The PolyVent FLOSS Ventilator

A Free-libre Respiration EcoSystem (Freespireco)

– Robert L. Read, Victor Suturin, Antal Zuiderwijk

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"Invent in the public, for the Public."

https://www.pubinv.org/

Setting: USA, Spring 2020…

100 humanitarian engineering teams started

- PolyVent formed by Victorin Suturin, PhD, and Nathaniel Bechard
- PolyVent started with Bellows
- PolyVent was designed to be resilient to supply chain disruptions
- Originally team did not embrace open-source production due to the siren-song that manufacturers wouldn’t like it

We know because we evaluated them all.

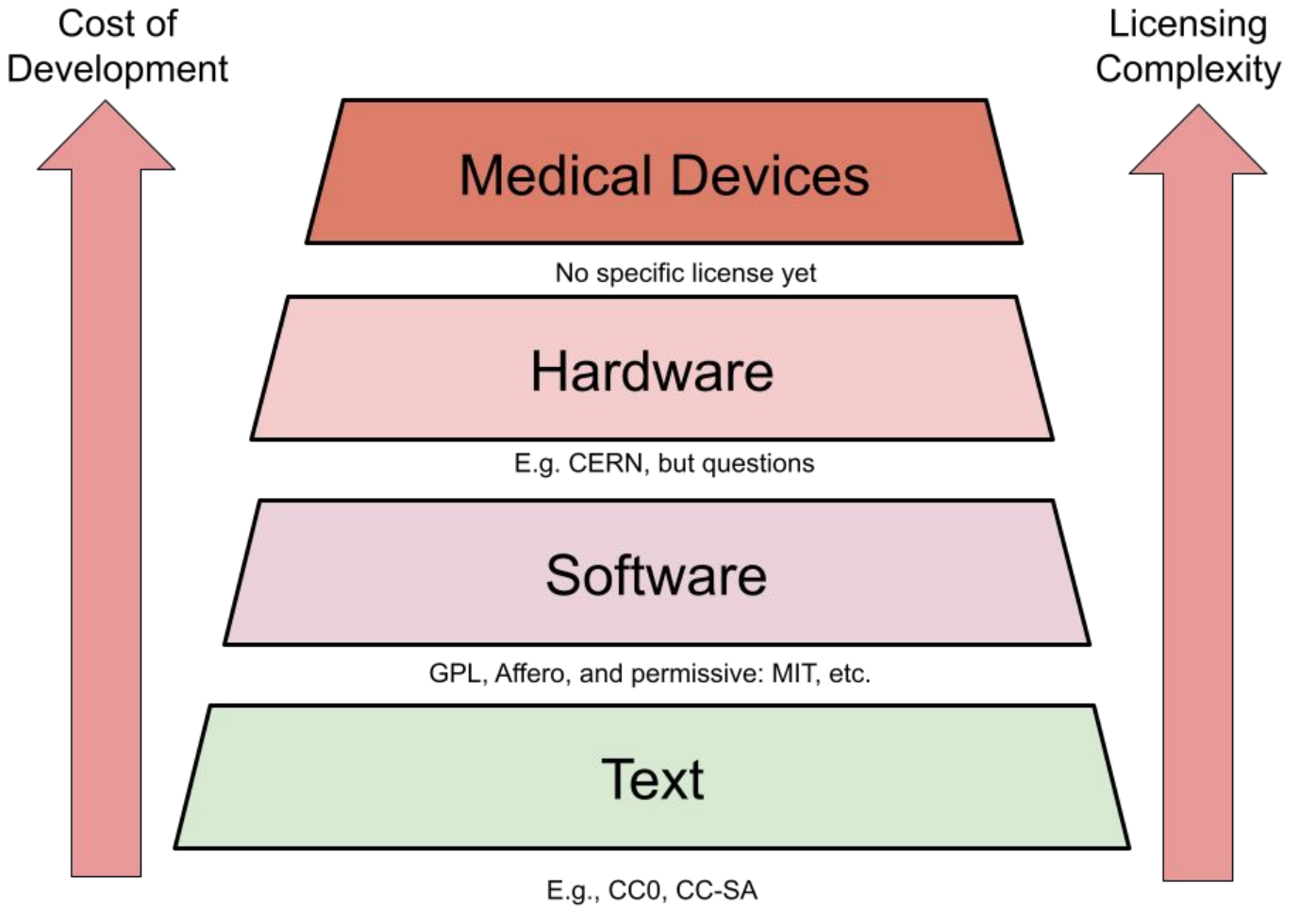
Analysis of Free-Libre Open Source COVID-19 Pandemic Ventilator Projects

Look Down! We've added tabs for modules to encourage modularity!

Apr 29, 2021 | Public Invention | https://www.pubinv.org | Home Repo: | https://github.com/PubInv/covid19-vent-list

Link to definition of evaluation criteria: https://docs.google.com/document/d/e/2PACX-1vRl9yZ27KvslftcNvweHgH1A81pO8gHL62TWpY_VY-UELWdK9x-4-3hNw3DbkemClzExPsg8RfnxilP/pub

Project Name	Project Link	Openness	Buildability (1 unit)	Community Support	Functional Testing	Reliability Testing	COVID-19 Suitability	Clinician Friendly	Electromagnetic compatibility Testing	National Agency / EUA approvals	Usage in Field	Average	Finar
Medtronic Puritan Bennett (PB) 5	http://newsroom.medtronic.co	4	3.5	3.5	5	5	4	5	5	5	5	4.50	
Protofy Team OxyGEN	https://oxygen.protofy.xyz/	5	4	4	5	4.5	4	3.5	5	5	5	4.50	2
Ambovent	https://1nn0v8ter.rocks/AmboV	5	5	5	5	5	5	4.5	5	3.5	1.5	4.45	1
Flow-i Bridge Project	https://grabcad.com/library/flo	5	5	3	5	2.5	3.5	4	2.5	5	4.5	4.00	2
Rice OEDK Design: ApolloBVM	http://oedk.rice.edu/apollobvm	5	5	5	4.5	5	4	4	1	5	1	3.95	
LEITAT1 Respirator	https://www.3dnatives.com/en	1	2	2	4.5	5	5	5	5	5	5	3.95	
The Open Ventilator	en.theopenventilator.com	3	2	3	5	4.5	4	3	5	5	5	3.95	
MakAir	https://github.com/makers-for-	5	4	5	4.5	3.5	4.5	4.5	1	0	5	3.70	
Mechanical Ventilator Milano (MV	http://mvm.care/design-en/	3	3	3	5	3	4	3	5	5	3	3.70	
CoroVent	https://www.micomedical.cz/	1.5	2	3.5	4.5	3	5	5	5	5	1	3.55	2
A.R.M.E.E. Ventilator	www.armeevent.com	5	5	4	3.5	3.5	3.5	2.5	5	2	1.5	3.55	1
RespiraWorks	https://respira.works/	5	4.5	5	3.5	3.5	4	4.5	2	2	1.5	3.55	1
Open Source Ventilator Project	https://simulation.health.ufl.ed	5	4.5	5	3.5	3.5	4	3.5	1	4	1	3.50	
Respirador-DQ3D-NICA	https://github.com/DQUEROL/	5	4	4	3.5	5	3.5	3.5	2	1	3	3.45	
SmithVent2020	https://drive.google.com/drive/	5	4.5	5	4.5	1.5	4.5	5	1	2	1	3.40	
People's Vent	https://www.peoplesvent.org/e	5	4.5	3.5	4.5	2.5	4.5	4.5	1	2.5	1.5	3.40	
CAM Ventilaor	https://github.com/Arcus-3d/co	5	2.5	4	3	3.5	3.5	5	1	3	3	3.35	
OpenVent-Bristol V3.0	https://app.jogl.io/project/563/	5	4	3.5	5	2	3.5	3.5	1.5	2.5	1	3.15	
VentilAid	https://www.ventilaid.org/	3.5	2.5	4	3	4	4.5	3.5	1	2.5	1.5	3.00	



The Open Medical Technology Manifesto

Open, shareable, repairable, medical technology will make us all healthier.

