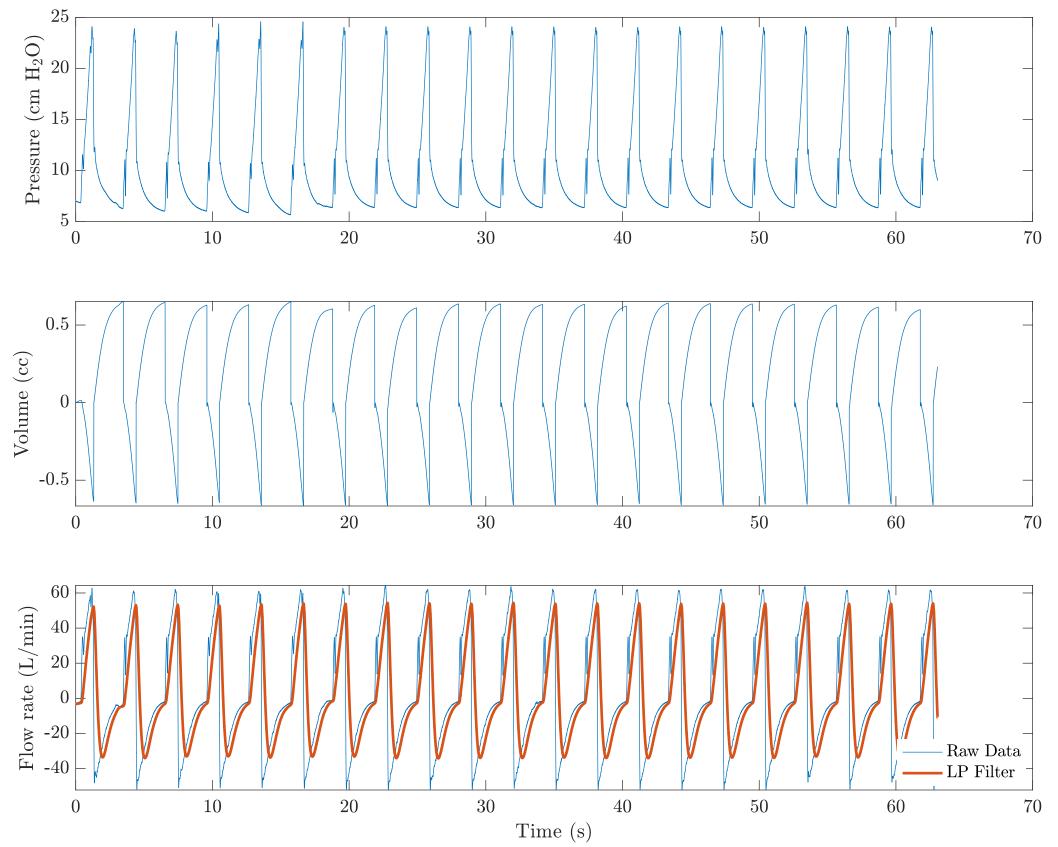


TEST 2

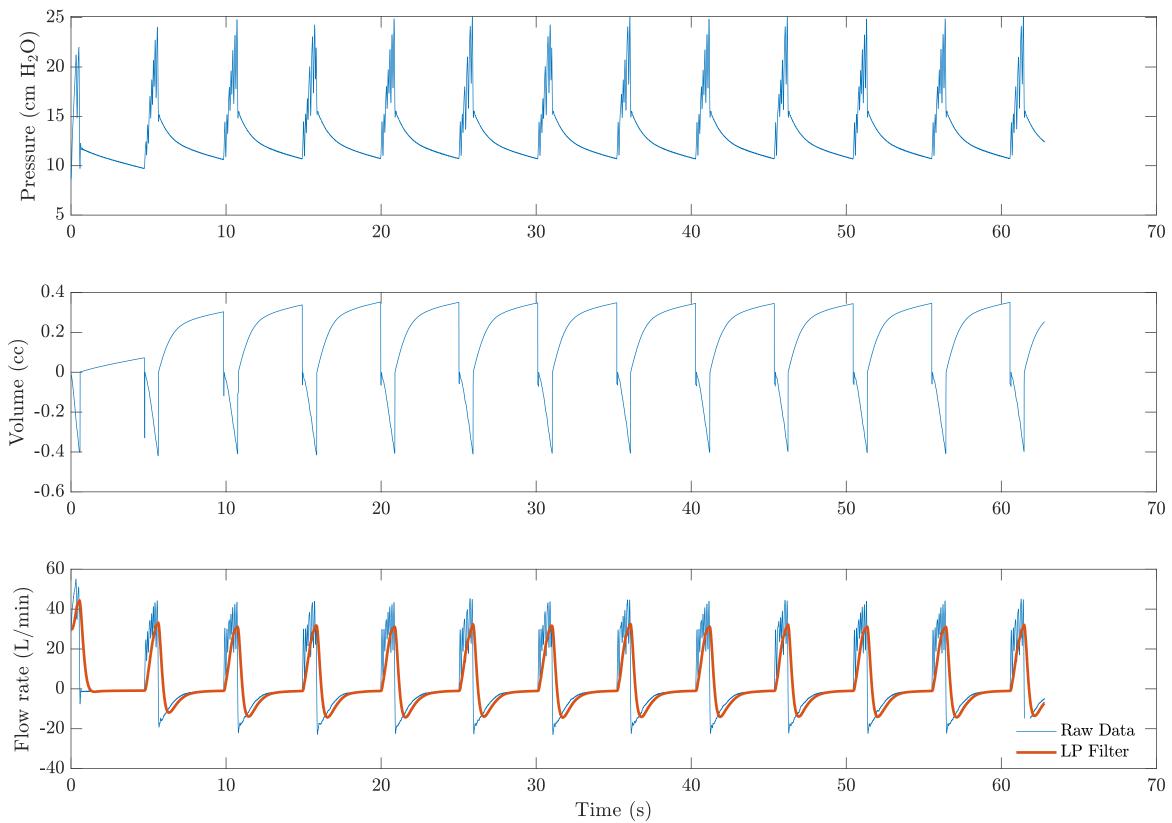


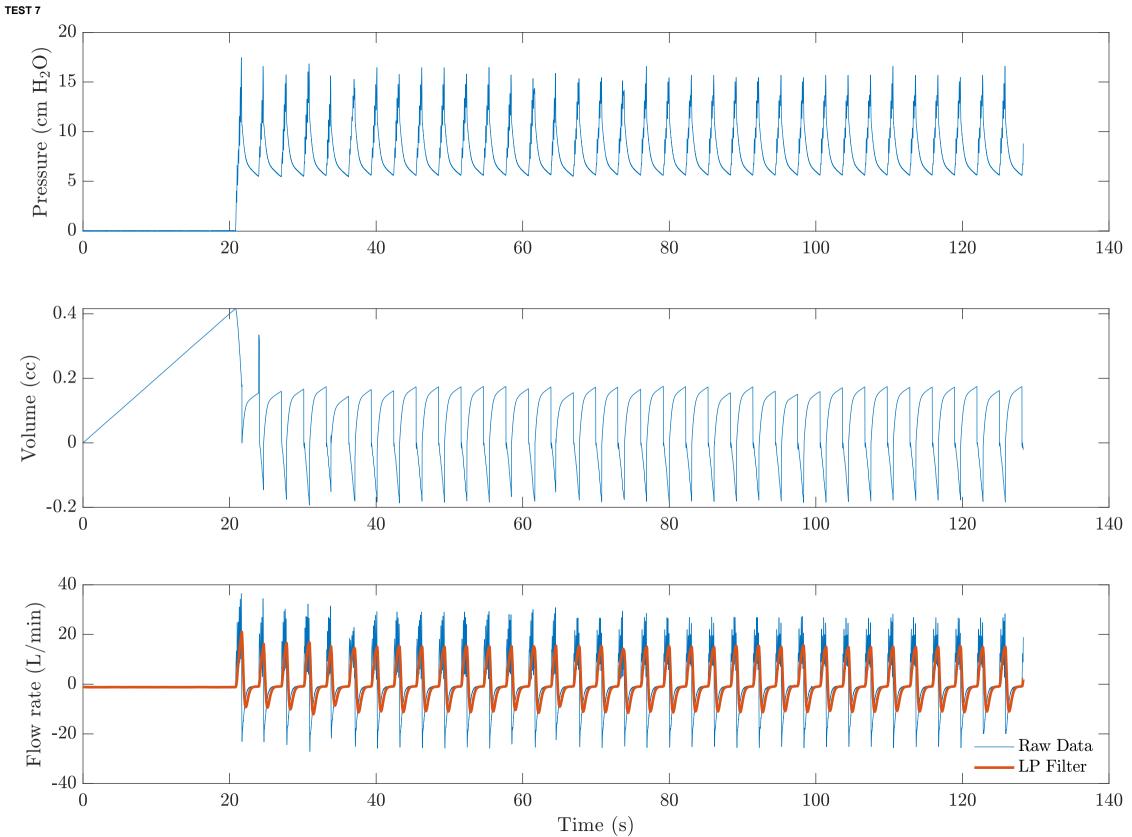


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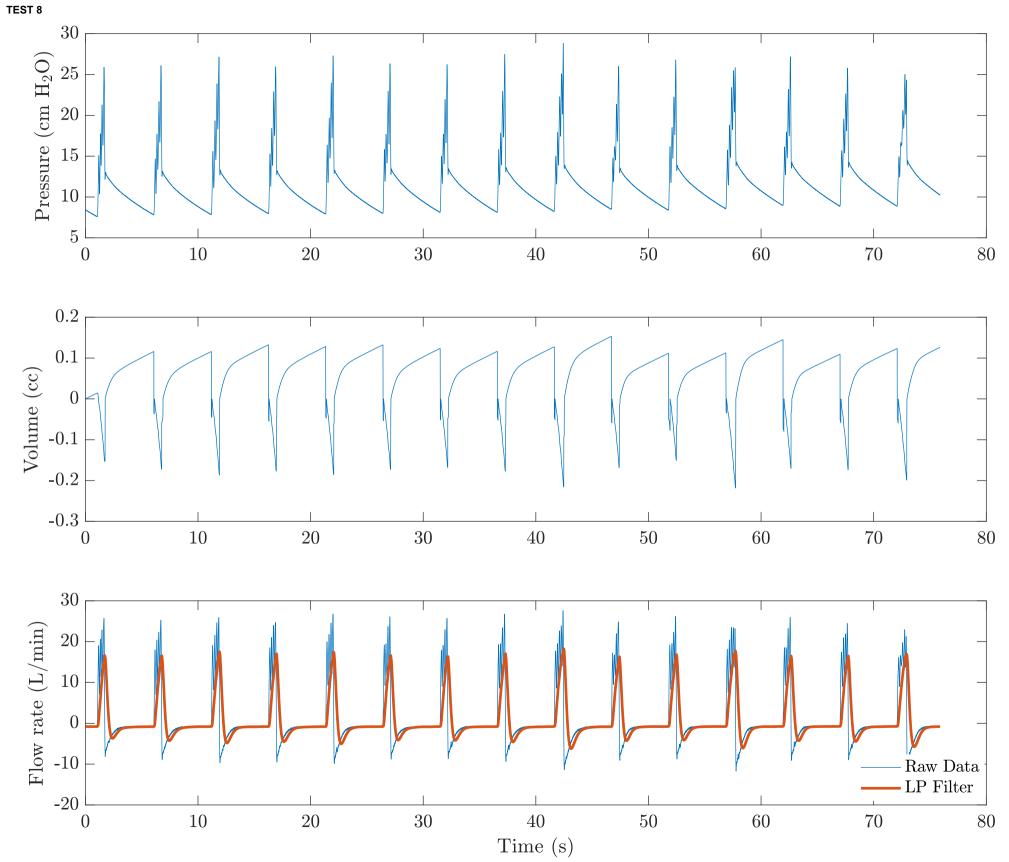


