Rapidly Deployable Breast Pump Ventilator

Ventilation requirements for adult COVID-19 patients, analysis and documentation of proposed modified breast pump solution

6 April 2020 - Breast Pump Ventilator Team, within Southern Maryland Loves You, non-profit engineering collaboration

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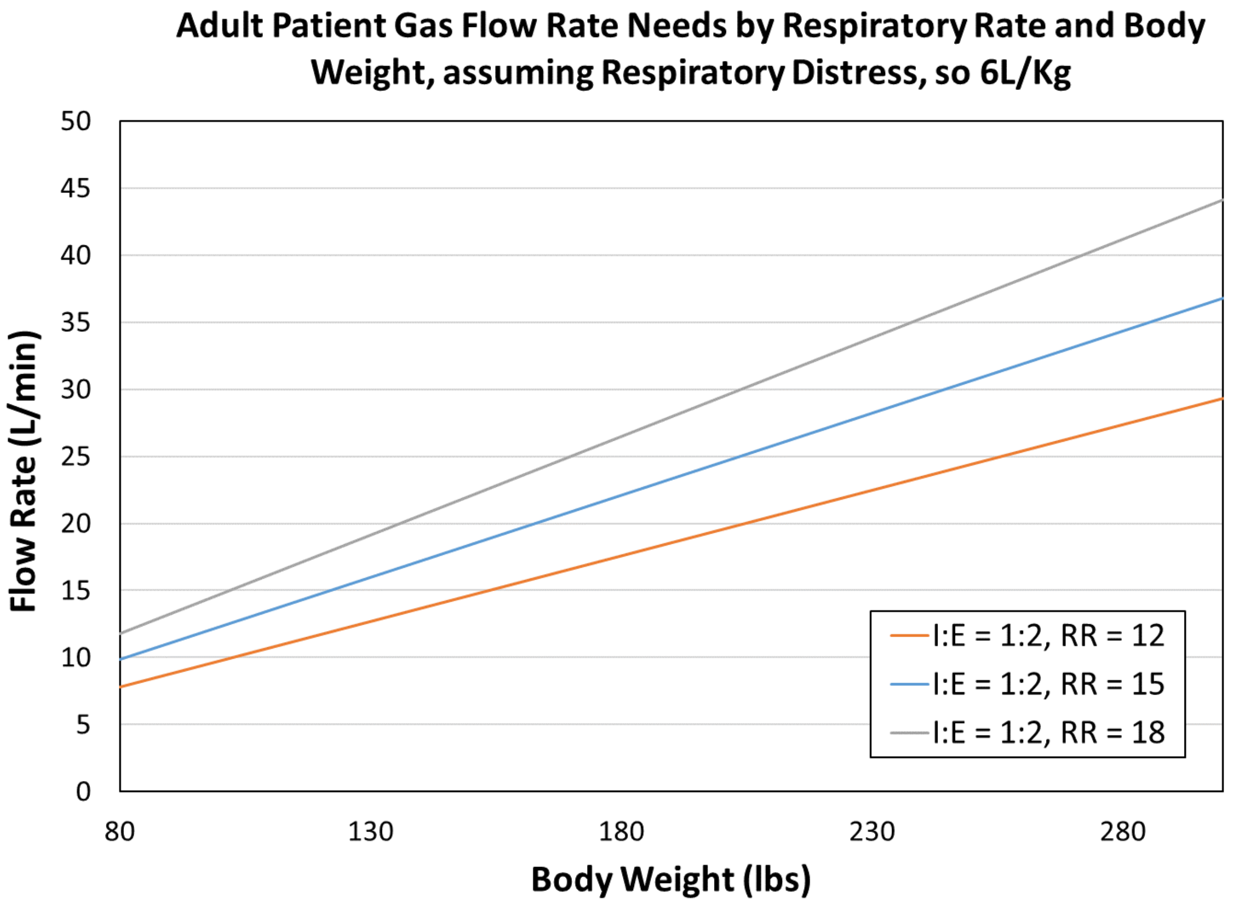
Benefits

- Prototype is operational at TechPort
- Redundant pneumatic AND electronic safety release mechanisms
- Affordable: $500/unit cost, or $300 with donated pump
- Producible in supply-chain constrained environment, with many available part substitutions if components become limited
- Simple to assemble, particularly if we have custom PCBs made
- Requirements have been refined and reviewed by respiratory therapist and doctor
- Already available collaborators: pump manufacturers, physicians, manufacturing facility, non-profit team leadership, pro-bono legal support, biomedical engineers