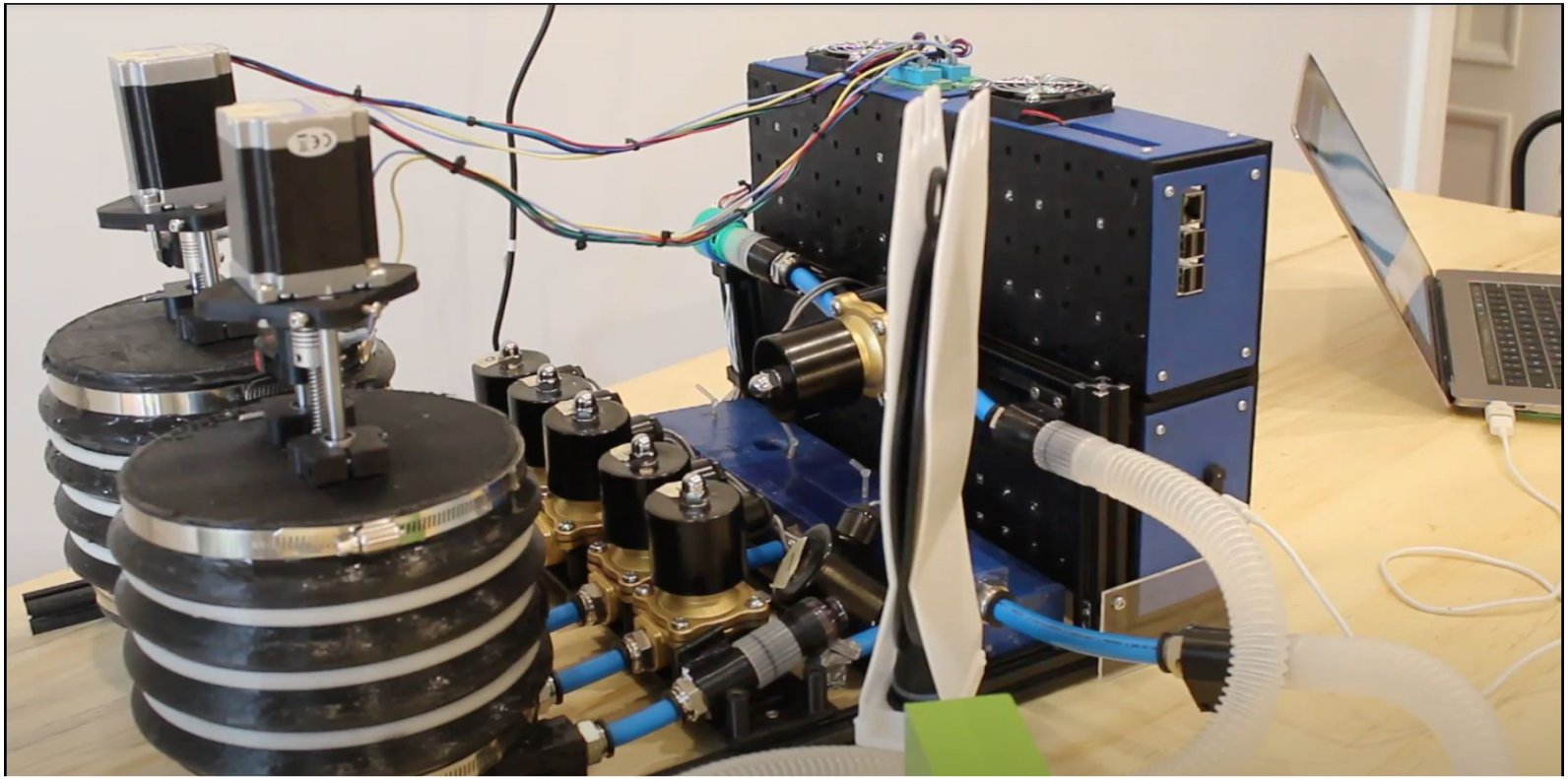
RespiraCon II
2022

https://www.change.org/p/the-open-medical-technology-manifesto-outlines-10-ways-to-make-open-sharable-repairable-medical-technology-a-reality-that-will-make-us-all-healthier

PolyVent Team formed and Success in Linz

- Team built a working ventilator
- But the bellows created a problem
- Nathaniel Bechard (16 years old) designed easily extensible card-based control module
- Global pandemic urgency dissipating
- Agreed to become fully open source by joining Public Invention in exchange for paying for parts and manual labor
- Helpful Engineering and Public Invention had the VentOS software, and the team was weak on software

The Dual-Bellows Version of PolyVent (July 2021)

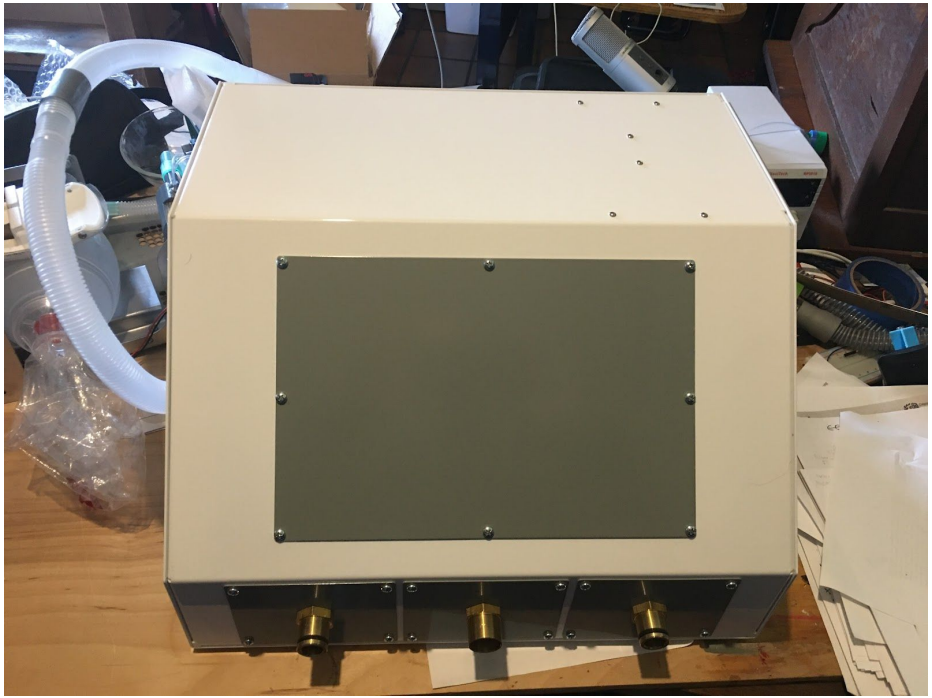


Big Switch to a Proportional Valve

- We had seen the SmithVent and Dr. Erich Schulz pointed out advantages of this approach
- Team switched and Developed PolyVent 1
- Public Invention had the Ventmon
- The PolyVent 1 worked well,
  - but teams were dying left and right,
  - US FDA had ended emergency use authorization,
- We redesigned for education

Proportional valves are not that easy to source…

PolyVent 1 with a Proportional Valve…

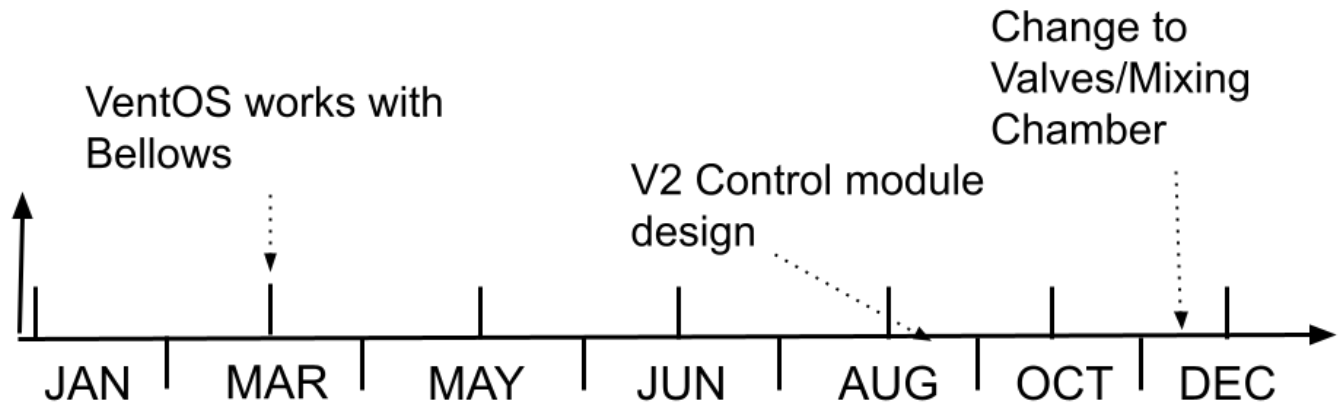


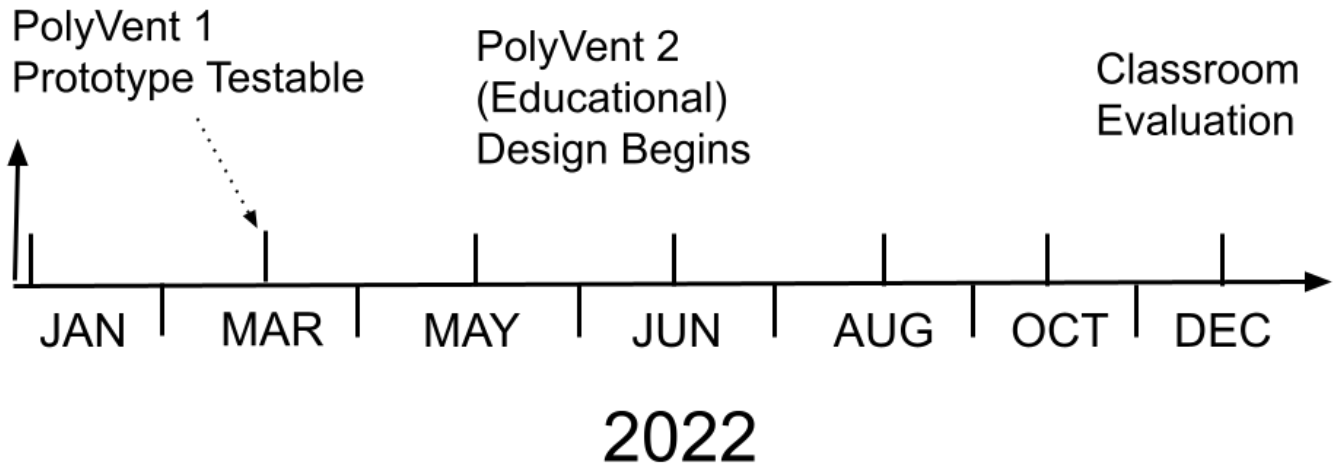
Fully Functional, but large, heavy, and cramped for classroom study…