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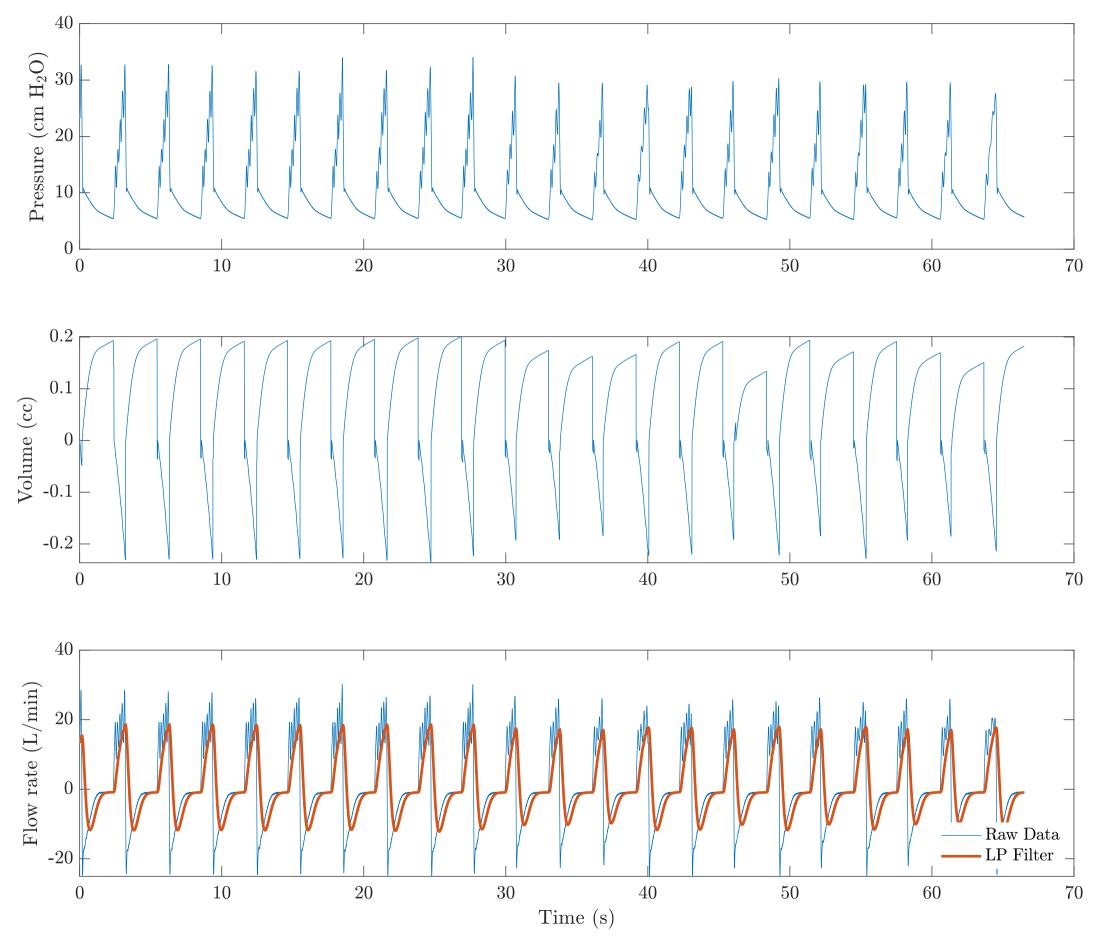


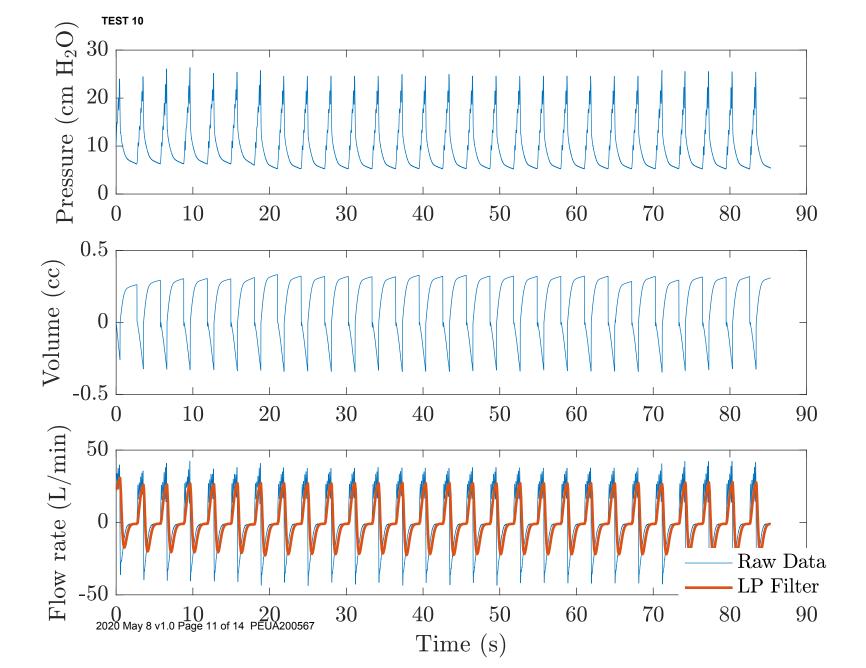


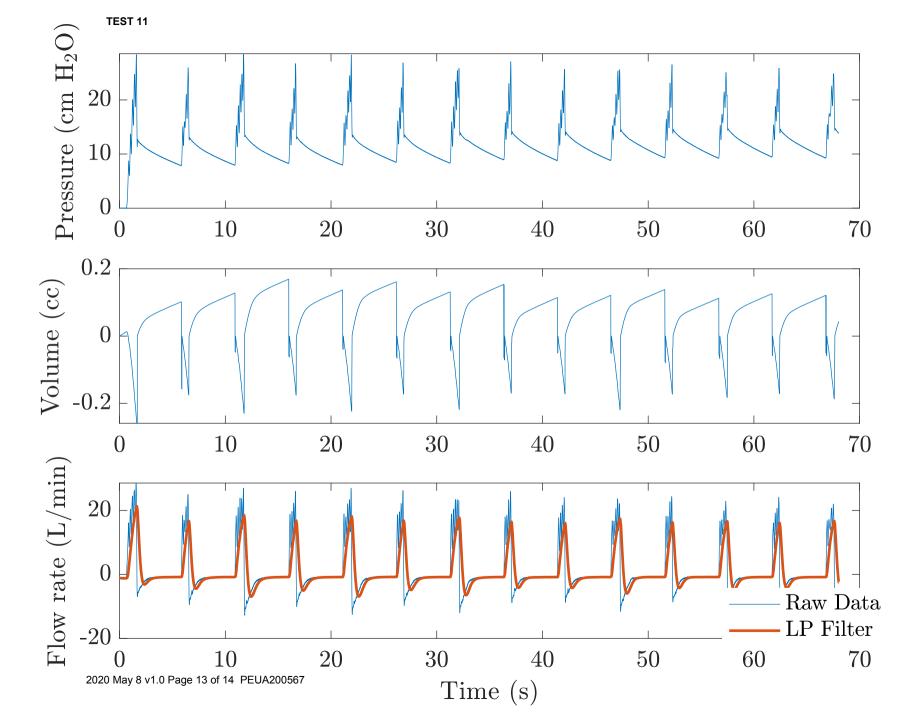
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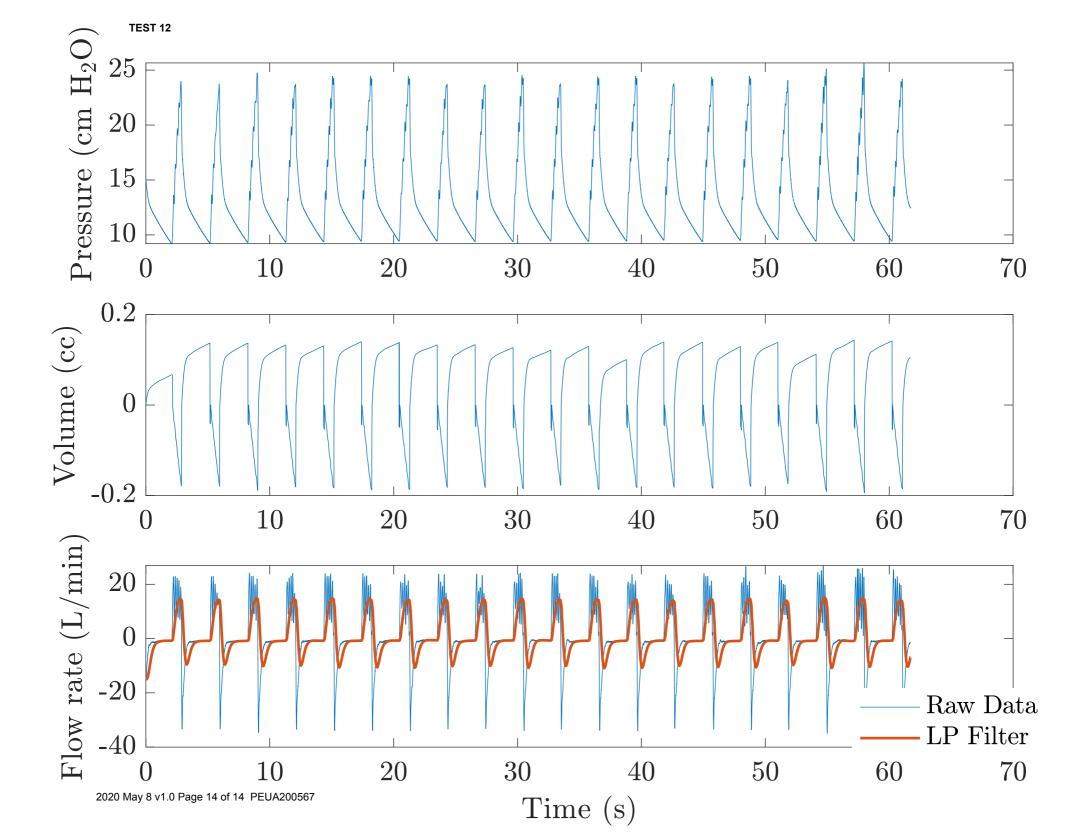