Limitations

- Testing needed, ventilator test unit being supplied to TechPort by University of Maryland Charles Regional Medical Center (part of MedStar)
- May be limited to serve a subset of the patient population, due to flow rate limits and requirements
- Additional analysis of pneumatic constraints is needed



Nominal Respiratory Rate Fundamentals

- Initial respiratory rate **15 breaths / minute**
- Initial inspiratory:expiratory duration ratio of **I:E = 1:2**
- Each inhalation = 1.33 seconds
- Total inhalation = 20 seconds / minute

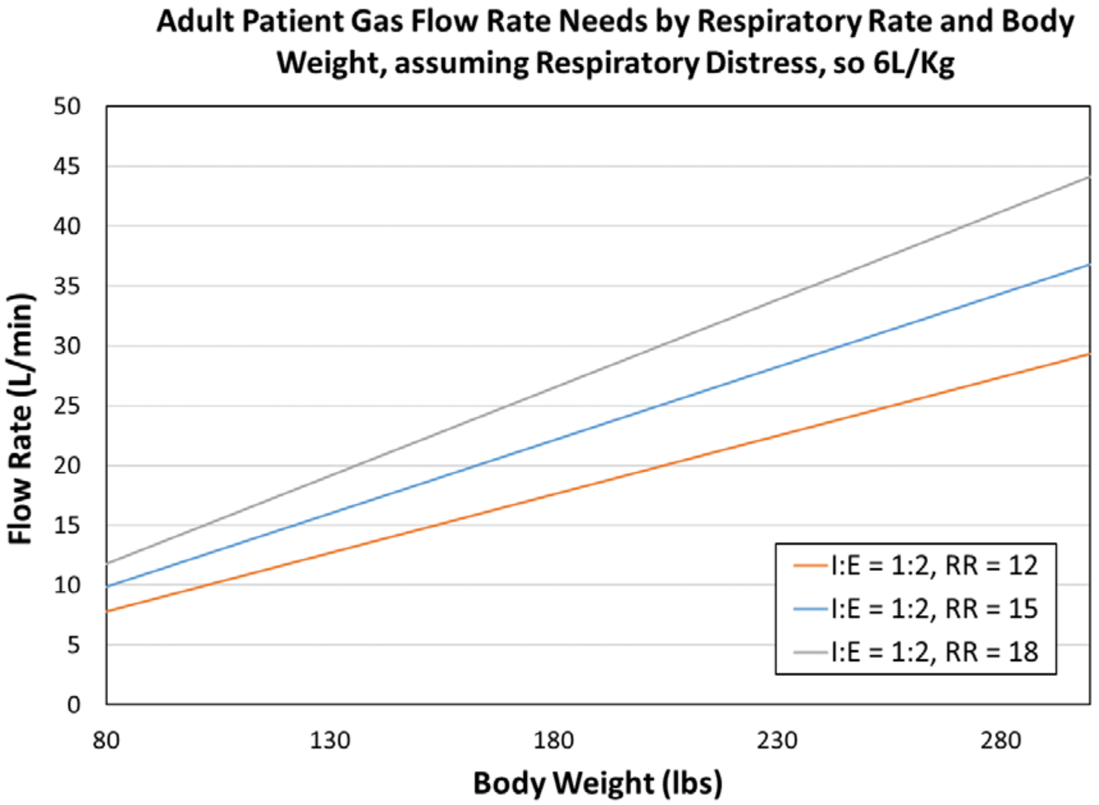
Ideally, respiratory rate could be varied between 12 and 20 breaths/min, and I:E could be modified to 1:3 or 1:4, but based on medical recommendation, the above nominal values are used for the preliminary requirements derivation.