Setting: Inda, May 2021

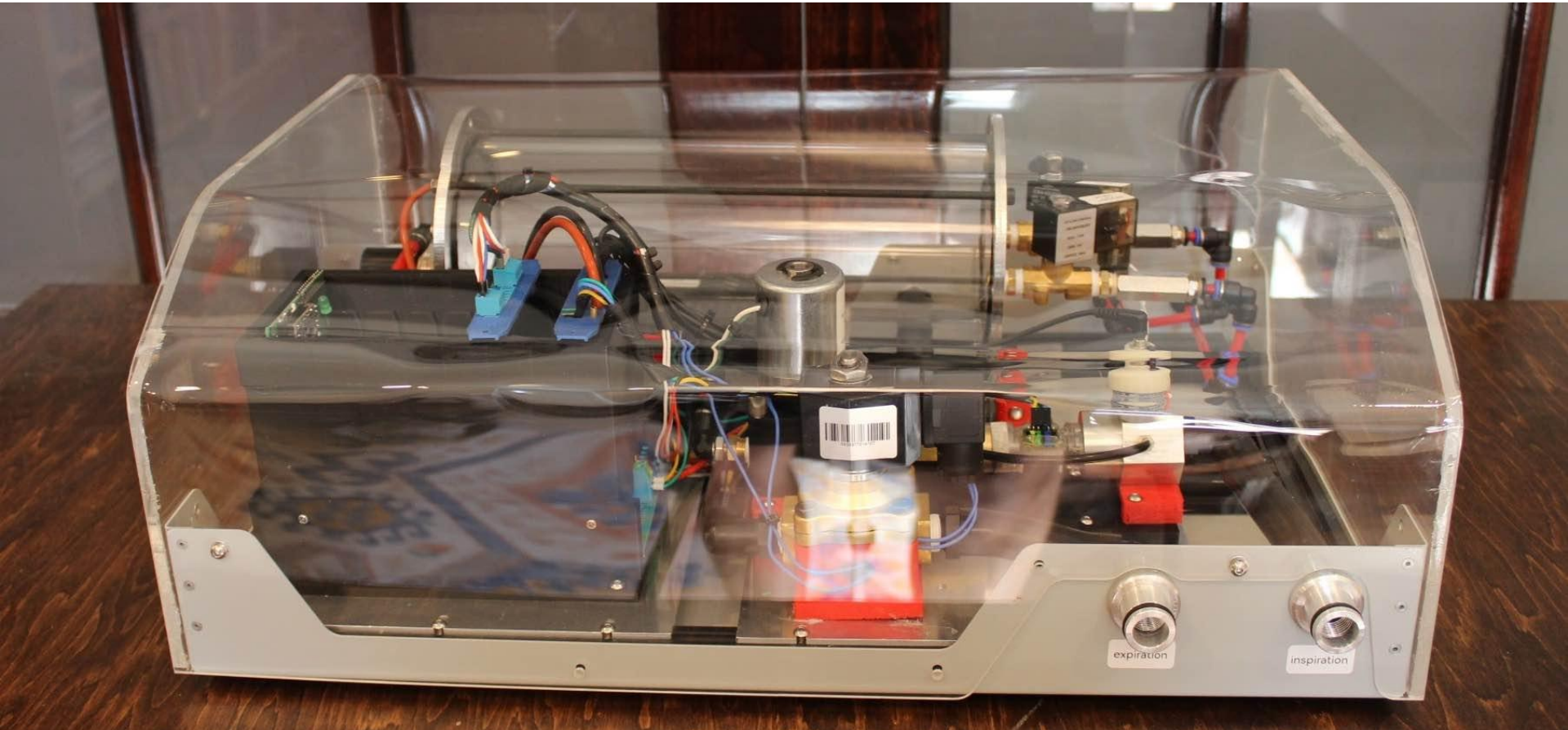
PolyVent 2 - Redesigned based on educator feedback

- Lighter, single-deck design
- Transparent Case
- Spacious, modular interior
- Modular card-based control paid-off: GPAD team added an SPI interface card

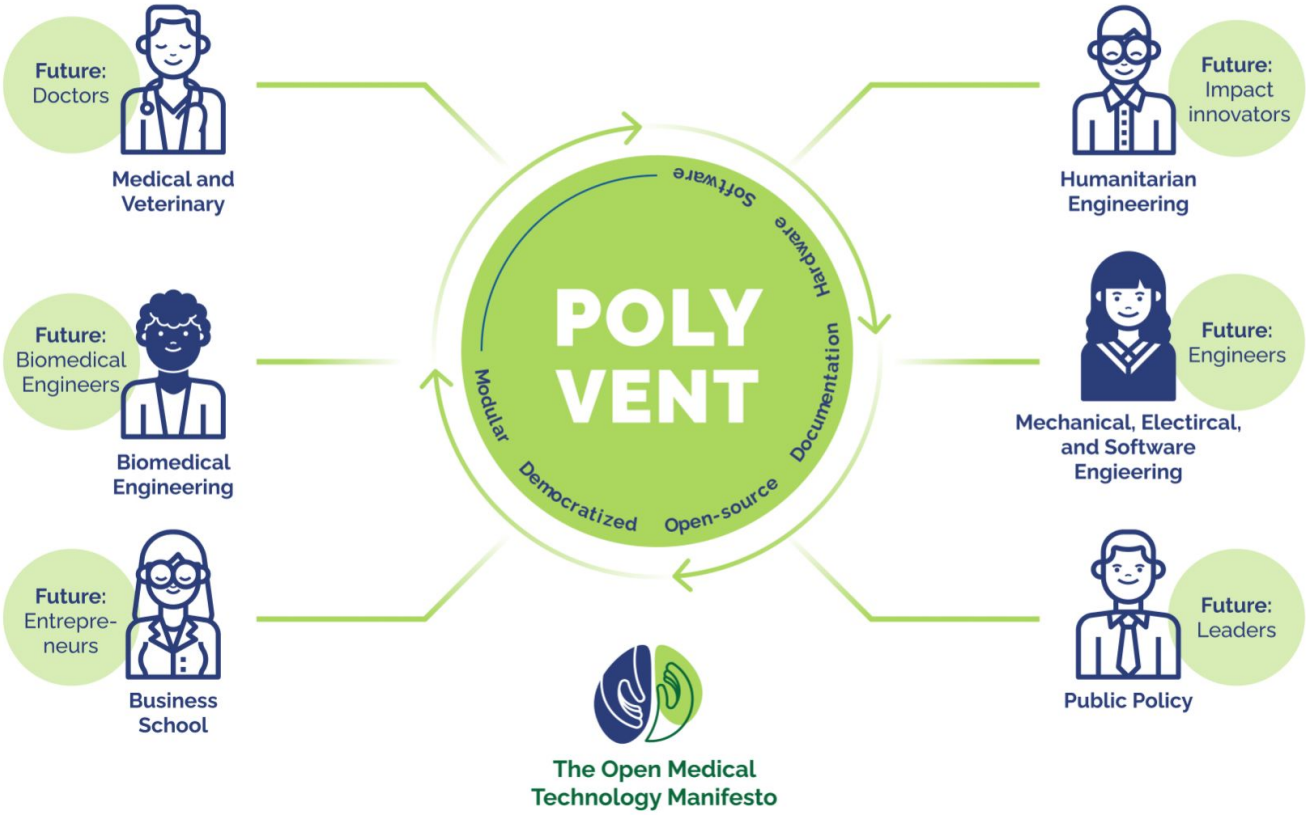

VentOS works with Bellows
V2 Control module design
Change to Valves/Mixing Chamber
JAN
MAR
MAY
JUN
AUG
OCT
DEC
2021


PolyVent 1 Prototype Testable
PolyVent 2 (Educational) Design Begins
Classroom Evaluation
JAN
MAR
MAY
JUN
AUG
OCT
DEC
2022

PolyVent 2 Educational Platform



The PolyVent Educational Platform: For Whom?



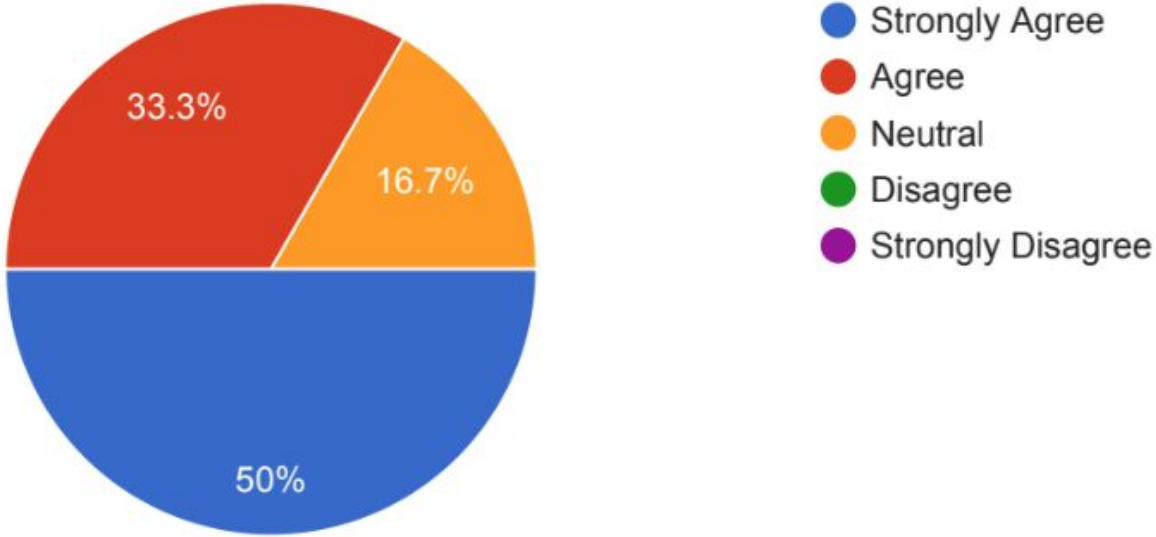
Classroom instruction module designed

- Extra-credit two hour module at Rice University in Houston
- Senior Biomedical Engineering Troubleshooting class
- Prepared fake “broken” parts and installed them to be found by troubleshooting
- Survey results