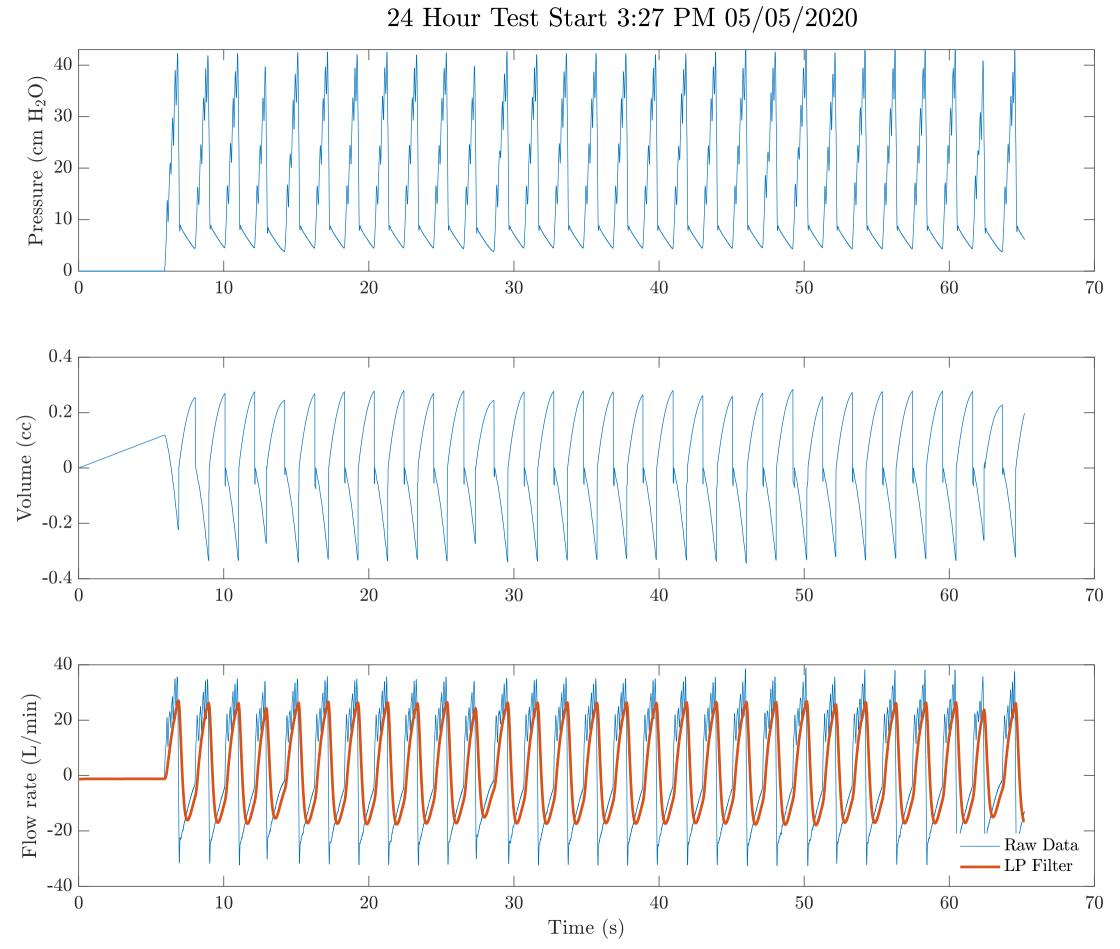




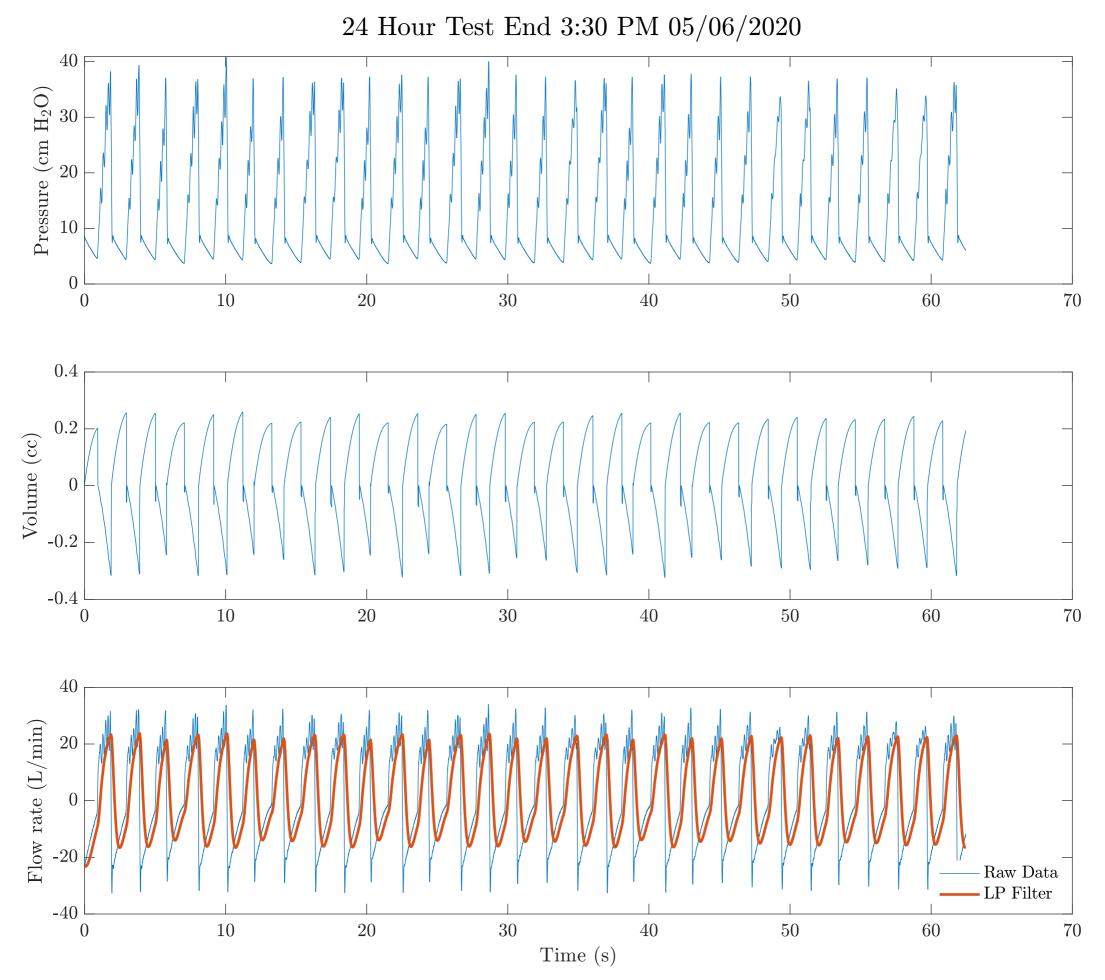




Supplementary Information for MADVent: A low-cost ventilator for patients with COVID-19 — ISO 80601-2-80 24-Hour Validation Test



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Supplementary Information for MADVent: A low-cost ventilator for patients with COVID-19 — Detailed Parts and Assembly Guide (required by FDA)

MADVent Mark V ventilator parts and detailed assembly procedure guide





Mark V Ventilator parts & detailed assembly procedure guide 2 of 20

Introduction

This document details the parts and assembly procedure for MADVent.

The system is designed to be assembled using the following instructions in under 15 minutes by unskilled personnel.

Step 1: Ensure that the package comes with all the components listed below and pictured in Figure 1.

Component	Quantity
Stepper motor	1
Optical switch with attached wire	1
Spool	1
Velcro	1 packet
Base and lever arm part kit: lever arm A & B, Base and Base 1, Compressor A & B	1
Slotted L-bracket	2
L-bracket	4
High-strength braided nylon lanyard	1
Spacer ID 4.2 mm x 22 mm length	10
Torsion Spring	1
M3 nuts	2
M3 Screw 12 mm length	3
M4 flange nuts	26
M4 Screw 8 mm length	4
M4 Screw 12 mm length	6
M4 Screw 20 mm length	3
M4 Screw 30 mm length	3
M4 Screw 65 mm length	10
M5 Shoulder screw 60 mm length	
Spacer ID 4.2 mm x 10 mm length	10
Spacer ID 6.3 mm	2
M5 Nylock Nut	1
Set screw	1
Electronics box	1
Back-up battery	1
The items below are not shown in Figure 1 for clarity but should be present in your kit	
Wall power adapter	1
Bag valve respirator	1
PEEP valve	1
Rotary encoder	1
Pressure sensor	2
Viral filter	1

Step 2: Take lever arm A [Refer to Fig.1 and identify **Part 1**] (Fig. 2a) and insert M4X30 socket head screws [Fig.1: Part 2] into each of the following holes: one is offset from the midline near the bottom of the arm (Fig. 2b) and two more are at the top of the arm (Fig. 2c). Set this lever arm aside.

Step 3: Take compressor A [Part 3] and insert the two M4X65 socket head screws [Part 4] into the two holes (Fig. 2d).

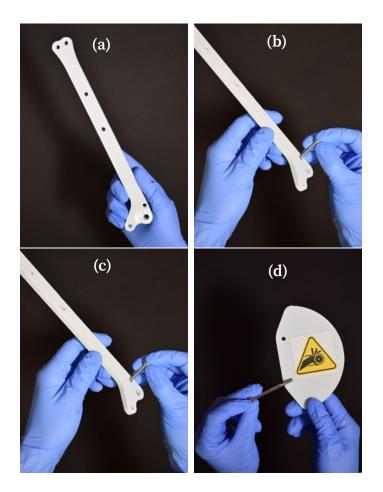


Figure 2

Step 4: Place one 4.2mm x 10mm spacers [Part 5] on each of the M4X65 screws [Part 4] that were previously inserted into the compressor (Fig. 3). A total of two spacers should be used on this step.

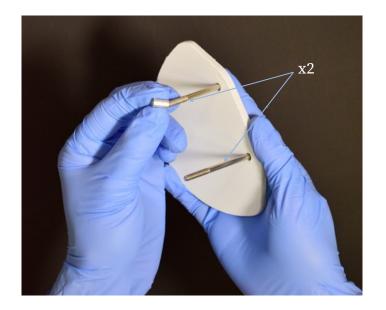


Figure 3

Step 5: Take the lever arm, screw assembly from step 2, with the offset hole pointed down, and insert the ends of the two M4X65 screws [Part 4] from the compressor, screw, and spacer assembled in steps 3 and 4 into the two open holes near the center (Fig. 4).

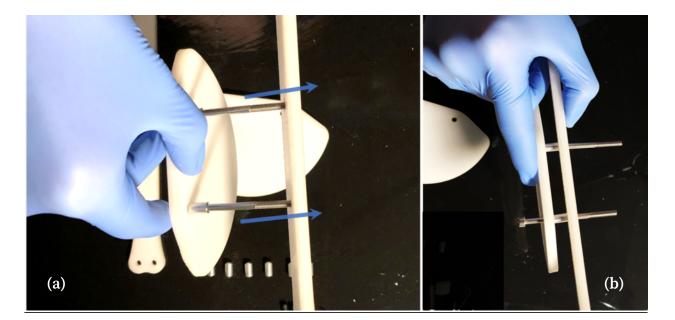


Figure 4

Step 6: Place one 4.2mm x 10mm spacer [Part 5] on each of the five screws (Fig. 5). A total of five (5) spacers should be used on this step.



Figure 5

Step 7: Take lever arm B [Part 6] and slide it onto all five screws (Fig. 6). Be sure to match the holes on the lever arms.

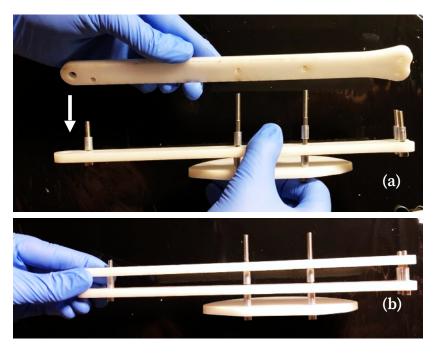
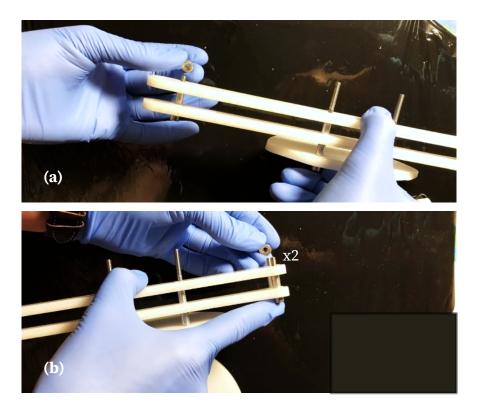


Figure 6

Step 8: Place and partially tighten one M4 flange nut [Part 7] on each M4X30 screw [Part 2] (Fig. 7). A total of three nuts should be used in this step.





Step 9: Place one 4.2mm x 10mm spacers [Part 5] on each of the M4X65 screws [Part 4] (Fig. 8a). A total of two spacers should be used on this step.

Step 10: Place compressor B [Part 8] onto the two M4X65 screws [Part 4] (Fig. 8b). Both compressor parts should be in the same orientation.

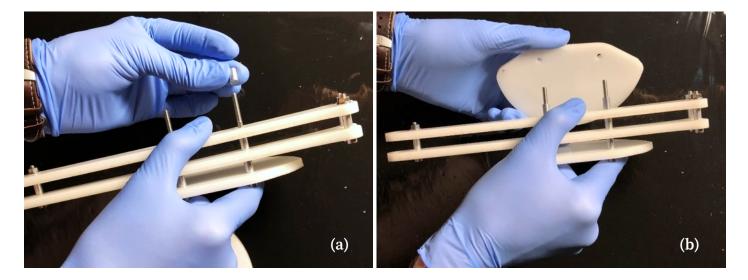


Figure 8

Step 11: Place and tighten one M4 flange nut [Part 7] on each M4X65 screws [Part 4] (Fig. 9a). A total of two nuts should be used on this step.