Oxygen Concentration Delivery

- Respiratory therapy guidelines recommend transitioning patients to a ventilator when they require 5 LPM of supplemental oxygen by cannula, or 40% fraction of inspired oxygen (F_iO_2)
- Note that conversion from LPM of supplemental oxygen varies widely by delivery method, from intubation, to face mask, to cannula, etc., so the requirements are derived in F_iO_2
- Respiratory therapists working with COVID-19 often need much higher rates of oxygen delivery for more critical patients, but F_iO_2 >80% is potentially dangerous for extended periods of time, >8-24 hrs depending on the circumstance
- Doctors and respiratory therapists need the ability to vary this parameter over a wide range of **$40\% \leq F_iO_2 \leq 90\%$** and maintain control based on patient needs

Gas Volume Delivery Requirements: Pulmonologist Review Needed – Conflicting Information from Reliable Sources

- Standard adult tidal volumes for intubated ventilation vary roughly by body weight at 6 mL / kg / breath, or an approximate value of 500 mL / breath
- Many COVID-19 patients with ARDS and/or pneumonia have reduced lung compliance, requiring a lower tidal volume of ~350 mL / breath to avoid trauma
- Based on our research, minimum tidal volume delivered / breath is a key effectiveness parameter, and needs to be **Tidal Volume ≥ 150 mL / breath**
- Maximum tidal volume / breath is a safety limit **Tidal Volume ≤ 350 mL / breath** for a typical adult



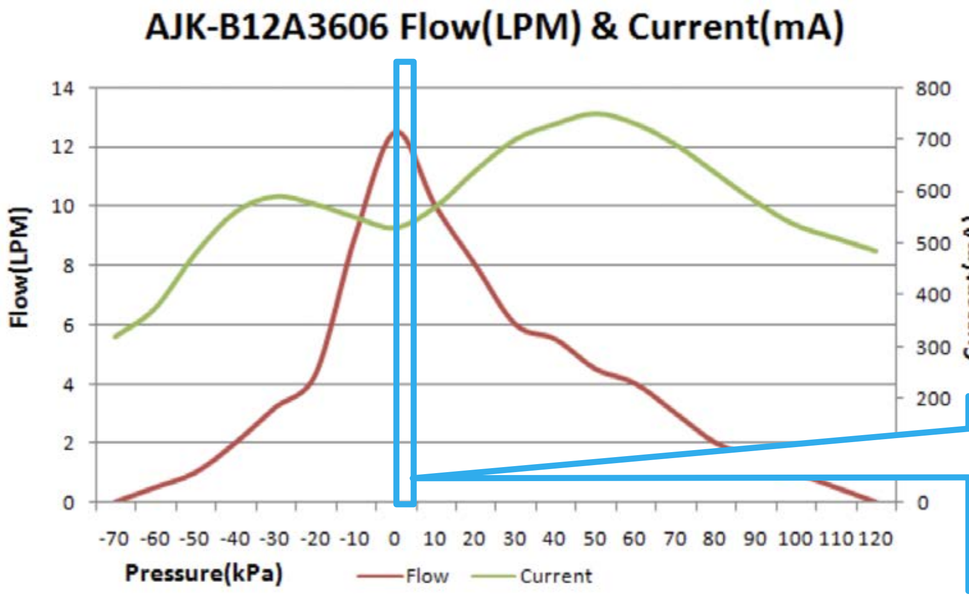
Positive Inhale Pressure Delivery

- Standard adult Peak Inspiratory Pressure (PIP) for intubated ventilation has a maximum between 30 and 40 cmH_2O depending on circumstance
- Many COVID-19 patients with ARDS and/or pneumonia have reduced lung compliance, and require a lower PIP of 25 cmH_2O to avoid trauma
- We treat **PIP ≤ 25 cmH_2O** as a safety threshold
- Interfacing with larger patient ventilation tubing will

help reduce pressure

Spectra S2 Internal Pump System

- Per vendor specification, the internal pump provides 70 to 120 kPa controllable by the applied current



Unit Conversion:
2.45 kPa = 25 cmH_2O

https://ajkpump.com/high-flow-micro-vacuum-pump_P30.html

Gas Flow Dynamics:
Testing and Simulation Still Needs to be Done to finalize Tubing Size for Patient Interface

PUMP

- Inspiration : Expiration = 1:2
- Respiratory Rate = 15 breaths/min
- Inhale Duration = 1.33se
- Gas Flow Rate Range = 0-12 LPM
- Tube Size = 22mm

PATIENT

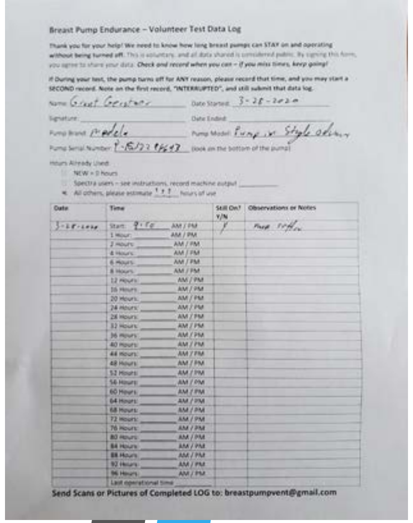
- Inspiration : Expiration = 1:2
- Respiratory Rate = 15 breaths/min
- Inhale Duration = 1.33sec
- Tidal Volume = 350 mL/breath
- Required Gas Flow Rate = 15.75L/min
- Max Pressure = 2.45kPa = 25cmH_2O
- Tube Size = ¼”