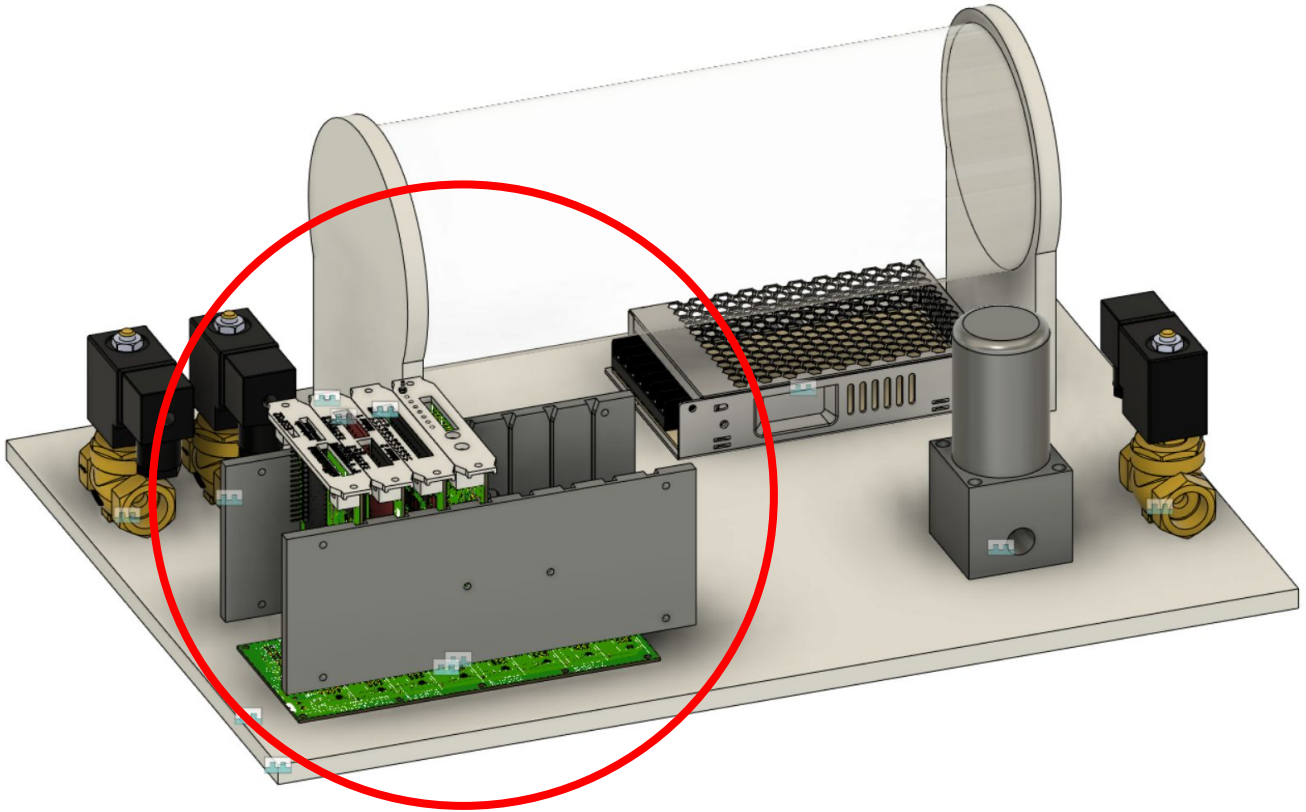
I would recommend this type of experience to other bioengineering programs in universities.

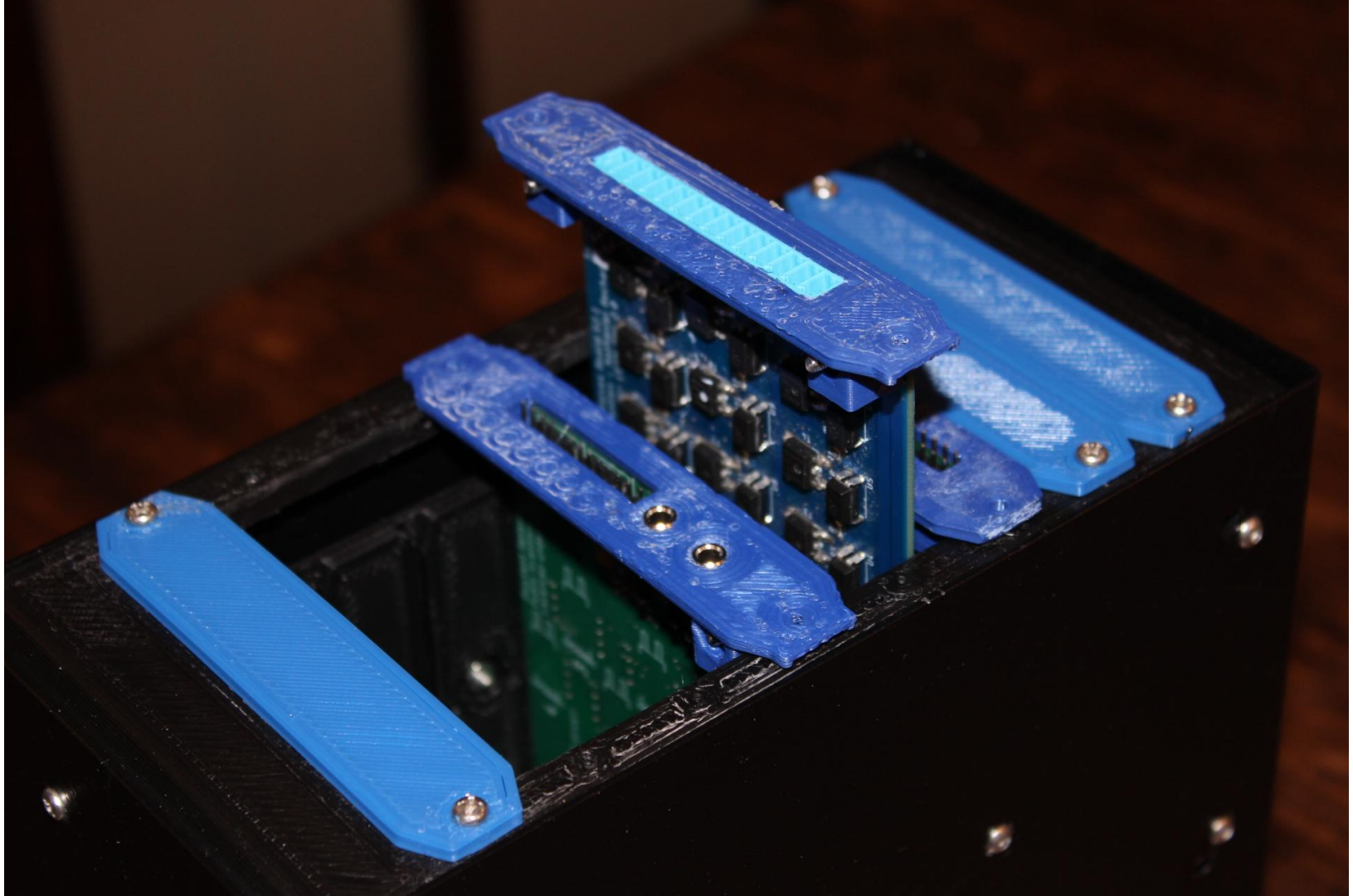
Copy

12 responses



The Electronic Control Module…





VentOS

- A project of Helpful Engineering, started by Dr. Erich Schulz, Ben Coombs, and Rob Read
- Forked to make an Oxygen Concentrator (“the Ox”) by Ben and improved…
- That fork was forked for NASA by Rob to make a control system for an ceramic oxygen generator…
- Significant improvements in that code that have not been merged back yet….need volunteers!

VentOS Architecture

- Arduino Platform compiled with PlatformIO
- Configuration modes in PlatformIO set C-Pre-Processor compile time switches…
- Barely runs (due to size) on an Arduino Uno,
- PolyVent uses and ESP32
- Has a good Hardware Abstraction Layer
- Super-loop (or Simple-loop) architecture

Possible because all Ventilators do the same thing…

- (Almost) Always there is a breathing cycle that doctors vary:
  - Breaths per minute
  - Inhalation time, exhalation time ratio
  - Pressure Controlled Ventilation keeps constant pressure through inhalation (doctor sets as a parameter)
  - Lung change in volume with change in pressure (and flow) (compliance) varies with disease condition and even moment-to-moment, so…
  - Pressure and flow have to be precisely controlled.
  - Too much pressure damages the patient…
  - Not enough air exchange suffocates patient…

The UNIX Way…

- Write programs that do one thing and do it well.
- Write programs to work together.
- Write programs to handle text streams, because that is a universal interface

…transformed to an open source hardware:

- Build Machines that do one thing and do it well.
- Build Machines to work together.
- Build Machines to handle ~~text streams~~ JSON communicated via SPI or I2C, because that is a universal interface

Q: How realistic is this?