Step 12: Place a 4.2mm x 10mm spacer [Part 5] on a M4X30 socket head screw [Part 2]. Feed the screw through the hole as shown in figure 9(c) and attach a flange nut until snug. Fig 9(e) represents a completed lever assembly.

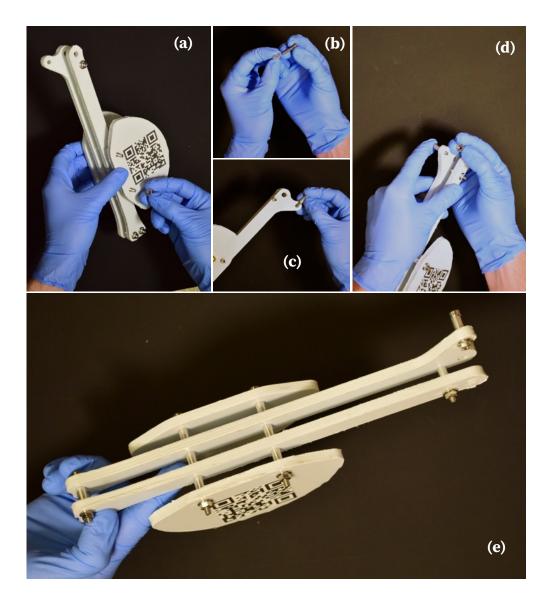


Figure 9

Step 13: Take Base 1 [Part 9] and place one M4X65 screw [Part 10] into the hole near the front which is offset from the midline (Fig. 10b).

Step 14: Place two 4.2mm x 22mm spacers [Part 11] onto the M4X65 screw [Part 10] (Fig. 10c).

Step 15: Slide the M4X65 screw [Part 10] from step 14 onto the matching hole in Base 2 [Part 12] (Fig. 10d). Be sure all other matching holes align correctly.

Step 16: Place and partially tighten one M4 flange nut [Part 13] onto the M4X65 screw [Part 10] (Fig. 10e).

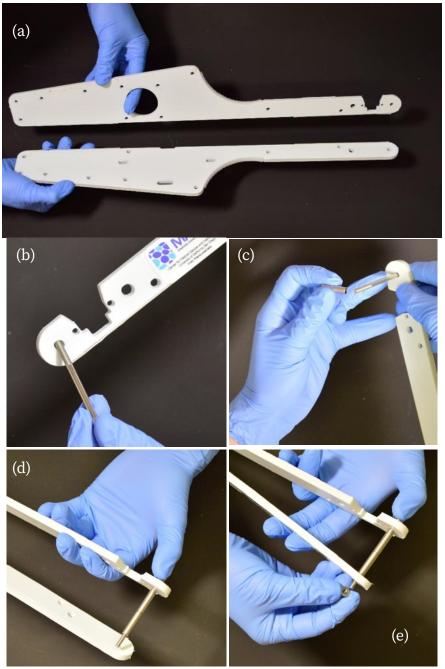


Figure 10

Step 17: Repeat steps 13 through 16 for each of the holes indicated in Figure 11.



Figure 11

Step 18: Take the **stepper motor [Part 14]** and place its shaft into the motor hole of **Base 1 [Part 9]** (Fig. 12). Orient the motor such that the wire exit points towards the back of the base.

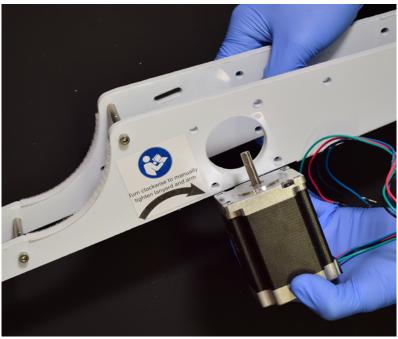


Figure 12

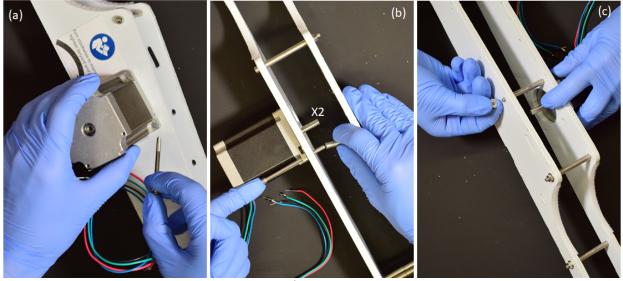


Figure 13

Step 19: Align the corner hole of **Base 1 [Part 9]** with the corresponding hole in the **stepper motor [Part 14]** mounting flange and slide one **M4X65 screw [Part 10]** through both holes (Fig. 13a).

Step 20: Place two 4.2mm x 22mm spacers [Part 11] onto the M4X65 screw [Part 10] from step 19 (Fig. 13b).

Step 21: Feed the M4X65 screw [Part 10] into the corresponding hole on Base 2 [Part 12] (Fig. 14).

Step 22: Place and partially tighten one **M4 flange nut [Part 13]** on to the **M4X65 screw [Part 10]** from steps 19, 20, 21 (Fig. 14d). A total of one nut should be used on this step.

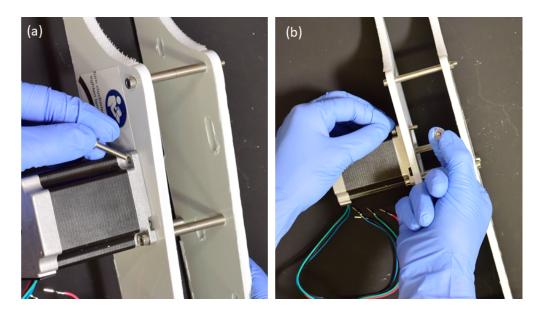


Figure 14

Step 23: Place one **M4X20 screw [Part 15]** into one of the open holes on the **stepper motor [Part 14]** mounting flange.

Step 24: Place and partially tighten one **M4 flange nut [Part 13]** on to the **M4X20 screw [Part 15]** from step 23. A total of one nut should be used on this step.

Step 25: Repeat steps 23 and 24 for the remaining two mounting holes on the stepper motor [Part 14]

Step 26: Tighten all nuts until snug. The screws and spacers should no longer be free to rotate. Refer to Figure 15.

Step 27: Take an L-bracket [Part 16] and insert an M4X12 screw [Part 17] into one of the holes.

Step 28: Insert the end of the **M4X12 screw [Part 17]** into one of the mounting holes behind the motor.

Step 29: Place and tighten an **M4 flange nut [Part 18]** on to the **M4X12 screw [Part 17]** such that the bracket is nearly flush with the top surface of the base.

Step 30: Refer to Figure 16 and repeat steps 27-29 for each of the four mounting holes.

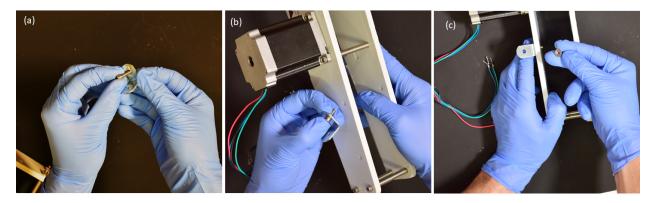


Figure 16

Step 31: Take a **slotted L-bracket [Part 19]** and insert an **M4X12 screw [Part 17]** into the non-slotted hole.

Step 32: Insert the end of the M4X12 screw [Part 17] into the small horizontal slots on the base 2 [Part 12].

Step 33: Place and partially tighten an M4 flange nut [Part 18] on to the M4X12 screw [Part 17].

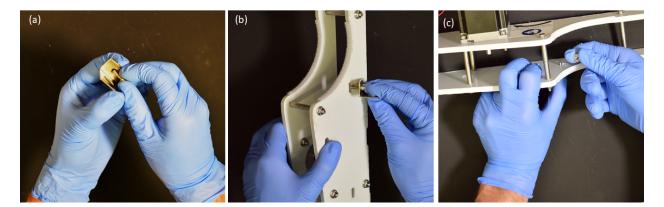


Figure 17

Step 34: Repeat steps 31-33 for both small horizontal slots. Refer to Figure 17.

Step 35: Take the **optical limit switch [Part 20]** and place an **M3X12 screw [Part 21]** through one of the holes.

Step 36: Insert the end of the M3X12 screw [Part 21] into the optical switch cradle on the base 1[Part 9] such that the optical limit switch [Part 20] is resting as shown in figure 18b.

Step 37: Place and tighten an M3 flange nut [Part 22] onto the M3X12 screw [Part 21].

Step 38: Refer to Figure 18. Repeat steps 35-37 for both holes on the optical limit switch [Part 20].

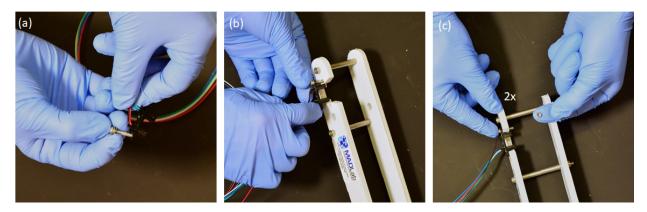


Figure 18

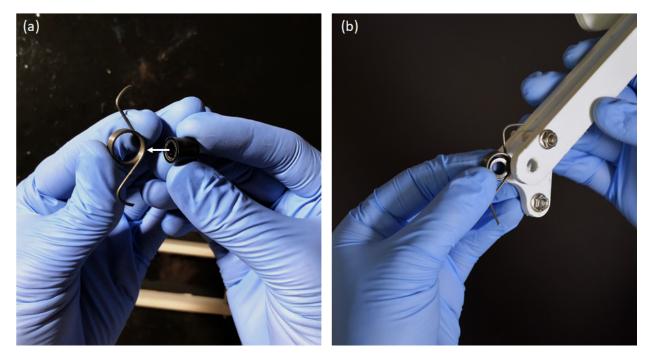


Figure 19

Step 39: Place the 6.3mm x 10mm black spacer [Part 23] into the torsion spring [Part 24] (Fig. 19a).

Step 40: Lay the assembled arm and base inline such that the hinge holes are approximately aligned and the **compressors [Parts 3 & 8]** are facing up (Fig. 19b)

Step 41: Place the **torsion spring [Part 24]**, **black spacer [Part 23]** assembly into the opening of the lever arm assembly (Fig. 15b) such that the arms of the **torsion spring [Part 24]** hook around the spacers of the offset holes on both the base and lever arm assemblies (Fig. 19b).

Step 42: Place a **6.3mm x 10mm white spacer [Part 25]** into the gap between **Base 1 [Part 9]** and the lever arm assembly such that the hole aligns with the hinge hole (Fig. 20b).

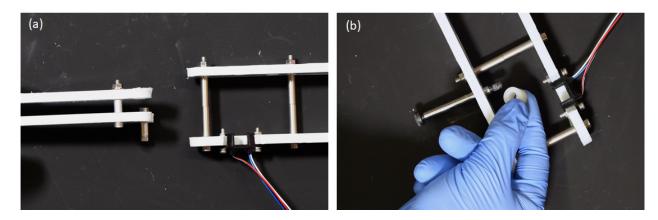


Figure 20

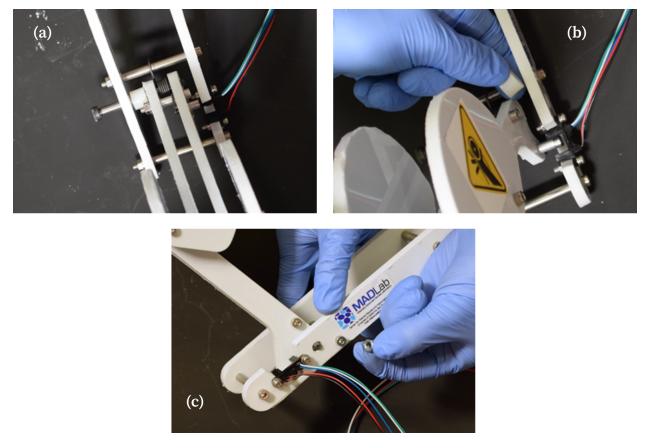


Figure 21

Step 43: Feed the M5X6X60 shoulder screw [Part 26] into the hinge hole on Base 1 [Part 9] and through the 6.3mm x 10mm white spacer [Part 25], the first lever arm assembly hole, the 6.3mm x 10mm black spacer [Part 23] hole, and then the second lever arm assembly hole (Fig. 21a).