Pump: 22mm Tubing

¼” Tubing (current system output)

Peak End Expiratory Pressure Delivery

- PEEP supports maintaining alveolar inflation during exhalation. Typical ventilation PEEP values range from 4-10 cmH_2O
- More severe COVID-19 cases require higher PEEP values, ranging from 12-20 cmH_2O to prevent lung collapse
- We therefore treat **PEEP ≥ 8 cmH_2O** as a safety threshold
- Excessive PEEP may limit the patient’s ability to expel CO_2 so **PEEP ≤ 22 cmH_2O** is a safety threshold
- Doctors and respiratory therapists need the ability to set **PEEP = 10-20 cmH_2O** according to patient needs



Breast Pump Endurance – Volunteer Test Data Log

Thank you for your help! We need to know how long breast pumps can STAY on and operating without being turned off. This is voluntary, and all data shared is considered public. By signing this form, you agree to share your data. Check and record when you can – if you miss times, keep going!

If During your test, the pump turns off for ANY reason, please record that time, and you may start a SECOND record. Note on the first record, "INTERRUPTED", and still submit that data log.

Name: [illegible] Date Started: 3-28-2020

Signature: ______ Date Ended: ______

Pump Brand: Medela Pump Model: Pump in Style [illegible]

Pump Serial Number: [illegible] (look on the bottom of the pump)

Hours Already Used:

- NEW = 0 hours
- Spectra users – see instructions, record machine output ______
- All others, please estimate [illegible] hours of use

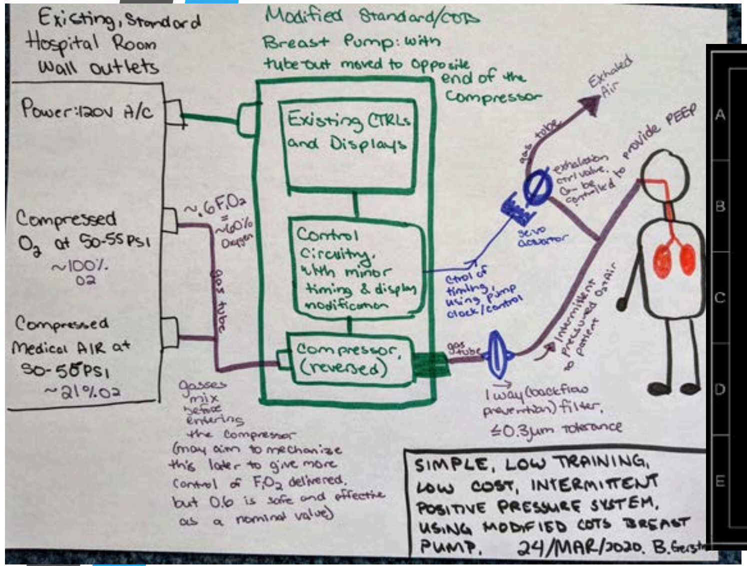
Date	Time	Still On? Y/N	Observations or Notes
3-28-2020	Start: 9:10 AM / PM	Y	[illegible]
	1 Hour: ______ AM / PM		
	2 Hours: ______ AM / PM		
	4 Hours: ______ AM / PM		
	6 Hours: ______ AM / PM		
	8 Hours: ______ AM / PM		
	12 Hours: ______ AM / PM		
	16 Hours: ______ AM / PM		
	20 Hours: ______ AM / PM		
	24 Hours: ______ AM / PM		
	28 Hours: ______ AM / PM		
	32 Hours: ______ AM / PM		
	36 Hours: ______ AM / PM		
	40 Hours: ______ AM / PM		
	44 Hours: ______ AM / PM		
	48 Hours: ______ AM / PM		
	52 Hours: ______ AM / PM		
	56 Hours: ______ AM / PM		
	60 Hours: ______ AM / PM		
	64 Hours: ______ AM / PM		
	68 Hours: ______ AM / PM		
	72 Hours: ______ AM / PM		
	76 Hours: ______ AM / PM		
	80 Hours: ______ AM / PM		
	84 Hours: ______ AM / PM		
	88 Hours: ______ AM / PM		
	92 Hours: ______ AM / PM		
	96 Hours: ______ AM / PM		
	Last operational time ______		