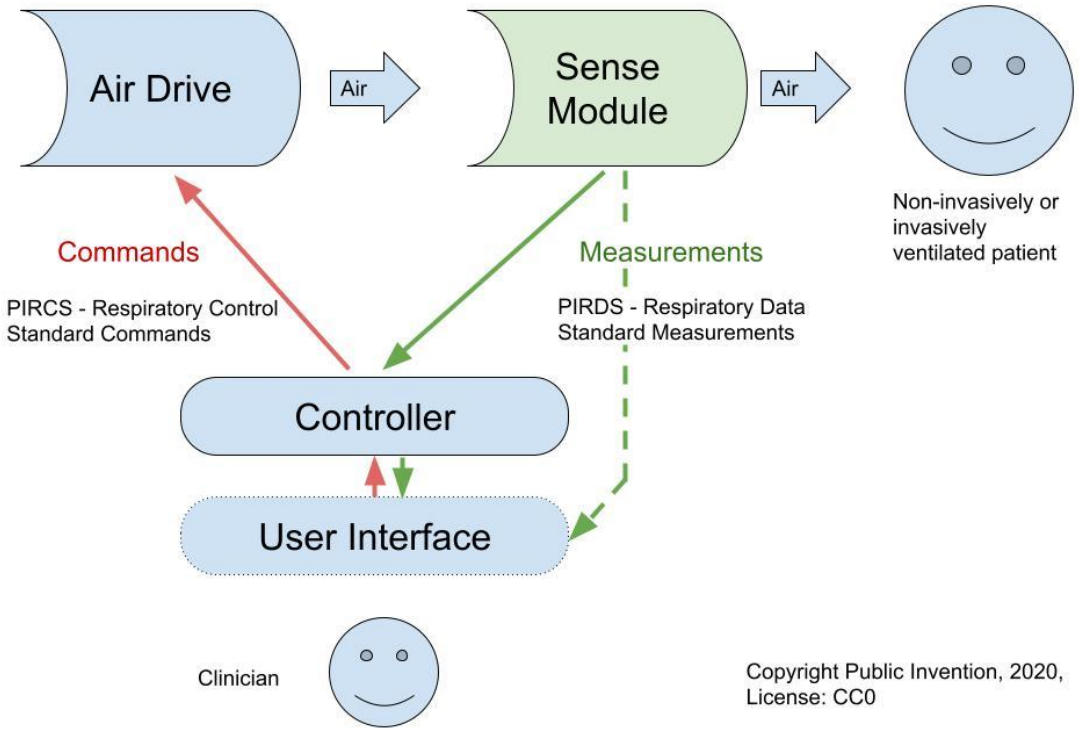
A: Public Invention, with less than $100,000 (in partnership with Helpful Engineering) has already created:

- VentMon - tester
- VentOS - operating system
- PolyVent - ventilator
- PIRDS - data standard
- PIRCS - control standard
- The Ox - oxygen concentrator
- VentDisplay - test display GUI

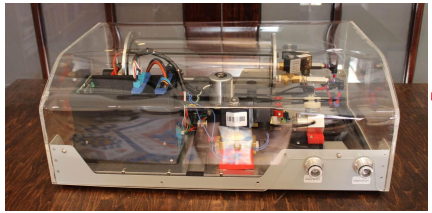
…other pieces of the ecosystem are being worked on by other teams.

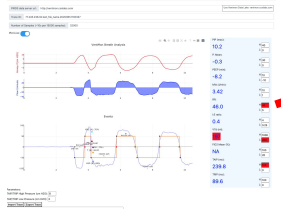
All of these are 100% free, open, modular, and reusable.

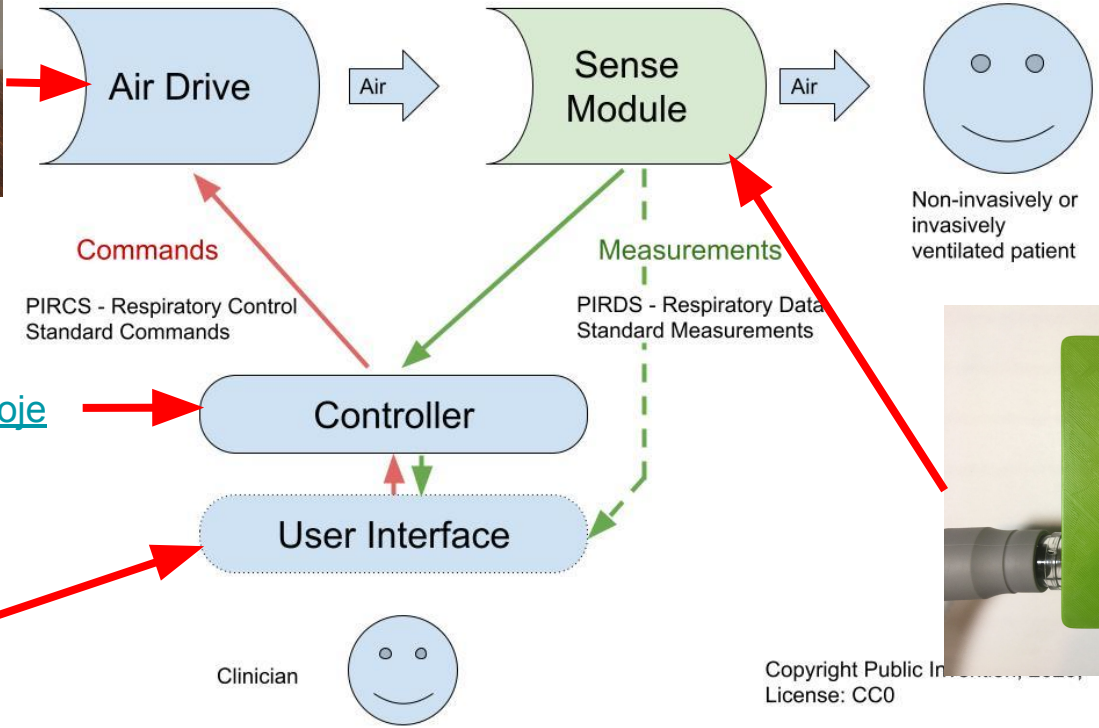
An Example: A Universal Ventilation Model