Step 44: Place a **6.3mm x 10mm white spacer [Part 25]** into the gap between the second lever arm assembly hole and the hinge hole in **Base 2 [Part 12]** (Fig. 21b).

Step 45: Continue feeding the **M5X6X60 shoulder screw [Part 26]** from step 31 through the **6.3mm x 10mm white spacer [Part 25]** and into the hinge hole on **Base 2 [Part 12]** (Fig. 21c).

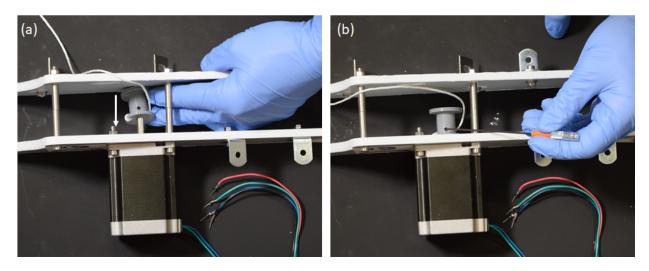
Step 46: Place and tighten the **M5 nylock nut [Part 27]** onto the **M5X6X60 shoulder screw [Part 26]** from steps 31&33 (Fig. 21c).



Figure 22

Step 47: Take the **high strength braided nylon twine [Part 28]** and feed it through the **spool [Part 29]** (Fig. 22).

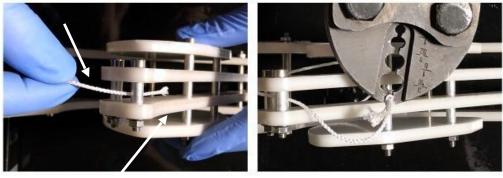
<u>Step 48</u>: Pull the **twine [Part 28]** through the wall hole of the **spool [Part 29]** and loop around the wall and through such that pulling on the free end of the string tightens down on the looped end (Fig. 22).





Step 49: Place the **spool [Part 29]**, **twine [Part 28]** assembly inside the base aligning the shaft hole with the **stepper motor [Part 14]** drive shaft. Be sure to place the **spool [Part 29]** oriented such that the **twine [Part 28]** tie off is closest to the **stepper motor [Part 14]** and the set screw is perpendicular to the flat of the drive shaft (Fig. 23).

Step 50: Slide the **spool [Part 29]** until the wall closest to the **stepper motor [Part 14]** is close to aligned with the inside face of **Base 1 [Part 9]** and tighten the set screw (Fig.23).





Step 51: Take the free end of the **twine [Part 28]** and feed it through the opening between the two **spacers [Part 5]** at the top of the lever arm assembly and loop it around the next **spacer [Part 5]** (Fig. 24).

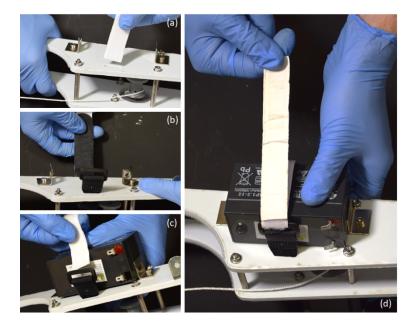
Step 52: Tie off the looped **twine [Part 28]** using an aluminum ferrule and crimping tool (Fig. 24).

Step 53: Take the **hook-and-loop strap [Part 30]** and insert the non-buckle end into the large horizontal slot in **base 2 [Part 12]**.

Step 54: Feed the strap through the slot and down under **base 2 [Part 12]** such that it rests in the notch at the bottom.

Step 55: Place the battery [Part 31] into the space between the slotted L-brackets [Part 19].

Step 56: Wrap the hook-and-loop strap [Part 30] around the battery [Part 31] and through its buckle.





Step 57: Cinch the **hook-and-loop strap [Part 30]** down around the **battery [Part 31]** until snug. Then tighten the **M4 flange nuts [Part 18]** on each of the **slotted L-brackets [Part 19]** to fully fix the battery in place. Refer to figure 25.

Step 58: Take an M4X8 screw [Part 32] and place it in the open hole of one of the L-brackets [Part 16].

Step 59: Place the **electrical box [Part 33]** onto the **L-brackets [Part 16]** and align the holes on the bottom and feed the **M4X8 screw [Part 32]** through one of the open holes. Be sure to orient the **electrical box [Part 33]** such that it's longest side is perpendicular with the **bases [Parts 7 and 8]**.

Step 60: Place and tighten an M4 flange nut [Part 19] on the M4X8 screw [Part 32].

Step 61: Repeat steps 58 and 60 for all four holes on the electrical box [Part 33]. Refer to figure 26.

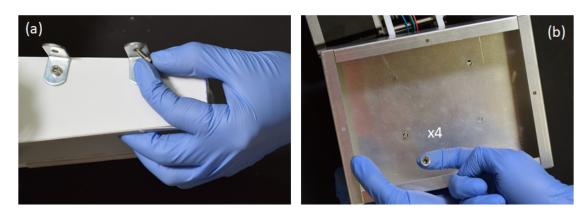
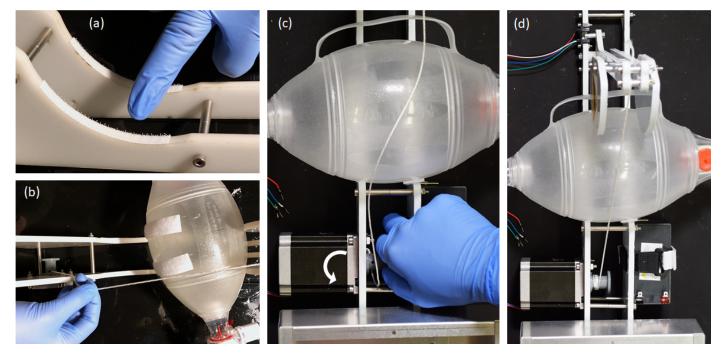


Figure 26





<u>Step 62:</u> Place strips of hook and loop fastener (Velcro) along the bag cradles of **Base 1 [Part 9]** and **Base 2 [Part 12]** (Fig. 27). Place corresponding strips on the bag (Fig. 27). It is recommended to place the hook side in the cradle and the loop side on the bag.

<u>Step 63:</u> Place the bag in the cradle (Fig. 27) and rotate the **spool [Part 29]** in the clockwise direction to tighten the lever arm assembly onto the bag (Fig. 27). Rotate the **spool [Part 29]** until the **compressors [Parts 3 & 8]** just begin to depress the bag (Fig. 27). This should be approximately 2-3 turns of the **spool [Part 29]**.

Aditya Vasan, Reiley Weekes, William (Bill) Connacher, Jeremy Seiker, Mark Stambaugh Prototype put together by above authors at UCSD's MADLab and Bill/Aditya's garage during the 2020 COVID Pandemic.

Work(s) (the "Work") by: COVID-19 Acute Ventilation Rapid Response Taskforce (AVERT) Medically Advanced Devices Laboratory Department of Mechanical and Aerospace Engineering Jacobs School of Engineering and the School of Medicine University of California, San Diego 9500 Gilman Drive MC411 La Jolla, CA 92093-0411

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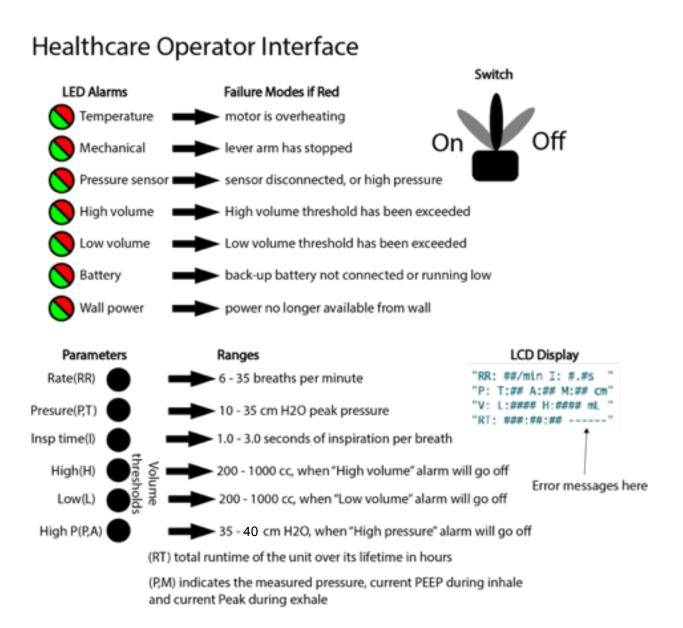
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Supplementary Information for MADVent: A low-cost ventilator for patients with COVID-19 — Operating Instructions (required by FDA)

MADVent Mark V OPERATING INSTRUCTIONS

The **MADVent Mark V** is a single-mode continuous, mandatory, closed-loop pressure controlled timeterminated emergency ventilator meant for sedated, intubated patients being cared for in a professional healthcare facility **only**. It employs an FDA-recognized single-use and disposable, automatically self-inflating manual ("ambu") ventilator bag with attached positive endexpiratory pressure (PEEP) valve.



Assembly, start-up and functional test procedure by healthcare professional operator (13 total steps)

- Step 1: Ventilator assembly procedure: consult the separate documents MADVent
 Mark V ventilator parts and detailed assembly procedure guide and MADVent
 Mark V product labeling provided with these instructions, and the Healthcare
 Operator Interface figure above. If needed, additional technical information is
 provided in the separate document Mark V ventilator technical description.
- **Step 2:** Plug the ventilator power supply into a standard 120V 60Hz wall outlet (USA Standard). Verify charge status of integrated rechargeable battery, on start up an LED will appear either green if the battery is sufficiently charged or red if on low charge. The integrated battery is solely for use as an emergency or temporary backup for disconnection or loss of mains (wall) power. It is not to be used as the primary method to power the ventilator.
- NOTE: Place ventilator at least 3 feet away from other electromagnetically active equipment. This Resuscitator has not been tested for electromagnetic compatibility (EMC). It may produce electromagnetic disturbances that will affect the performance of other equipment. It may fail to perform as expected in the presence of electromagnetic disturbances from other equipment.
- <u>Step 3:</u> Choose and prepare a bag-valve resuscitator (colloquially known as a BVM e.g. an "Ambu Bag") for use. The MADVent has been calibrated for use with the Ambu SPUR II (adult size).
- <u>Step 4:</u> Attach the provided hook and loop fasteners as shown in the separate document MADVent Mark V Parts and Detailed Assembly Procedure to the bag-valve resuscitator.
- **<u>Step 5:</u>** Place the bag-valve resuscitator into the cradle. Be sure the hook and loop fastener on the bag-valve resuscitator securely attaches to the corresponding hook and loop fastener in the cradle.
- **Step 6:** Note arrow indicating manual rotation direction to rotate the spool and loop the lanyard around the spool. Continue manually rotating the spool in the direction indicated by the arrow and wind the lanyard around it until the lever arm just begins to compress the bag of the bag-valve resuscitator. Approximately 4 to 5 turns is sufficient.

<u>Step 7:</u> Place the ventilator system as close to the patient as practically possible.