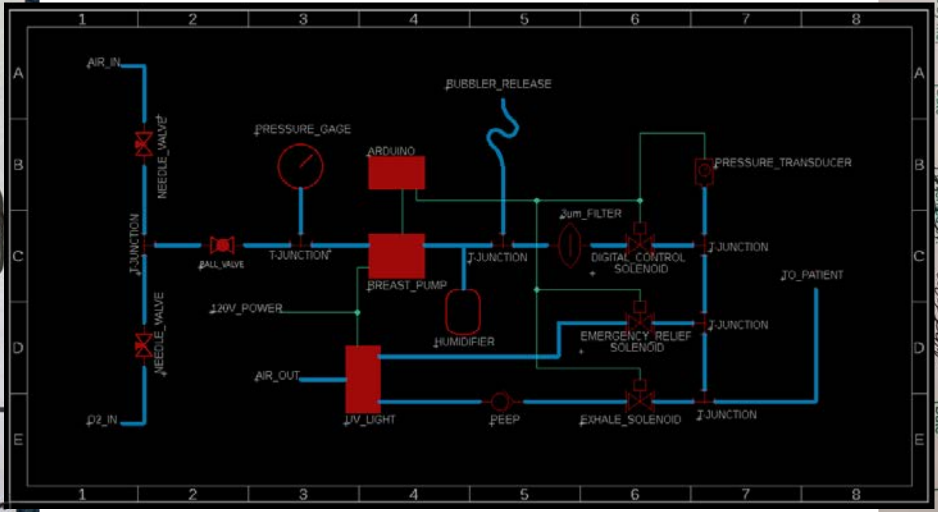
Send Scans or Pictures of Completed LOG to: breastpumpvent@gmail.com