Components in Place

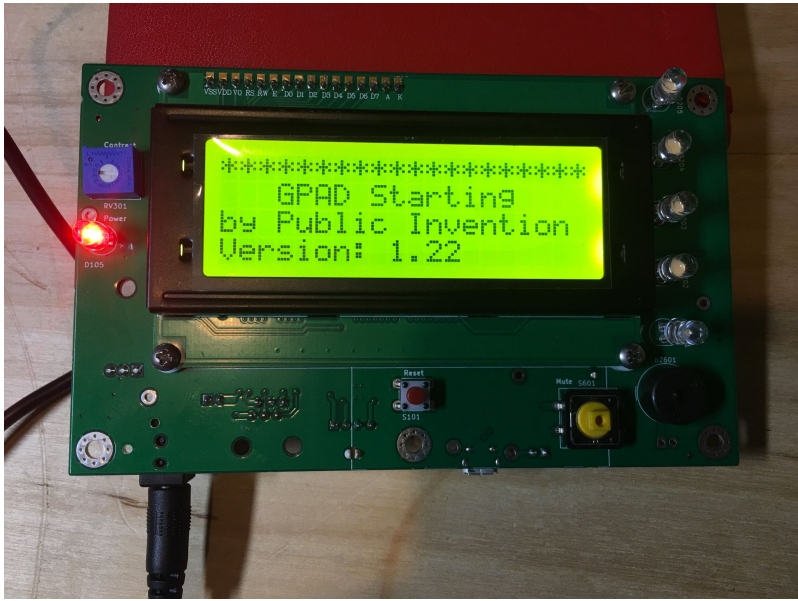




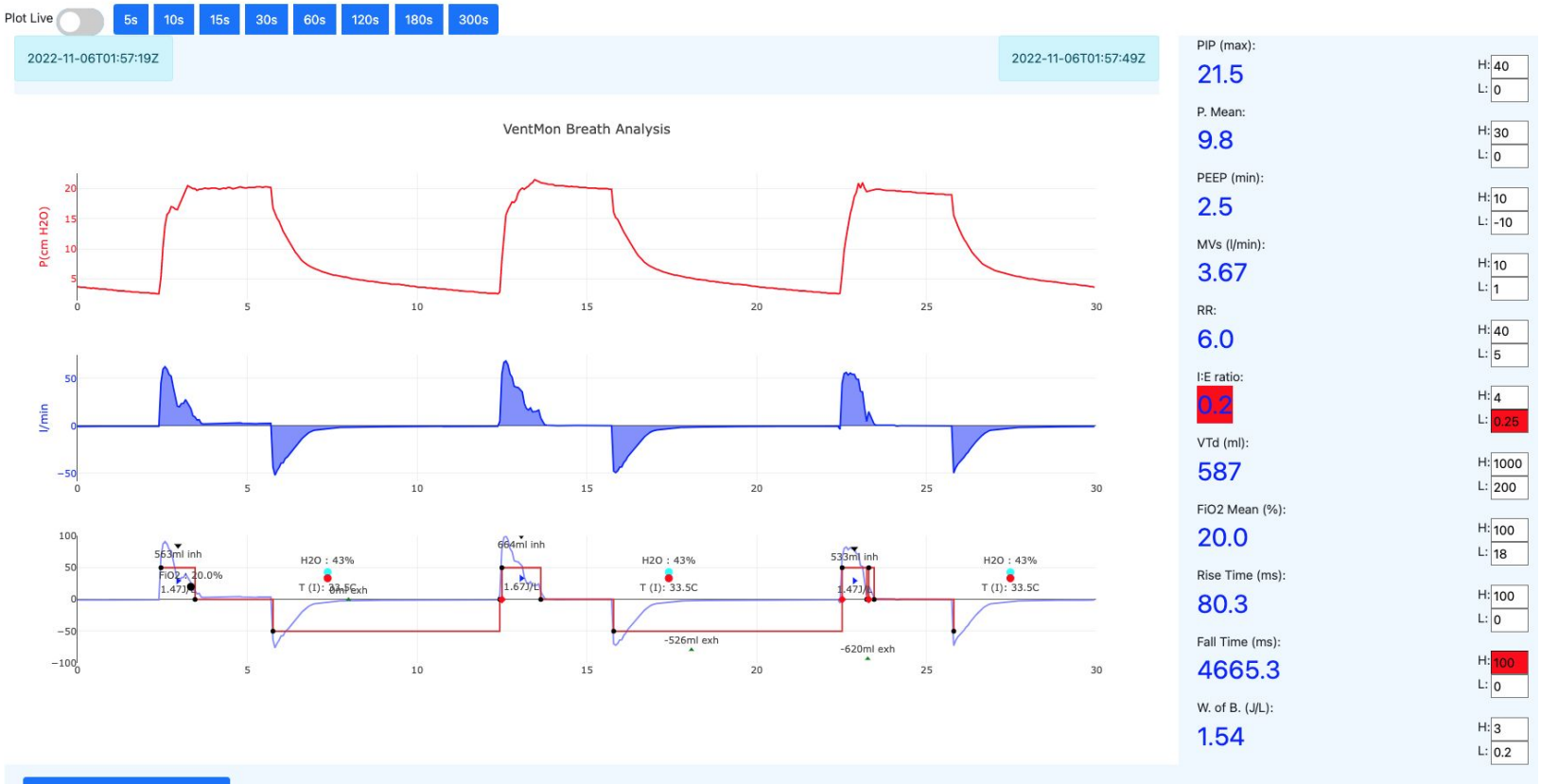


https://gitlab.com/project-ventos/ventos

External Module: The GPAD



VentMon/VentDisplay



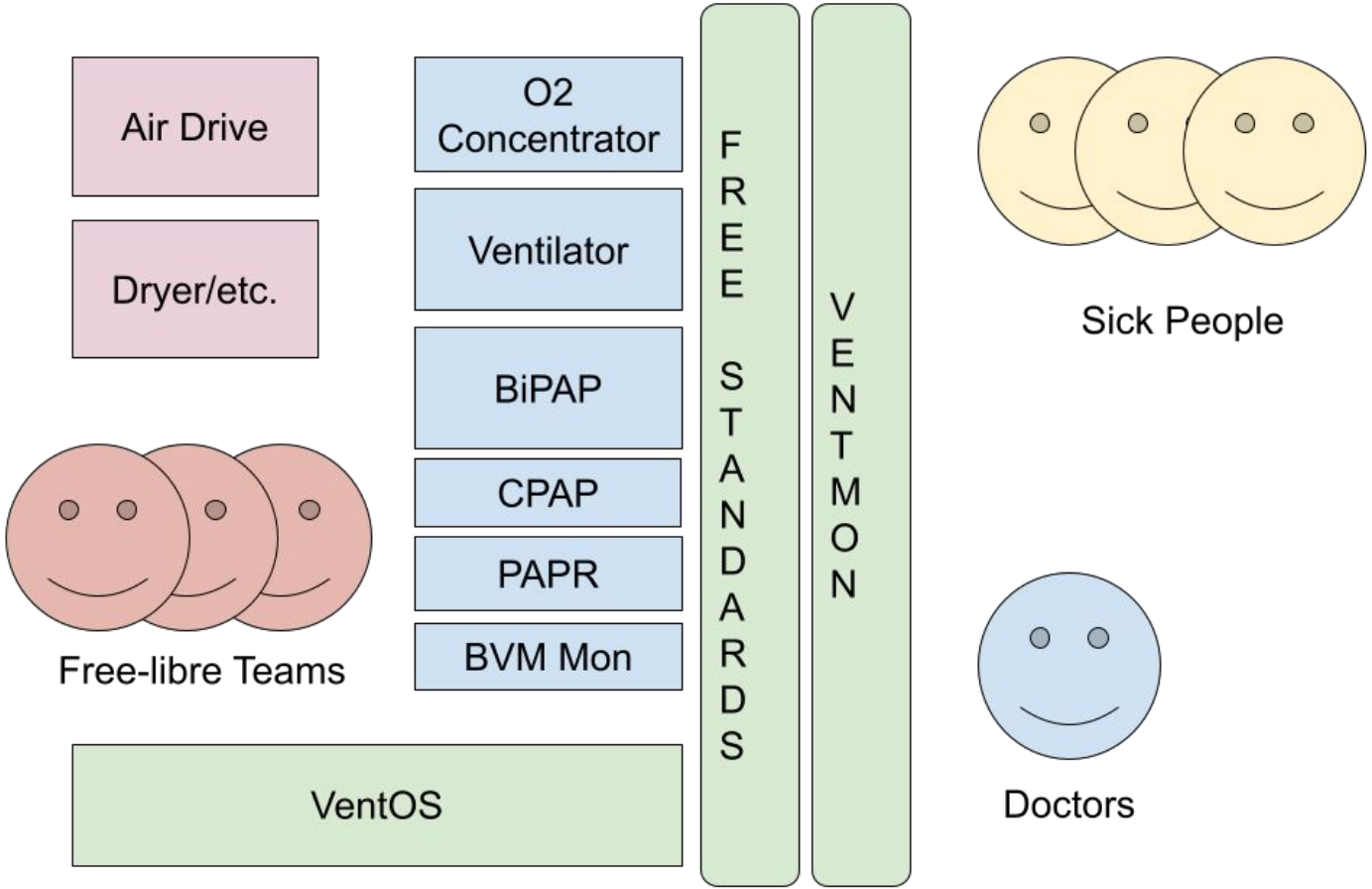
But these things are true no matter how air is produced…

- Every ventilator has a Patient Inflating Valve
- Every PCV ventilator has to carefully control pressure (obvious solution is a PID loop)
- Every (modern) ventilator monitors pressure and flow in the airway

…so VentOS can be “Universal” by implementing a Hardware Abstraction Layer

Following open source methodology…

- It is not so much a machine as an “ecosystem”
- Some monitoring is completely separated from the Ventilator via the VentMon
- Alarm device designed as a completely separate machine (The GPAD project).
- New features can be added by designing cheap PCBs for the control module
- Even the valve control board uses its own microcontroller (SAMD21) and is communicated with via SPI



MAKE OPEN STANDARDS!

- https://github.com/PubInv/PIRCS-pubinv-respiration-control-standard
- https://github.com/PubInv/PIRDS-pubinv-respiration-data-standard

The Open Secret

The Open Source Software world has already shown us the way:

Open Source software is (approximately) taking over the whole world. It's (open) secret weapon is the creation of standards. The software world has a mature *culture of standards*.

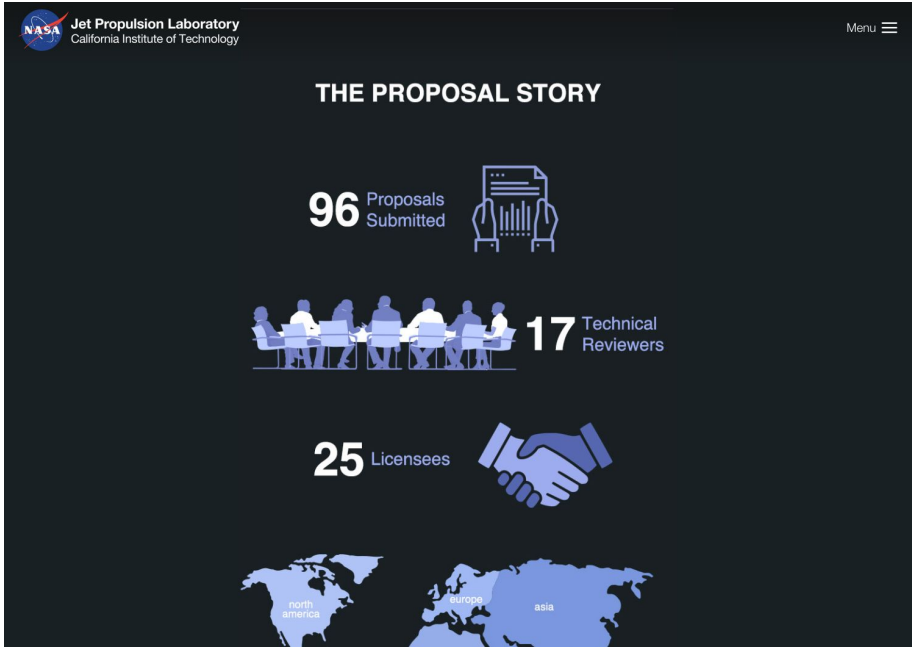
Examples: HTTP, HTML, JSON, APIs, OAuth, SSL, IEEE floating point standards, C itself, I2C, SPI, The Arduino Uno, Arduino Shields, the Raspberry Pi, etc.

We need Respiration Standards.

In Short…

- It’s an open, extensible ecosystem
- We sell it for classroom and research use, but you can build your own
- It is the **most open**, best documented open source ventilator
- Proven to be extensible

Counter Example: The VITAL (WTF?) ventilator developed by JPL



Our Goals…

- Democratizes human ventilation
- We hope a firm uses this design as a basis for a regulatory-approved human ICU ventilator, and make big $$$

- Claim: if you needed a ten-thousand ventilators quickly due to a medical crisis, the PolyVent would be the best starting point.