- **Step 8:** Attach the patient inspiration line to the ventilator output. The healthcare professional operator should carefully consider the *dead space* in the ventilation tubing between the ventilator and the patient. The dead space is the volume within the tubing from the patient's lungs to the ventilator bag, and during ventilation this may be cycled back and forth into and out of the patient without removal from the ventilation system, with decrease in oxygen and increase in carbon dioxide in that volume. The healthcare professional operator must shorten the inspiratory tubing as much as practical, include appropriate valving, and provide expiratory flow ventilator tubing to minimize the dead space and risk of inadequate patient oxygenation.
- **<u>Step 9</u>:** Turn on the ventilator by plugging the barrel jack and the battery cable into the corresponding sockets on the control box. An automated startup procedure will begin and proceed for a few seconds.
 - During startup, the system first automatically tests the auditory and visual alarm indicators. The **alarm buzzer** will sound and all seven light emitting diodes (LED) will turn **red.** If ANY of these indicators do not occur, there is a fault in the system and the healthcare professional operator should not proceed past this step to move forward with using the system. To begin the rest of the set up the healthcare professional operator must flip the toggle switch from off to on and back to off.
 - During startup, the system then automatically tests the wall power, battery, pressure sensor, temperature sensors, motor, motor controller, the rotary encoder on the motor shaft, and the optical switch used to detect the motion of the lever arm. At each check, an **LED corresponding to each component will turn green to confirm its presence and safe operation** in sequence. If the corresponding LED turns **red**, the component is missing or not functioning as intended. In this case the healthcare professional operator should not progress beyond this step nor use the system. If this fails, the system should be taken out of service and replaced.
 - The testing of the motor and rotary encoder, and the optical switch requires input by the healthcare professional operator. The system will alert the healthcare professional operator on the screen to flip the toggle switch from

off to on and back to off to indicate the system is ready to test. The motor and arm will move a small amount as part of the test.

- Seven LEDs illuminated green and the word "READY" in the bottom right corner of the screen indicate the system is ready to be used. Continue to the next step.
- **Step 10:** Once the startup procedure has successfully completed (denoted by seven LEDs illuminated green), the healthcare professional operator should set the intended ventilation values: respiratory rate, peak pressure, inspiration time, and minimum and maximum volume alarm volumes and the high pressure limit. These settings are made by adjusting the knobs on the controller. If any respiratory settings are flashing on the LCD screen, it means that the ventilation parameters are in conflict and must be reconciled before the ventilator will operate.
- <u>Step 11:</u> Enable the ventilator using the **ventilator enable** switch from **off** to **on**. Ventilation should begin immediately. Monitor the first few ventilation cycles to ensure the ventilation parameters are being reasonably met.
- **Step 12:** Continue to monitor the ventilator screen and indicators for any errors that appear. If an LED has turned **red**, the corresponding label indicates the type of error detected. The screen may also flash the value related to the error. In addition, the ventilator may also take the additional following actions:
 - If a **high volume error** is detected, the system will flash a red light, trigger an audible alarm to alert the healthcare provider, and will immediately stop. This alarm indicates the volume entering the inspiratory line has increased above a set value. This may occur if there is an issue with the patient or there is a leak in the system. This issue *must* be resolved before ventilation may continue. If the high volume error remains **DO NOT CONTINUE WITH OPERATION**.
 - If a **low volume error** is detected, the system will flash a red light and trigger an audible alarm to alert the healthcare provider. This could happen in the event of a constriction or blockage in the tube that causes pressure build up but no appreciable volume change. If the low volume error remains **DO NOT CONTINUE WITH OPERATION**.
 - If a **high pressure error** is detected the system will flash a red light, trigger an audible alarm to alert the healthcare provider, and indicate the alarm on the

LCD screen. This alarm indicates the pressure in the inhalation line exceeds the set value.

- Other errors (temperature, lanyard arm position error, motor rotation error, integrated circuit (IC) fault) may not require changes in operation, but instead indicate cautious observance of the system by the healthcare professional provider is necessary. If the system appears to function incorrectly DO NOT CONTINUE WITH OPERATION, follow the correct shutdown procedures provided below, and replace the system.
- **Step 13:** In the event an error is detected and corrected, disable then re-enable the system by switching the **ventilator enable** switch to **off** then **on**. This will clear the error. The system will begin to function as normal. Note the power loss alarm will be active while the **ventilator enable** switch is in the **off** position. This is intentional as a safety measure to inform the healthcare provider if the switch is inadvertently activated.

Shutdown by healthcare professional operator (6 total steps)

- **<u>Step 1:</u>** Stop the ventilator by switching the **ventilator enable** switch from **on** to **off**. Note the power loss alarm may be deactivated by toggling the **ventilator enable** switch **off-on-off** a second time.
- **<u>Step 2:</u>** Disconnect the patient inspiratory line from the ventilator output.
- **<u>Step 3:</u>** Turn off the ventilator by unplugging the battery and wall power. The screen and LEDs should turn off.
- **<u>Step 4:</u>** Remove the bag-valve resuscitator by rotating the lever arm away from the bag and pulling the bag up and away from the hook and loop fasteners.
- **<u>Step 5:</u>** Unplug the ventilator power supply from the wall outlet.
- <u>Step 6:</u> Clean, disinfect, sterilize, and discard the components of the ventilator according to the **cleaning, disinfection, and sterilization** instructions provided below.

Pressure values

1. Maximum limited pressure, $P_{\text{LIM, max}} = 50 \text{ cm H2O}$.

2. Rated range of maximum working pressure that may be set by the provider: $P_{W, max} = 10$ cm H2O to 50 cm H2O, as defined by pressure limiting operation of the ventilator breathing system.

3. The rated range of inspiratory gas pathway resistance, over which the accuracies of the set and monitored pressure settings are maintained, is between 5 and 50 cm H2O/(L-s).

4. The rated range of compliance, over which the accuracies of the set and monitored pressure settings are maintained, is between 0.02 and 0.1 L/cm H2O.

Cleaning, disinfection, and sterilization

The manual ventilator bag should be changed or cleaned according to its instructions.

In compliance with clinical guidelines for ventilators, the **Mark V ventilator** should be wiped clean as necessary using either 70% ethanol or bleach free clorox wipes. Non-corrosive spray disinfectant is compatible with the ventilator.

The healthcare professional operator must consult the manual ventilator bag instructions regarding safe sterilization procedures for that component.

Invasive components will have to be sterilized and are not a part of the components included with the Mark V ventilator.

Additional technical information

Additional technical information is provided in the separate document **Mark V Ventilator Technical Description**, including the following parts:

- 1. Method for checking the function of the alarm system by healthcare professional operator.
- 2. Uncertainty for each disclosed tolerance.
- **3.** Pneumatic diagram of the ventilator.
- **4.** Summary description of the filtering or smoothing techniques for all measured or computer variables that are displayed or used for control.
- **5.** Summary description of the means of initiating and terminating the inflation phase in each ventilation mode of the ventilator.

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Supplementary Information for MADVent: A low-cost ventilator for patients with COVID-19 — Product Labeling (required by FDA)

MADVent Mark V PRODUCT LABELING

- The **MADVent Mark V** is a single-mode continuous, mandatory, closed-loop pressure controlled timeterminated emergency ventilator meant for sedated, intubated patients being cared for in a professional healthcare facility **only**. It employs an FDA-recognized single-use and disposable, automatically self-inflating manual ("ambu") ventilator bag with attached positive endexpiratory pressure (PEEP) valve.
- It is only an emergency use ventilator, for use only in a professional healthcare facility when *both* other ventilators are unavailable *and* patient survival depends upon having access to a ventilator during the Coronavirus Disease 2019 (COVID-19) pandemic. This product cannot be presumed to be safe or effective for the prevention or treatment of COVID-19.
- Healthcare providers administering the device must consult the <u>Fact Sheet for Healthcare</u> <u>Providers</u>: Emergency Use of Ventilators During the COVID-19 Pandemic.
- Patients and/or their guardian(s) must be provided the FDA <u>Fact Sheet for Patients</u>: Emergency Use of Ventilators During the COVID-19 Pandemic
- **NOTE:** This ventilator is for use only with intubated patients. It is not for use with masks nor nasal appliances.
- **WARNING:** Do not use this ventilator without first ensuring the included emergency backup battery has been fully charged. Do not attempt to use the ventilator only on battery power for more than 20 minutes. Doing either can possibly lead to ventilator stoppage, and to patient death or serious deterioration of health.
- **WARNING:** Do not cover or position the ventilator in a manner that prevents its motion, could potentially pinch or trap the ventilation tubes, or produce a safety hazard to the patient or others.
- **WARNING:** Always have immediate access to an alternative means of ventilation, which is ready for use, in order to reduce the possibility of patient death or serious deterioration of health.
- **WARNING:** The ventilator shall not be used in a hyperbaric chamber. Such use may cause ventilator malfunction, patient death, or serious deterioration of health.
- **WARNING:** The ventilator shall not be used with inlet gases not specified for use with the bag ventilator (standard BVM-bags, for example an Ambu-bag). Such use may cause ventilator malfunction, patient death, or serious deterioration of health.
- **WARNING:** The ventilator accuracy can be affected by the gas added to the ventilator breathing system by use of a pneumatic nebulizer.

- **WARNING:** It is the responsibility of the responsible organization to ensure that the oxygen source is compatible with the rated range of pressure, flow rate, and oxygen concentration as marked on the ventilator bag and indicated in the instructions for use, as this can affect the performance of the ventilator that can consequently result in patient death or serious deterioration of health.
- **WARNING:** The healthcare professional operator should carefully consider the *dead space* in the ventilation tubing between the ventilator and the patient. The dead space is the volume within the tubing from the patient's lungs to the ventilator bag, and during ventilation this can be cycled back and forth into and out of the patient without removal from the ventilation system. The healthcare professional operator must shorten the inspiratory tubing as much as practical, include appropriate valving, and provide expiratory flow ventilator tubing to minimize the dead space and risk of inadequate oxygenation, particularly in patients with compromised lung volume from acute respiratory distress syndrome (ARDS) and similar conditions.
- **WARNING:** It is the responsibility of the responsible organization to ensure that the manual ventilator bag (standard BVM-bags, for example an Ambu-bag), its parts, other parts and accessories used in the ventilation system are all compatible with the **Mark V ventilator**. Incompatible parts can result in degraded performance that could consequently result in patient death or serious deterioration of health.
- **WARNING:** When using nebulization or humidification, breathing system filters and heat and moisture exchangers can require more frequent replacement or prevent increased resistance and blockage.
- The **Mark V ventilator** mounts the manual ventilator bag in a motor-driven, programmable bag squeezing mechanism designed to compress and release the bag according to a set respiratory rate and defined high and low pressure thresholds. An integrated electronic pressure sensor provides feedback to the bag squeezing mechanism and controller to reduce the risk of overpressure lung injury or air leakage leading to failed ventilation. Alarms are also provided to alert the clinician to overheating of the device, sensor failure, or mechanical malfunction. A display screen is provided to inform the clinician of the current settings of the ventilator.
- **WARNING:** As with any continuous, mandatory ventilator, the patient will need to be sedated to avoid dyssynchronous breathing and system alarming from bucking and coughing. The healthcare provider must be aware of the risks of sedation.
- **WARNING:** This Resuscitator has not been tested for electromagnetic compatibility (EMC). It may produce electromagnetic disturbances that will affect the performance of other equipment. It may fail to perform as expected in the presence of electromagnetic disturbances from other equipment.

WARNING: Due to the rapid development cycle for this emergency use device, all efforts were made to verify the software, but defects may still exist. The consequences of these defects are unknown and may pose a risk to the patient.

Mark V ventilator capabilities:

- MADVent Mark V is a single-mode continuous, mandatory, closed-loop pressure controlled timeterminated emergency ventilator intended to be operated by the healthcare professional operator for sedated ventilator-dependent patients.
 - Ventilation mode: single-mode continuous mandatory pressure-controlled and time terminated operation
 - Single arm inspiration/expiration tube extending from the valve at the exit of the bag. Expiration from the patient goes through a filter and PEEP valve.
 - Target pressure 10-35 cm H2O (increment 1 cm H2O)
 - Respiratory rate 6-35 bpm (increment 1 bpm)
 - Inspiratory time 1-3 sec (increment 0.1 s)
 - High volume threshold 200-1000 cc (increment 20 cc)
 - Low volume threshold 200-1000 cc (increment 20 cc)
 - High pressure threshold 35-40 cm H2O (increment 1 cm H2O)
 - PEEP 0-20 cm H2O (increment 5 cm H2O)

Documentation provided with the system include the following:

- **1. MADVent Mark V product labeling** for the healthcare professional provider and other individuals to consult regarding the product.
- 2. MADVent Mark V operating instructions for the healthcare professional provider to test and operate the product.
- **3. MADVent Mark V ventilator parts and detailed assembly procedure** for the healthcare professional provider to assemble the product.
- **4. MADVent Mark V ventilator technical description** for additional details and information for the healthcare professional provider to consult as desired or needed.

