

Freespireco

A Free Respiration Ecosystem
...and why SCaLE 19x should care.

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This talk has links you may want to follow...

<https://bit.ly/3cTpoXp>



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.



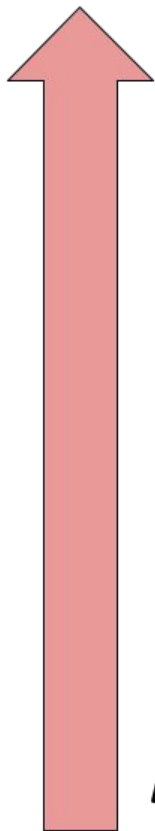
*“Invent in the public,
for the Public.”*

<https://www.pubinv.org/>

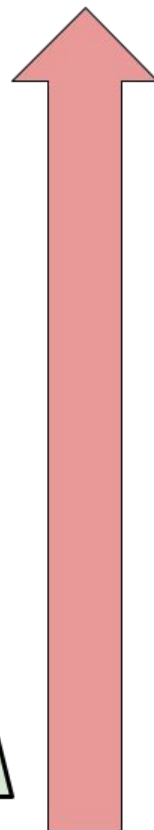
Timeline of free-libre open source

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

Cost of
Development



Licensing
Complexity



Medical Devices

No specific license yet

Hardware

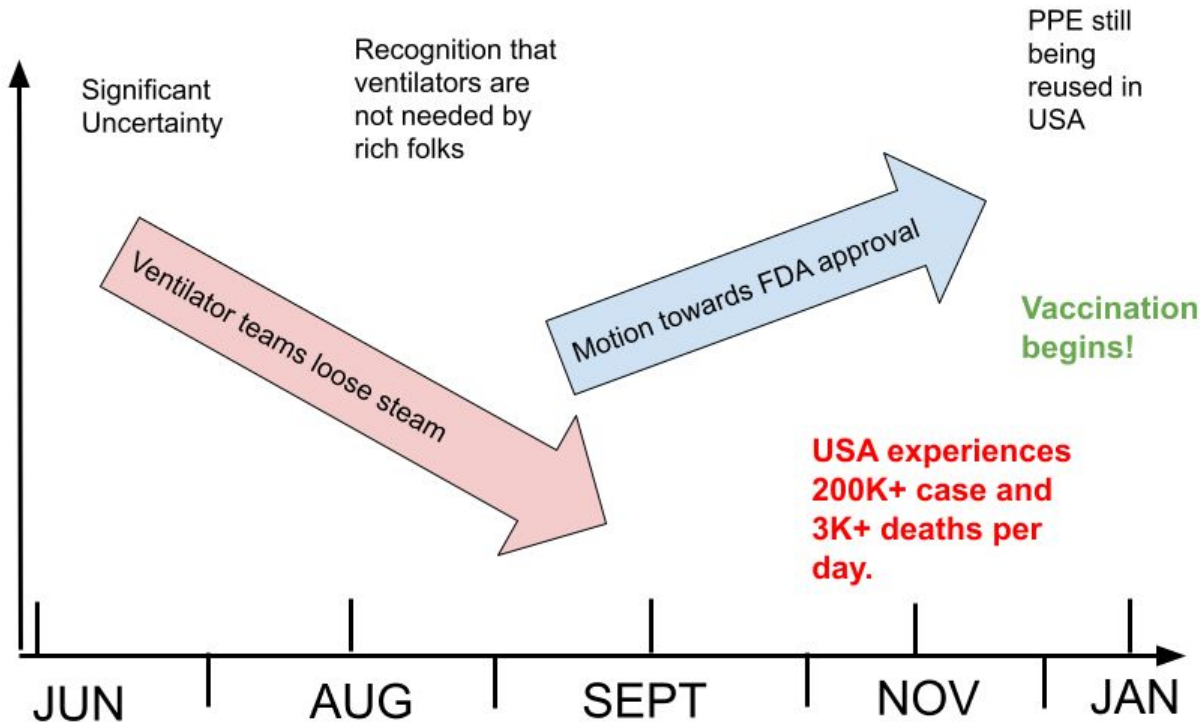
E.g. CERN, but questions

Software

GPL, Affero, and permissive: MIT, etc.