Help us make Public Invention and Humanitarian Open Source Hardware a movement!

https://www.pubinv.org/

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More Links

- Demo of the PolyVent 1 Machine: https://www.youtube.com/watch?v=4cNxsxGG3SU&list=PL9nAioXQFIE6OBPzdT58ey-rnCFJlofM2&index=8&t=290s
-

Freespireco

A Free Respiration Ecosystem

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<read.robert@gmail.com>
Twitter: @robertleeread
YouTube:
https://www.youtube.com/channel/UCJQg_dkDY3KTP1ybugYwReg

The Freespireco Manifesto:

The COVID-19 pandemic has demonstrated a clear and present need for a complete, free-libre open-source, easily repairable, widely usable, safe and effective respiratory support medical device ecosystem.

https://github.com/PubInv/freespireco

This talk combines…

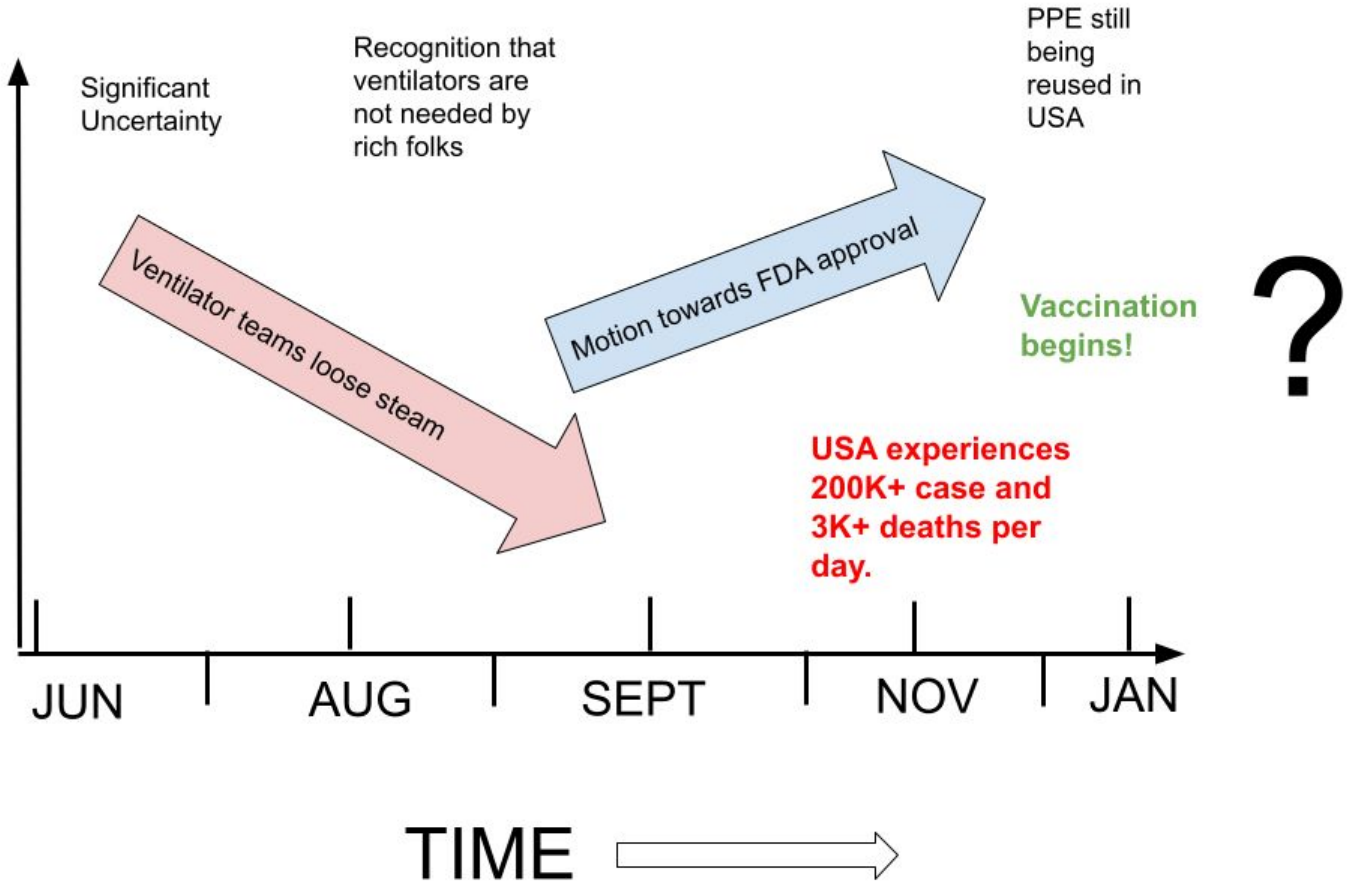
- Software
- Hardware
- Medicine
- Policy

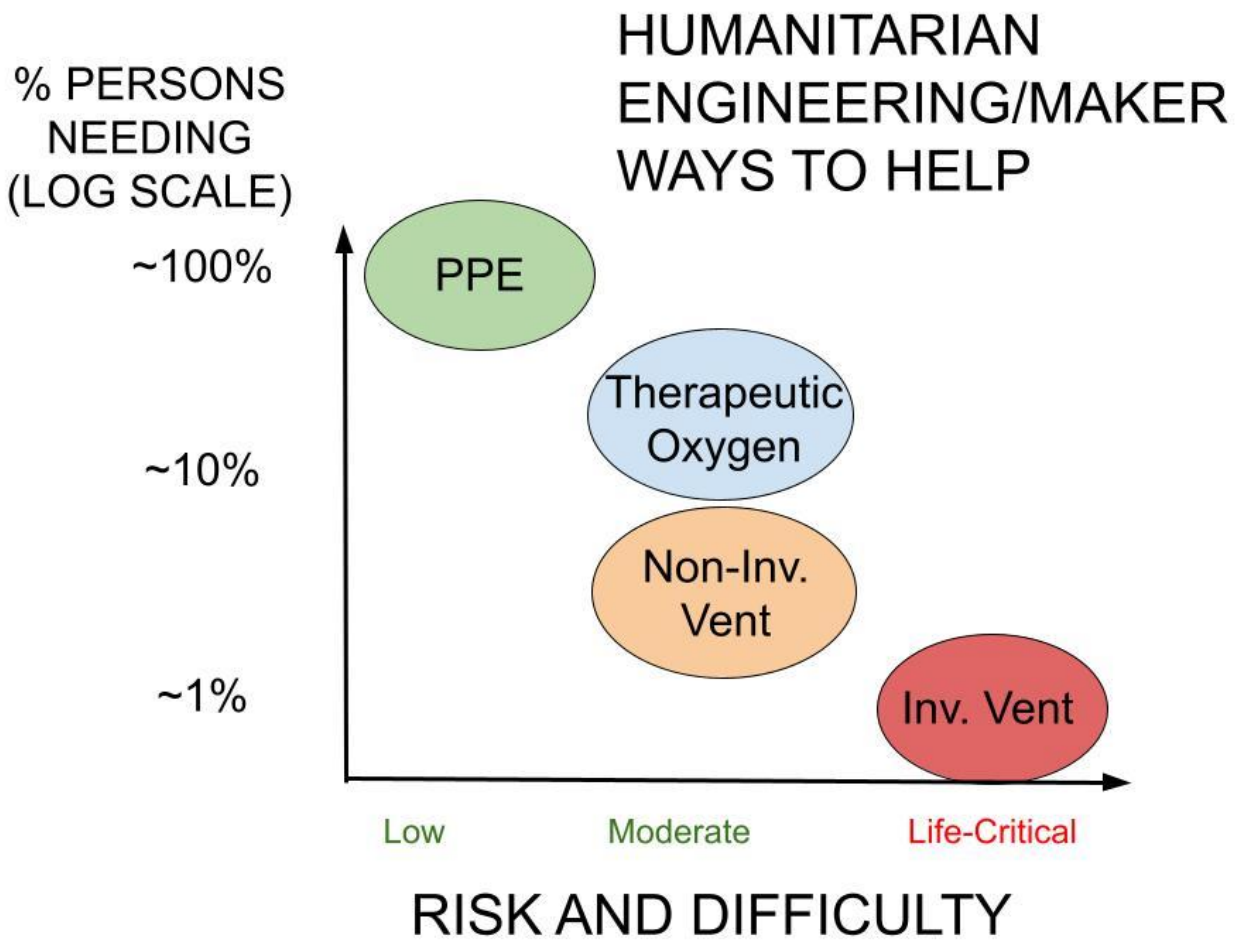
…and I don’t know this audience!

So please, stop me with questions, and if they get too much, I can moderate them to get through the talk.