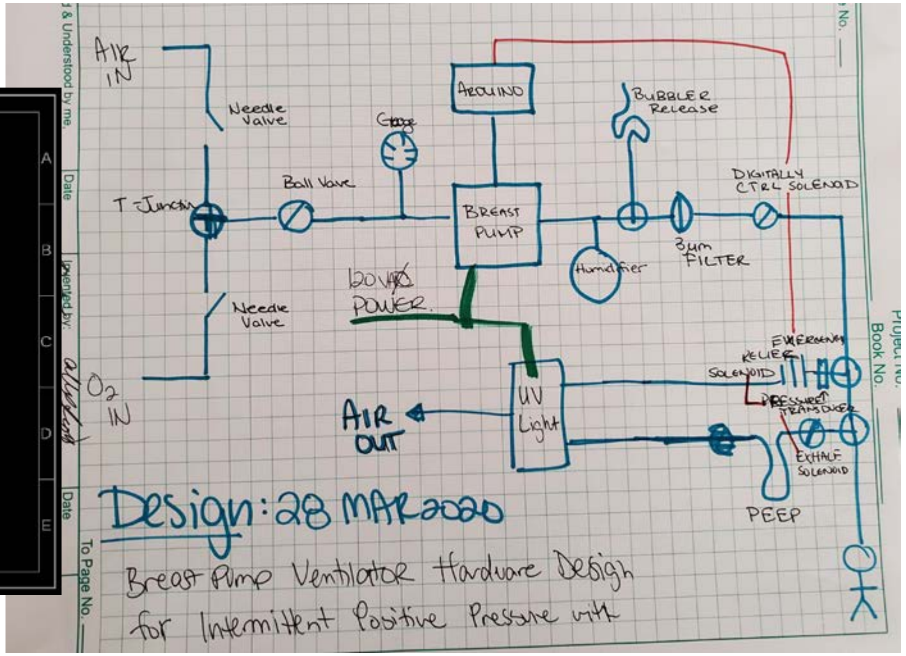
Ventilator Endurance Requirement

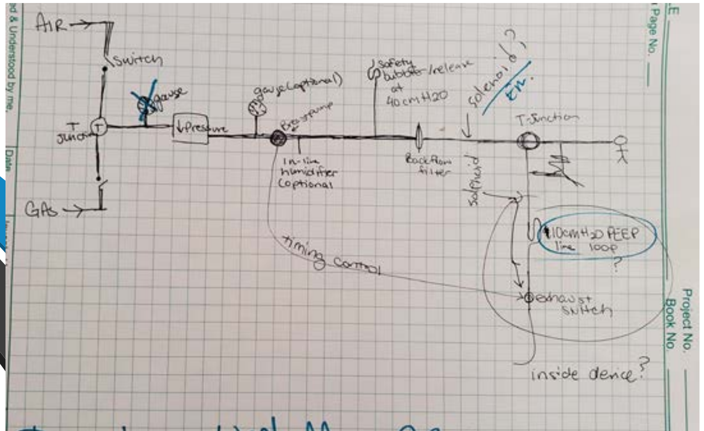
- Breast pumps are typically used for up to 30 minute intervals, not for days of continuous operation.
- 3 used, donated, Spectra S2 pumps were hacked to have full timing and power control delivered by an Arduino to provide slightly different yet relevant I:E and respiratory rates. The motor usage was recorded at the beginning of test, and all 3 pumps are still in continuous operation as of this writing, at 62+ hours.
- The expected life of a AJK-B3606 internal compressor is 1500hrs per specification, and anecdotally confirmed by breast pump support groups.
- This testing builds our confidence not only in the pumps, but in the Arduinos and control circuits.