Alarms provided with the system serve to monitor patient health and mechanical failure as follows:

- 1. **High volume alarm:** In the event of a high volume condition, the system flashes a red light and triggers an audible alarm to alert the healthcare provider. The system returns to the zero position and then continues ventilation with lower tidal volumes. This could happen in the event of a leak in the tube connecting the patient and the ventilator.
- 2. Low volume alarm: In the event of a low volume condition, the system flashes a red light and triggers an audible alarm to alert the healthcare provider. This could happen in the event of a constriction or blockage in the tube that causes pressure build up but no appreciable volume change.
- **3. High pressure alarm:** In the event of a high pressure condition the system will flash a red light, and trigger an audible alarm to alert the healthcare provider, and indicate the alarm on the LCD screen. This could happen in the event of a cough or other high pressure event.
- 4. **Overheating alarm:** The system is equipped with two temperature sensors, to be mounted on the motor controller and the motor. These sensors continually monitor temperature and flashes a red light and triggers an audible alarm to alert the healthcare provider if the system overheats.

- **5. Mechanical malfunction:** In the event of a mechanical malfunction, such as the lanyard from motor and spool to the bag compression arm losing tension or breaking, or the motor fails to rotate for an unknown reason, the system is equipped with sensors to trigger an alarm, flashing a red light and triggering an audible alarm to alert the healthcare provider.
- 6. Emergency battery usage: In the event of a power failure to the main power supply, the system resorts to drawing power from the back-up power supply. In this case, a red light flashes and alerts the healthcare provider to the power failure. This includes the case when the on-off switch is switched off, to alert the healthcare provider if the switch was operated inadvertently.
- 7. **Start-up error:** The system executes an automated start-up procedure to ensure that the lights, sensors, and motor are detected. If any of the components are missing, the system does not allow the healthcare provider to proceed and displays an error on the LCD screen and flashes a red light.

The **sensors and calibration procedure** that enable the detection of the faults outlined above include:

- **1. Pressure sensor**: The system is equipped with a differential pressure sensor (Honeywell SSCMRRN060MDSA5 or equivalent) that records ambient air pressure and in-line pressure.
- 2. Calibration protocol for volume: The system has been calibrated to calculate volume delivered to the patient based on ISO80601-2-12:2020 section 201.12.1.102.
- **3. Optical switch**: The system tracks the position of the lever arm used to compress the bag using an optical switch.
- **4. Rotary encoder:** The device uses a motor to rotate a spool attached to its shaft. The rotary encoder (Cui Devices C14D32P-A3 or equivalent) is attached to the same shaft to continually monitor its rotation position. The spool collects and releases a lanyard by rotation, and the lanyard pulls and releases a lever arm against the bag-based ventilator.
- **5. Thermistors:** Temperature sensors (Daburn electronics 2200/22SWH-100) continually monitor the temperature of the motor and the motor controller.

WARNING: As an emergency ventilator system, the Mark V ventilator does NOT include the ability to connect to a distributed alarm system or electronic health record system.

- **The liquid crystal display** (LCD) screen provides information on the currently set values of the high and low volume alarm limits, high pressure alarm limit, target pressure, cumulative run time, inspiration time, and respiratory rate.
 - The peak pressure is set by the healthcare professional provider and the system operates based on this set value.
 - The high and low volume alarm limits and the high pressure alarm limit are set by the healthcare professional provider.
 - The inspiration time is the time taken by the system to reach the peak pressure defined by the healthcare professional provider.
 - The respiratory rate is the number of breaths per minute.
 - Cumulative runtime is the total time the unit has been in ventilation mode over its lifetime.

- The **emergency operation battery** included with the system is a BP1.2-12-T1 battery (BB Tech), and conforms to **IEC 61056-1**. It is a 12V, 1.2Ah maintenance-free lead acid rechargeable battery mounted to the side of the frame. The battery can be easily removed for recharging using the hook and loop straps. The battery is designed to provide at least 30 minutes of backup power in case of mains (wall) power failure. While the battery is being used, an LED labeled "battery" will flash red indicating the mains power is disconnected. The battery must be removed to be charged, and the system should not be used without a charged emergency operation battery.
- The **manual ventilation bag** patient connector has both a 22 mm male and a 15 mm female connection per **ISO 5356-1** and can connect to a single limb ventilation line with passive exhalation.
- The **manual ventilation bag** expiratory connector is 30 mm female per **ISO 5356-1**. It is intended for use with a PEEP valve attachment.
- The manual ventilation bag oxygen inlet line conforms with ISO 5359.
- **Expected service life** is two weeks. The healthcare professional operator must inspect the system, including compression lanyard, ventilator connections, and ventilator bag for visible wear or damage every six hours of operation at a minimum. Any system with visible wear or damage must be taken out of service and replaced or repaired.
- **Cleaning, disinfection, and sterilization**. The manual ventilator bag should be changed or cleaned according to its instructions. In compliance with clinical guidelines for ventilators, the **Mark V ventilator** should be wiped clean as necessary using either 70% ethanol or bleach-free disinfecting wipes. Non-corrosive spray disinfectant is compatible with the ventilator, but the healthcare professional operator must consult the manual ventilator bag instructions regarding safe sterilization procedures for that component. Invasive components will have to be sterilized and are not a part of the components included with the **Mark V ventilator**.

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Supplementary Information for MADVent: A low-cost ventilator for patients with COVID-19 — Technical Description (required by FDA)

MADVent Mark V Technical Description

The **MADVent Mark V** is a single-mode continuous, mandatory, closed-loop pressure controlled timeterminated emergency ventilator meant for sedated, intubated patients being cared for in a professional healthcare facility **only**. It employs an FDA-recognized single-use and disposable, automatically self-inflating manual ("ambu") ventilator bag with attached positive endexpiratory pressure (PEEP) valve.

1. Method for checking the function of the alarm system by healthcare professional operator

All alarm system checks are performed automatically during start-up.

The healthcare professional operator is only responsible for (1) reading the LED label adjacent any active alarm indicators and for (2) reading the LCD screen that will further indicate which alarm has been triggered.

2. Uncertainty for each disclosed tolerance

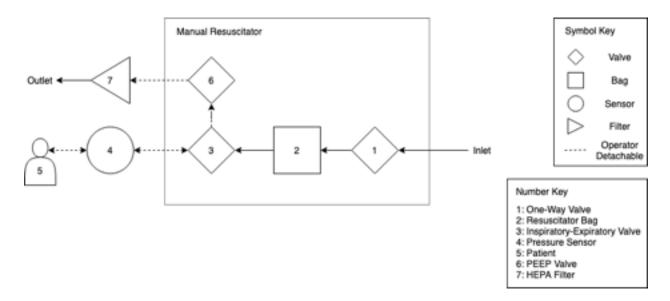
The measurement uncertainty for each disclosed tolerance is +/-5% in accordance with **ISO 80601-2-12:2020**, except as follows:

The Honeywell SSCMRRN060NDSA5 pressure measurement sensor measurement uncertainty is +/- 2%. The Bosch BMP180 pressure measurement sensor measurement uncertainty is +/- 0.12 cm H2O.

All time measurements are accurate to within 1000 ppm.

Motor rotation measurements are accurate to within 0.9 degrees.

3. Pneumatic diagram of the ventilator



4. Summary description of the filtering or smoothing techniques for all measured or computer variables that are displayed or used for control

There are two equivalent sensor configurations: (1) Two Bosch BMP180 pressure sensors, one measuring ambient air pressure and the other measuring inline ventilator pressure. (2) A single Honeywell SSCMRRN060NDSA5 differential pressure sensor that measures the differential pressure between ambient air pressure and the other measuring inline ventilator pressure. These sensors have been manufactured to comply with ISO 9001 and are suggested for use in medical devices, including ventilators.

The system reads raw data from the Bosch BMP180 every 3 ms for 30 ms and takes the average value. That average value is input into an algorithm provided by Bosch (see "Figure 4" below taken directly from the Bosch datasheet) to provide a pressure value in Pascals. The **Mark V** software converts this to cm H2O as 98 Pa = 1 cm H2O.

When the Honeywell SSCMRRN060NDSA5 is incorporated, the system will again read data every 3 ms for 30 ms and take the average value. However, this sensor has a built-in *Application Specific Integrated Circuit* (ASIC) that performs a calibration before it is read by the system. This calibration consists of calculating the "Pressure" based on the "Output" of the sensor via Equation 1 below (taken from Honeywell documentation) for each port and then subtracting a known zero-level stored on the ASIC for each port in order to get a corrected pressure in mbar. The **Mark V** software then converts 1 mbar = 1.02 cm H2O.

In both cases, during start-up the system will check that the difference between ambient and inline measurements is less than or equal to 50 Pa. If not, the LED corresponding to the pressure sensor will flash red and the LCD will display "Pressure Read Error".

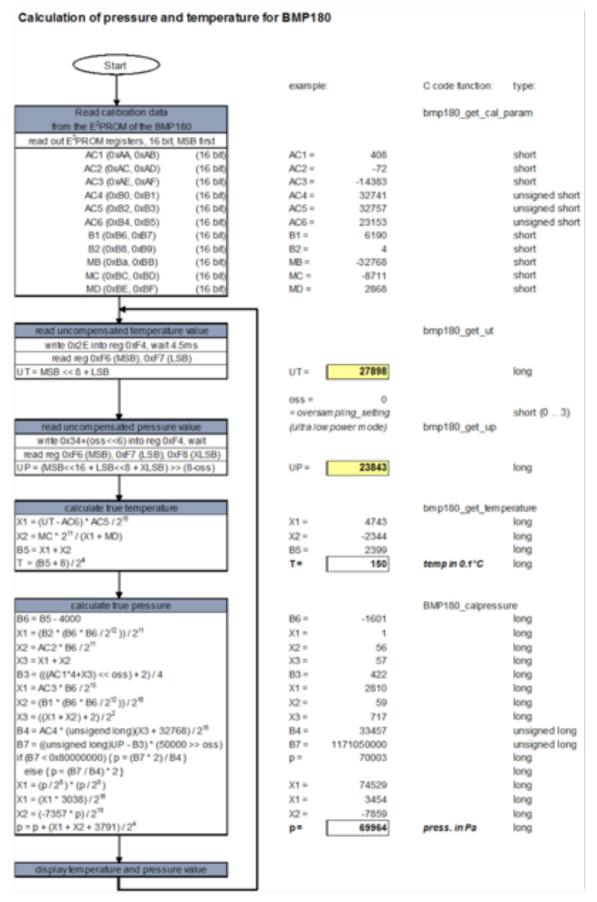


Figure 4: Algorithm for pressure and temperature measurement

Equation 1:	$Output = \frac{Output_{max.} - Output_{min.}}{P_{max.} - P_{min.}} * (Pressure - P_{min.}) + Output_{min.}$
where:	
Output =	Pressure reading from the sensor [Volts, %2 ¹⁶ counts, %Vs, etc.]
Output _{min} =	Ideal output at minimum pressure [Volts, %216 counts, %Vs, etc.]
Output _{max} =	Ideal output at maximum pressure [Volts, %216 counts, %Vs, etc.]
P _{min} =	Minimum operating pressure [bar, mbar, psi, kPa, etc.]
P _{max} =	Maximum operating pressure [bar, mbar, psi, kPa, etc.]

5. Summary description of the means of initiating and terminating the inflation phase in each ventilation mode of the ventilator

The pressure-controlled mode of the ventilator takes input from a healthcare professional operator in setting a target pressure, inspiration time, and respiratory rate.

When inspiration begins the **MADVent Mark V** uses a differential pressure sensor to continuously monitor the inline pressure. The ideal inspiratory pressure is defined by a piecewise-linear profile, normalized by percentages such that at T=0, P=0, and at T=100, P=100 (see plot below). At each timestep in the inspiration cycle, the inline pressure is measured and the current time is computed as a percentage of the total inspiration time.