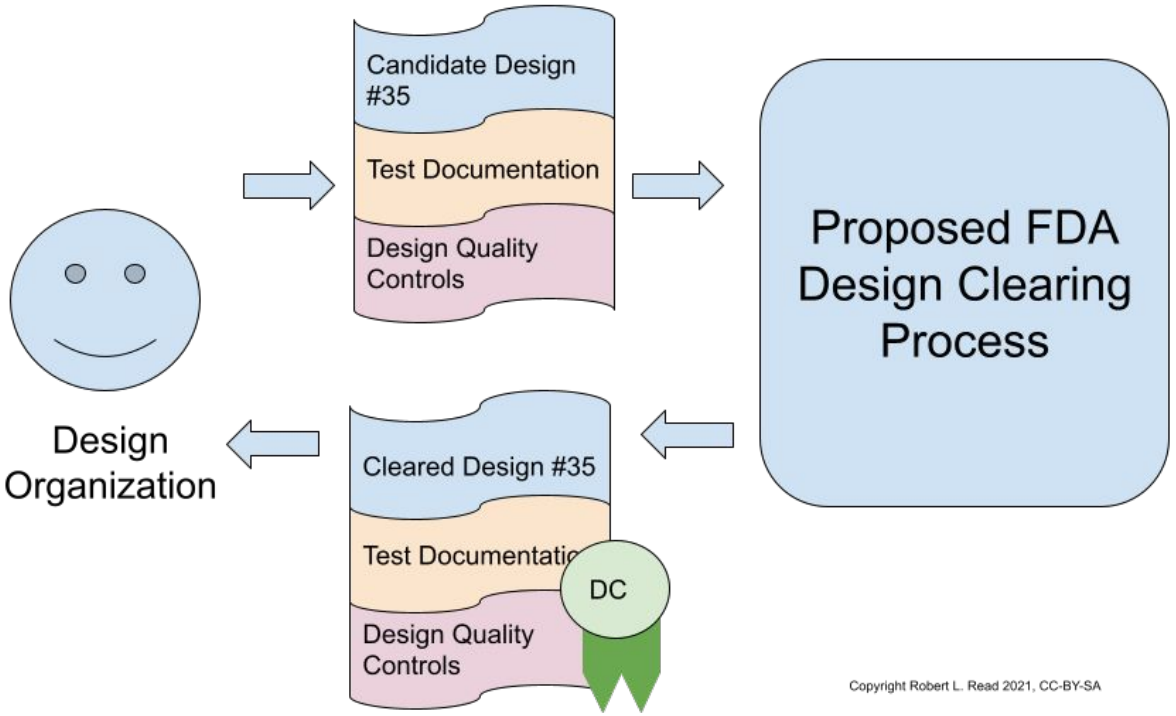
Timeline of free-libre open source

- FSF - 1985
- GNU Manifesto - 1985
- Linux - 1991
- Open Hardware - (Chips) ~2010+
- RISC-V - Foundation 2015
- Open Source Medical Devices - Pandemic Inspired, 2020

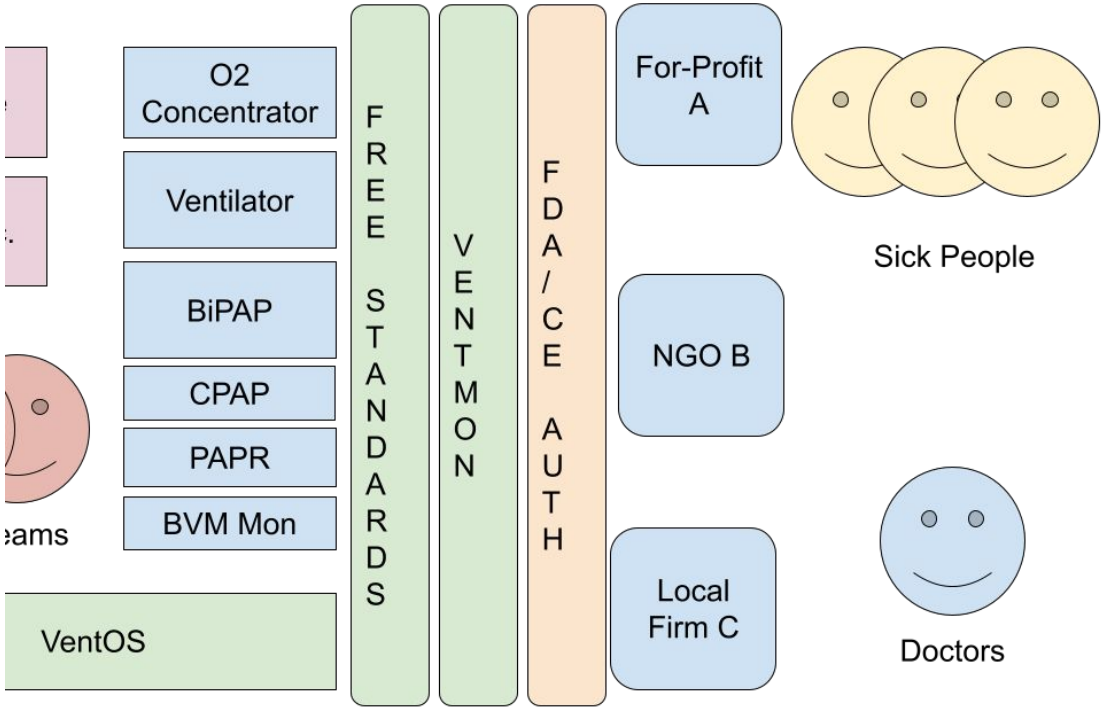

Significant Uncertainty
Recognition that ventilators are not needed by rich folks
PPE still being reused in USA
Ventilator teams loose steam
Motion towards FDA approval
Vaccination begins!
?
USA experiences 200K+ case and 3K+ deaths per day.
JUN
AUG
SEPT
NOV
JAN
TIME

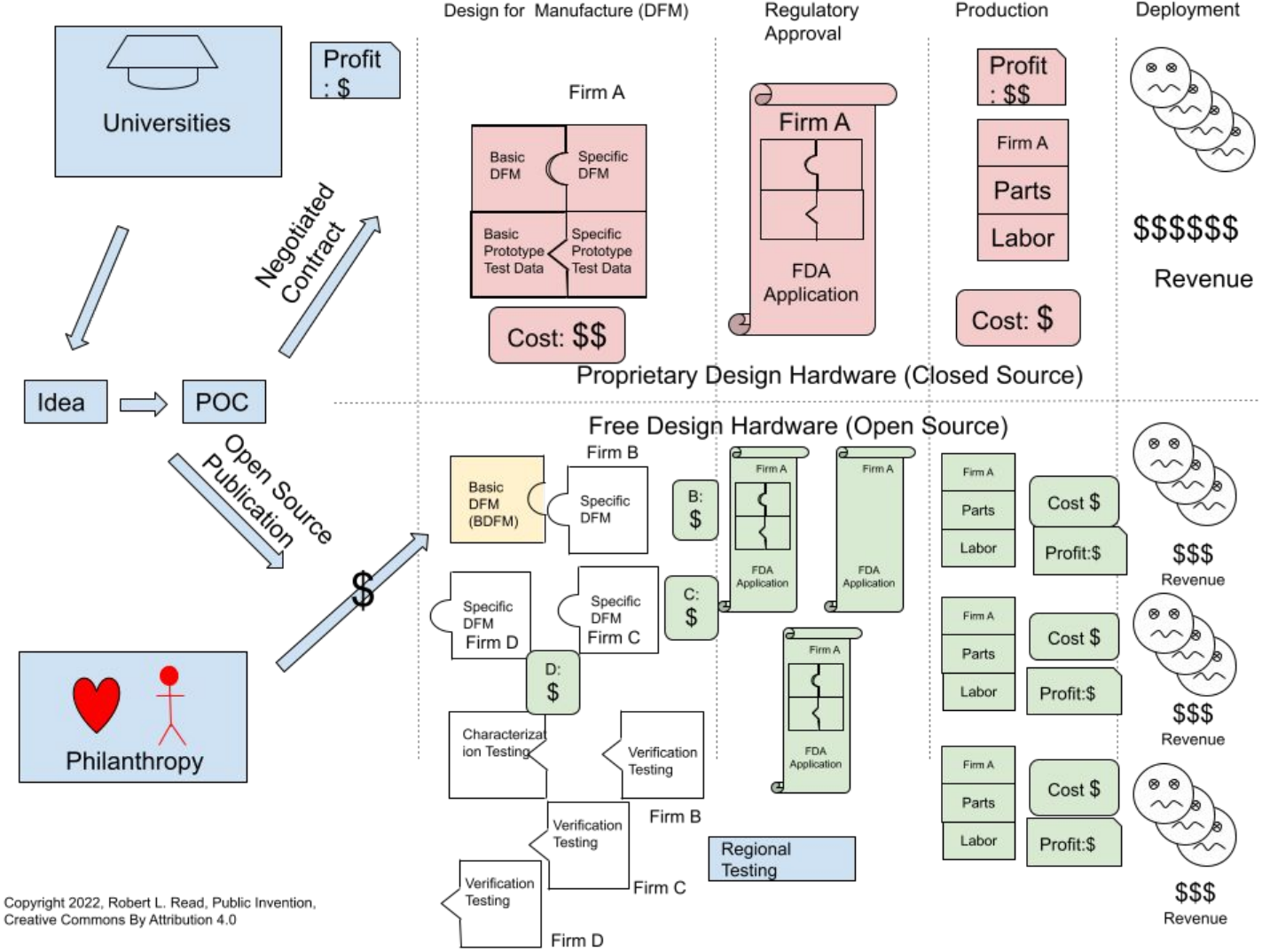

HUMANITARIAN ENGINEERING/MAKER WAYS TO HELP
% PERSONS NEEDING (LOG SCALE)
~100%
~10%
~1%
PPE
Therapeutic Oxygen
Non-Inv. Vent
Inv. Vent
Low
Moderate
Life-Critical
RISK AND DIFFICULTY

We have in fact proposed an augmentation of the FDA Clearing Process, but acceptance is NOT necessary.



Freespireco creates business opportunities…




Design for Manufacture (DFM)
Regulatory Approval
Production
Deployment
Universities
Profit : $
Negotiated Contract
Idea
POC
Open Source Publication
$
Philanthropy
Firm A
Basic DFM
Specific DFM
Basic Prototype Test Data
Specific Prototype Test Data
Cost: $$
Firm A
FDA Application
Profit : $$
Firm A
Parts
Labor
Cost: $
$$$$$$
Revenue
Proprietary Design Hardware (Closed Source)
Free Design Hardware (Open Source)
Firm B
Basic DFM (BDFM)
Specific DFM
B: $
Specific DFM Firm D
Specific DFM Firm C
C: $
D: $
Characterization Testing
Verification Testing
Firm B
Verification Testing
Firm C
Verification Testing
Firm D
Regional Testing
Cost $
Profit:$
$$$
Revenue
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