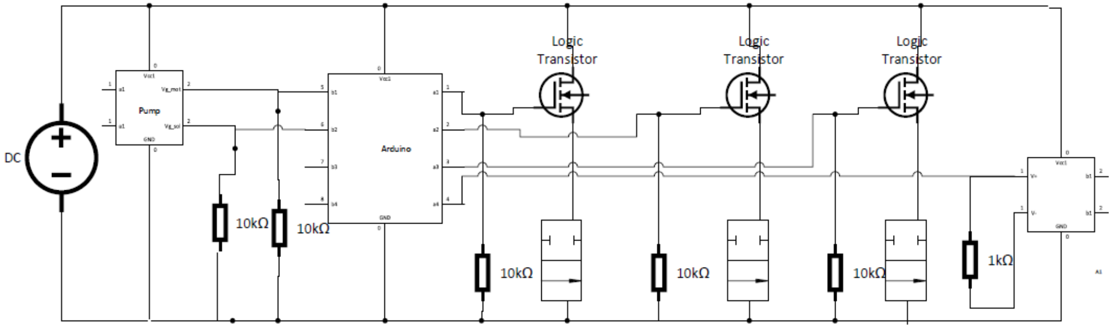
Concept and Design Progression



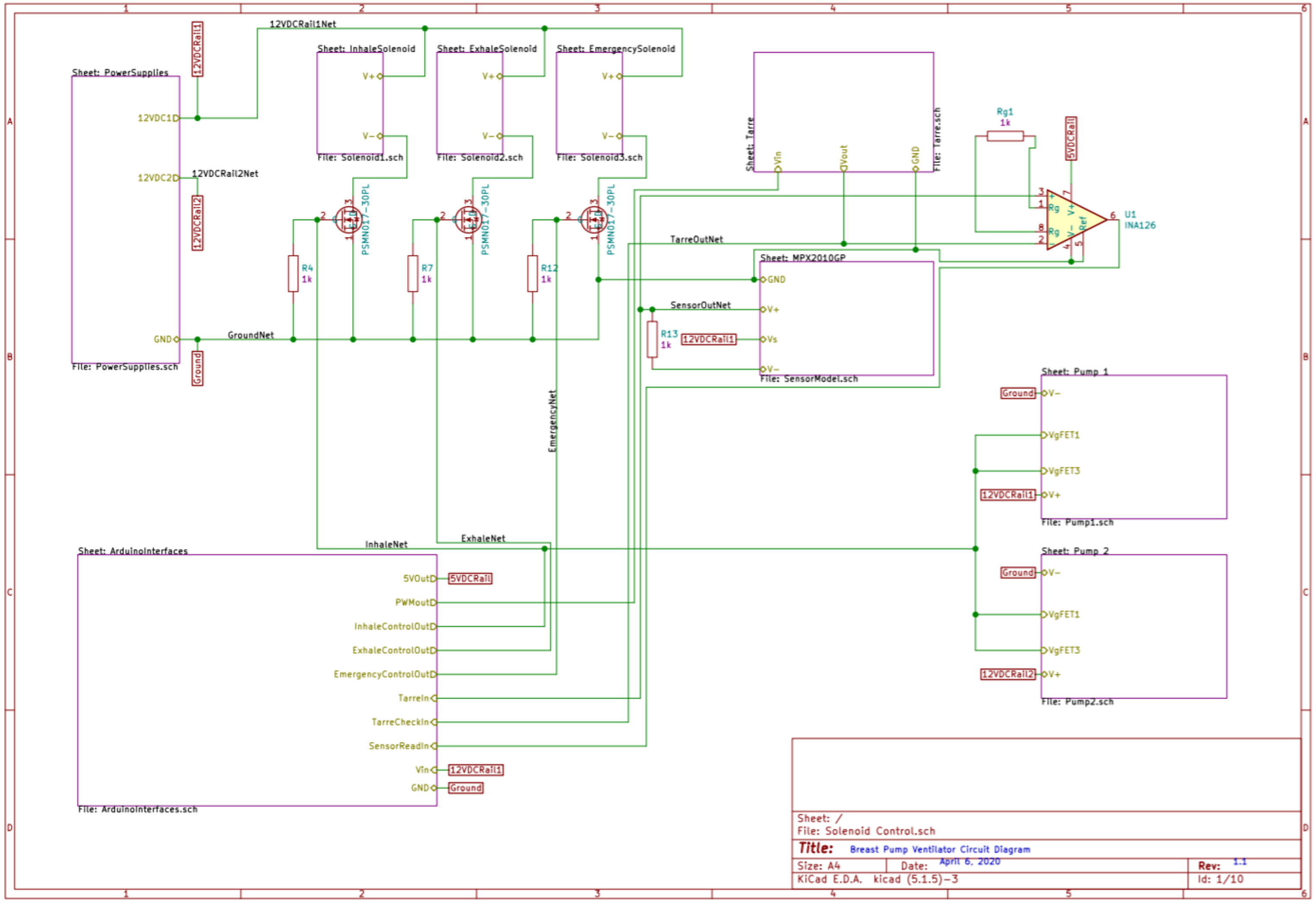








Electrical Designs are Maturing with Simulation



Bill of Materials – UPDATING DRAFT

Parts	Amount	Source	Part Number	Cost/Item	Cost/Unit
Spectra S1Plus Breast Pump	1	Spectra Baby	S1Plus* the S2Plus can be used, but lacks the backup battery	$ 199.00	$ 199.00
Pressure Sensor	1	DigiKey		$ 15.50	$ 15.50
Solenoid	3	US Solid		$ 12.50	$ 37.50
Arduino Mega	1	Arduino		$ 38.00	$ 38.00
1K Ohm Resistor	5	DigiKey		$ 0.45	$ 2.25
100K Ohm Resistor	1	Digikey		$ 0.10	$ 0.10
Amplifier	1	Digikey	INA126PA	$ 0.47	$ 0.47
Bread Board	1	Digikey		$ 4.50	$ 4.50
Jumper Wire Bundles 20 AWG 6"	2	Digikey	1568-1643-ND	$ 5.95	$ 11.90
Jumper Wire Bundles 26 AWG 12 "	2	Digikey	2183-1762-ND	$ 4.99	$ 9.98
Transistor	3	Digikey		$ 0.84	$ 2.52
1/4" MIP x 1/4" MIP (Hex Nipple)	1	Lowe's	Item #: 877223, Model#:	$ 2.84	$ 2.84
ID = .170", OD= 1/4" Polyethylene Tubing, 140PSI @70°F, non toxic (smaller PKG) 25 feet	1	Lowe's	#98632 (Item #: 814303, Model #: 98581)	$ 4.37	$ 4.37
ID = .170", OD = 1/4" Clear Vinyl tubing, 55PSI @70°F, non toxic (smaller pkg) 20 feet	1	Lowe's	#98616 (Item #: 814315 Model #: 98560)	$ 3.92	$ 3.92
Pressure Gauge, 100 PSI	1	Lowe's	Item #: 955580, Model#: 024771	$ 10.98	$ 10.98
1/4" FIP x 1/4" FIP x 1/4" FIP TEE (BF-730NLB)	1	Lowe's	Item #877207, Model: BF-730NLB	$ 7.38	$ 7.38
1/8" BARB x 1/4" MIP Barbed adapter (BHB-85NLB)	2	Lowe's	#877065	$ -	$ -
Cable ties. 8"x100 count	1	Lowe's	#0076023	$ 7.98	$ 7.98
1/2" Lead free Brass Ball valve.	1	Lowe's	#G200W (Bronze ball valve= Item #: 516004, Model#: NL950X6CL)	$ 17.00	$ 17.00
1/4" x 1/4" x 1/4" compression Tee	3	Lowe's	#877184	$ -	$ -
1/2" x 1/4" MIP --> FIP Reduction Bushing	2	Lowe's	#877203	$ 4.96	$ 9.92
3/16" x 3/16" BARB hose splicer	1	Lowe's	#877085	$ 3.37	$ 3.37
				$ 345.10	$ 389.48