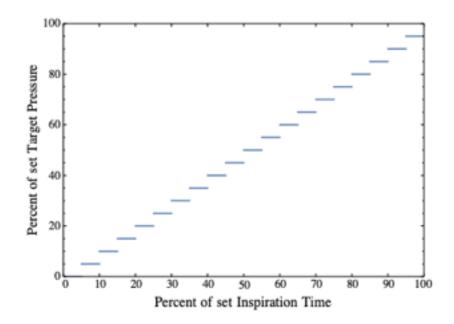
The target pressure (percentage) for that time is linearly interpolated from the ideal profile, then scaled by the peak pressure set by the operator.

The motor is then turned an angular amount proportional to the difference between the measured pressure and the target pressure. If the measured pressure is greater than the target, the motor is not moved.

Once the target peak pressure is reached or the inspiratory time limit is reached, the **MADVent Mark V** ceases compression of the bag ending the inspiration phase.

If the peak pressure was reached early, the proportionality constant is reduced by a fixed amount to discourage overshoot on the next cycle. If the inspiration time limit finishes without reaching the target peak pressure, the proportionality constant is increased to encourage tighter tracking on the next cycle.

Exhalation occurs passively at the natural rate of the patient. The next inspiration phase is then triggered by a timer such that the respiratory rate condition is met.



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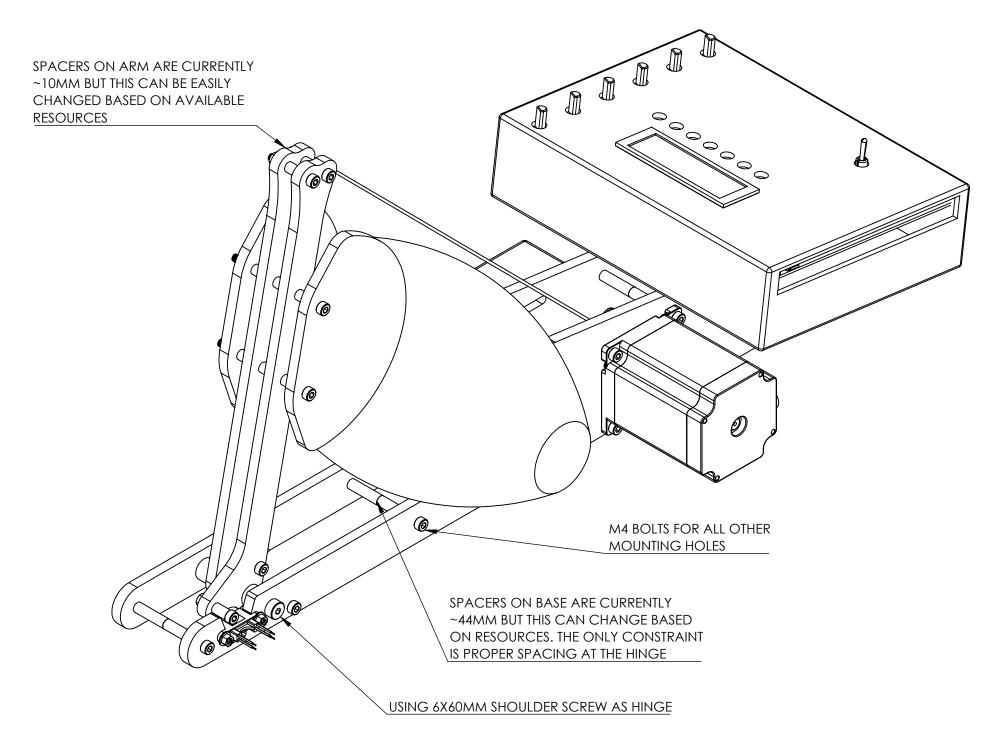
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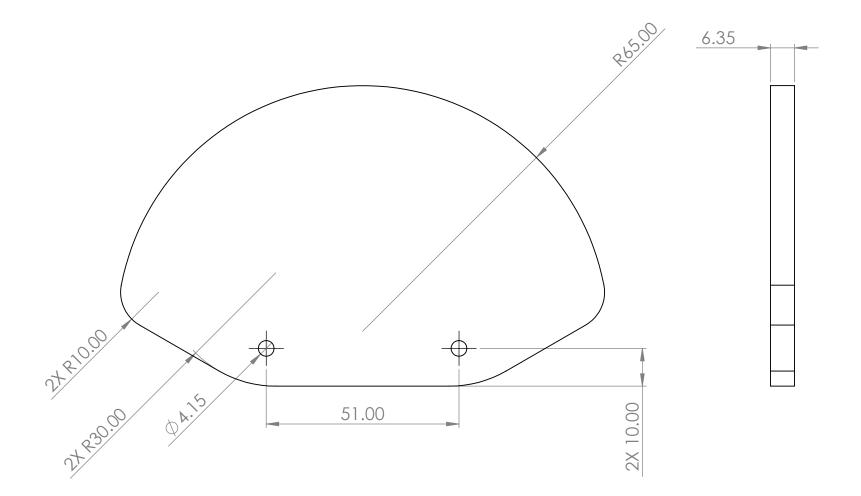
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Supplementary Information for MADVent: A low-cost ventilator for patients with COVID-19 — Mechanical and Electrical Drawings (required by FDA)

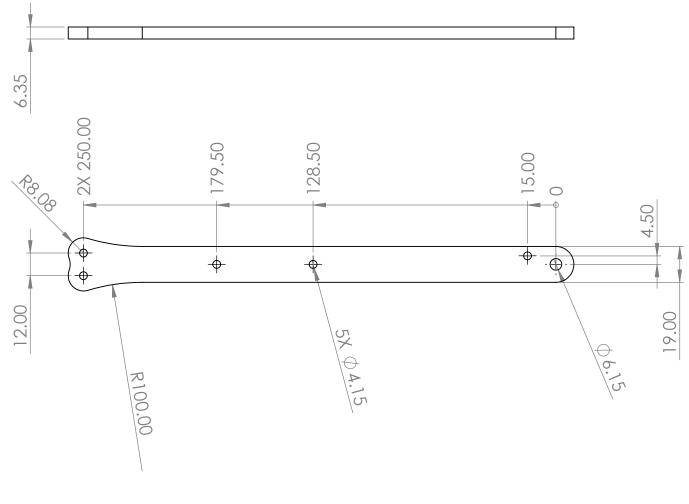


COMPRESSOR



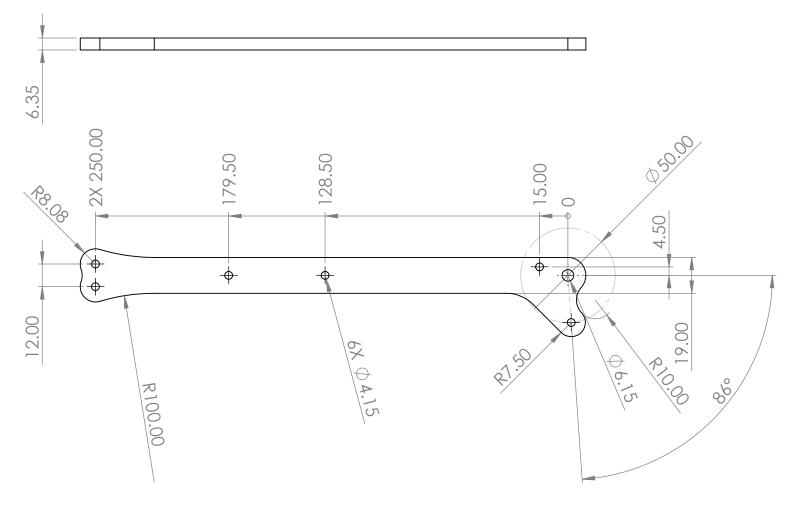
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LEVER ARM



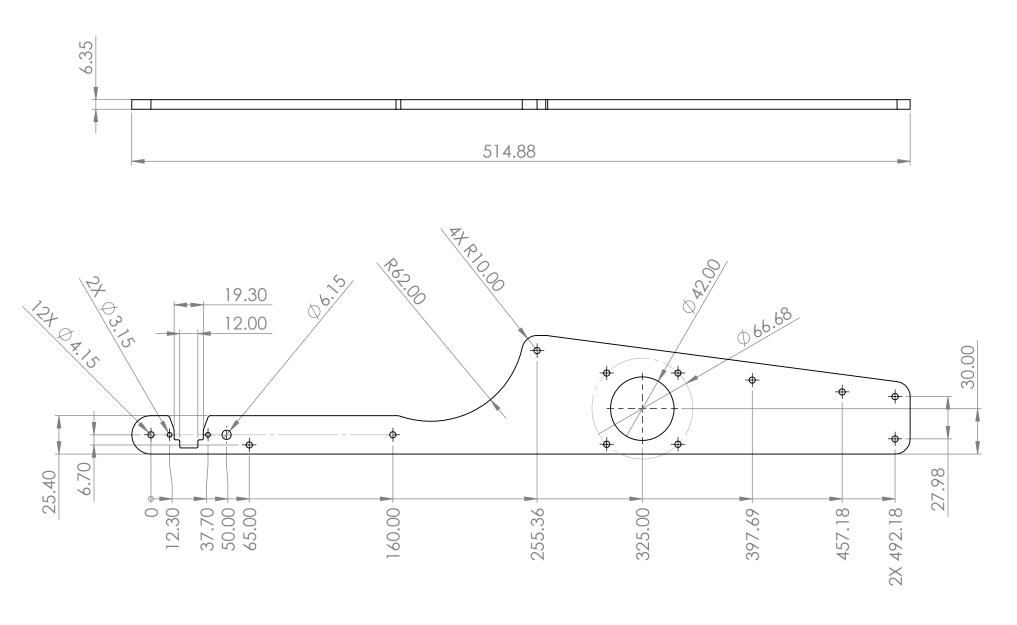
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LEVER ARM



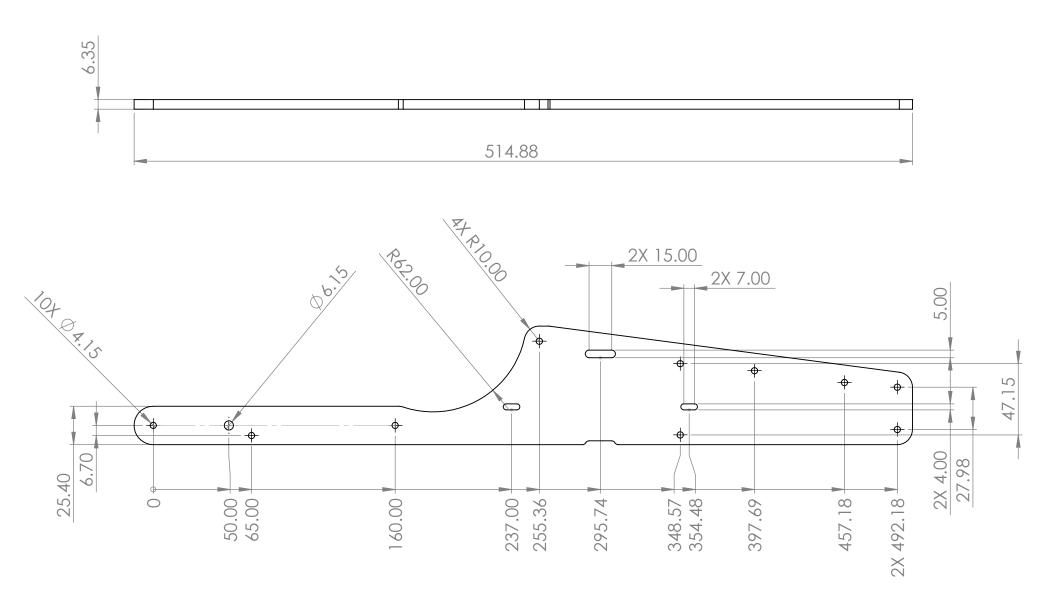
SCALE 1:2

BASE



SCALE 1:2.5

BASE



SCALE 1:2.5