Takeaways

- Charles hospital’s CEO has offered to support our development, in collaboration with the non-profit Southern Maryland Loves You.
- Preliminary agreement from SpectraBaby’s to help supply pumps and logistics support as well as technical review.
- The prototypes is ready for validation testing with standard hospital ventilation test equipment.
- Medical review is needed.
- Total system cost is roughly $500 / unit, with parts that are available in our current supply system, and do NOT interfere with any other ongoing ventilator production.
- Bill of materials and design are ready to attempt reproduction. System interfaces with standard 22mm medical tubing, hospital Air and O_2, and a rolling IV pole.
- All components can be sanitized with standard 70% to 100% ethanol.

Ventilation Mode: AVAPS
Average Volume-Assured Pressure Support

- **NON-INVASIVE**
- **Fixed Settings:**
- **Variable Parameters:**
- **Advantages:**
- **Risks:**
- As with any pressure-cycled mode, the dependent variable is volume and it may vary widely if there is patient dyssynchrony, changes in lung compliance, or changes in resistance that can occur with changes in body position that occurs in the very morbidly obese. [8] A fixed pressure support setting will not compensate for these changes, and, as a result, delivered tidal volume will fall. AVAPS allows a target tidal volume to be identified with a range of pressure support settings that fluctuate to meet the target tidal volume. AVAPS uses an internal algorithm to make changes in the pressure support supplied to achieve the target volume, but these changes are small and occur over minutes (typically 1-2.5 cm water per minute). That is why rapidly changing, acute respiratory conditions are not suited for AVAPS as the ventilator adjustments may not be timely enough to meet the patient's requirements. Typically, the pressure support required to produce the target volume during bedside titration is used to identify the minimal pressure with the set minimal pressure (min P), typically 2-3 cm water lower to allow flexibility for adjustment in the AVAPS mode. The maximal pressure (max P) is typically set in the 20-25 cm water range as higher pressures are not well tolerated. The min P is at least 8 cm water and usually higher. Additional parameters that are part of AVAPS setting are the target tidal volume, respiratory rate, EPAP, and inspiratory time.
- https://www.medscape.com/answers/304235-87846/what-are-the-benefits-of-average-volume-assured-pressure-support-avaps-in-noninvasive-ventilation-niv

Ventilation Mode: APRV
Airway Pressure Release Ventilation

- **INVASIVE / NON-INVASIVE / BOTH**
- **Fixed Settings:**
- **Variable Parameters:**
- **Advantages:**
- **Risks:**
- "…is inverse ratio, pressure controlled, intermittent mandatory ventilation with unrestricted spontaneous breathing. It is based on the principle of open lung approach. It has many purported advantages over conventional ventilation, including alveolar recruitment, improved oxygenation, preservation of spontaneous breathing, improved hemodynamics, and potential lung-protective effects. It has many claimed disadvantages related to risks of volutrauma, increased work of breathing, and increased energy expenditure related to spontaneous breathing. APRV is used mainly as a rescue therapy for the difficult to oxygenate patients with acute respiratory distress syndrome (ARDS). There is confusion regarding this mode of ventilation, due to the different terminology used in the literature. APRV settings include the "P high," "T high," "P low," and "T low"."
- http://rc.rcjournal.com/content/respcare/57/2/282.full.pdf

Ventilation Mode: PRVC
Pressure-Regulated Volume Control

- **INVASIVE / NON-INVASIVE / BOTH**
- **Fixed Settings:**
- **Variable Parameters:**
- **Advantages:**
- **Risks:**
- **mode** of ventilation in which the ventilator attempts to achieve set tidal volume at lowest possible airway pressure. This **mode** of ventilation is being commonly used as the initial **mode** of ventilation in many intensive care units.
- https://www.sciencedirect.com/science/article/pii/S2213007118303757