Text

E.g., CC0, CC-SA



TIME →

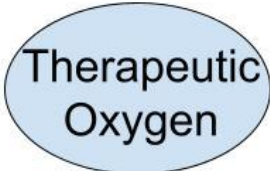
HUMANITARIAN ENGINEERING/MAKER WAYS TO HELP

% PERSONS
NEEDING
(LOG SCALE)

~100%



~10%



~1%



Low

Moderate

Life-Critical

RISK AND DIFFICULTY



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-shareable-repairable-medical-technology-a-reality-that-will-make-us-all-healthier>

Feel the energy here.....

Now imagine this much energy being applied to open source medical devices 10 years from now.

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>

Problem:

Fragile International Supply Chains Kill People

Solution:

Modular, open design respiration devices

But modern hardware devices...

Are ALWAYS software devices as well (almost).

The same advantage of open software accrue to open hardware devices, except:

- Hardware does not have zero marginal reproduction costs
- ...but the need for “many eyes on the problem” and trust through transparency is just as important.
- Unit tests cannot be fully automated

Embedded Systems = Hardware + Software

Just like the other topics discussed at SCaLE 19x, we need:

- GitHub (source control and forge)
- Code cooperation and review processes
- Understanding of licensing
(<https://github.com/PubInv/PubInv-License-Guidelines>)
- Social reward for contribution
- Potential financial reward for contribution

Linux Above, Arduino Below...

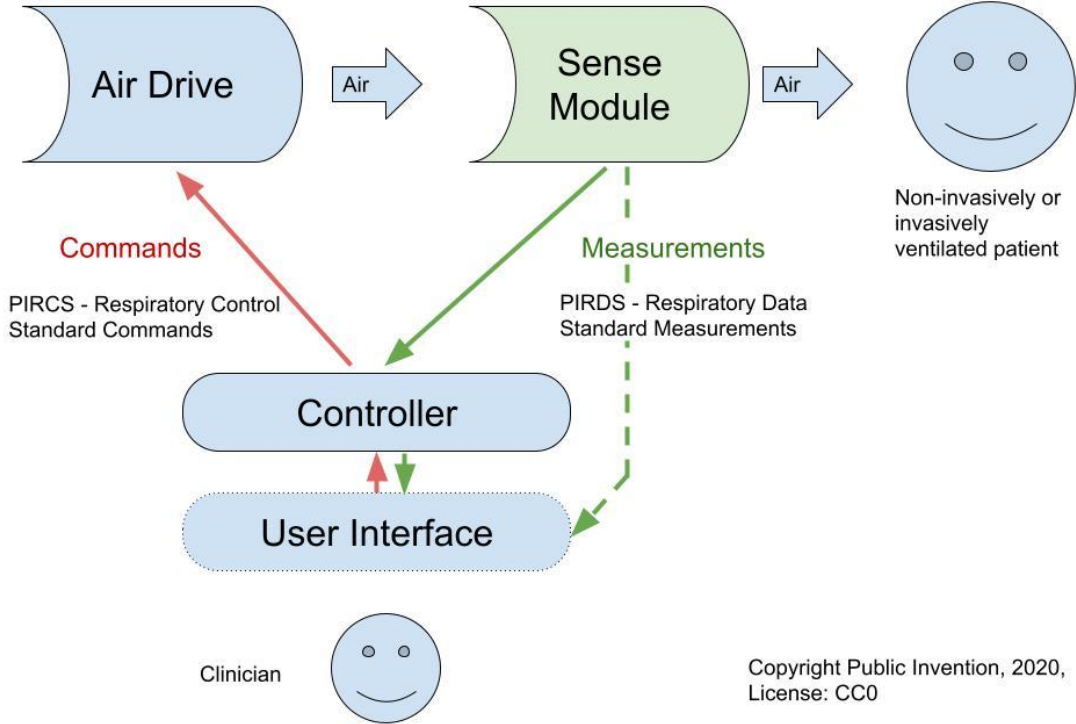
- Linux for “IoT” (Internet of Things) cloud-based data lakes
- VentMon uses a public data lake hosted on Linux
- But IMHO favor Arduino’s over RaspPis at the microcontroller level for simplicity, reliability, and security

Open Source Medical Devices will not be Free of Charge.

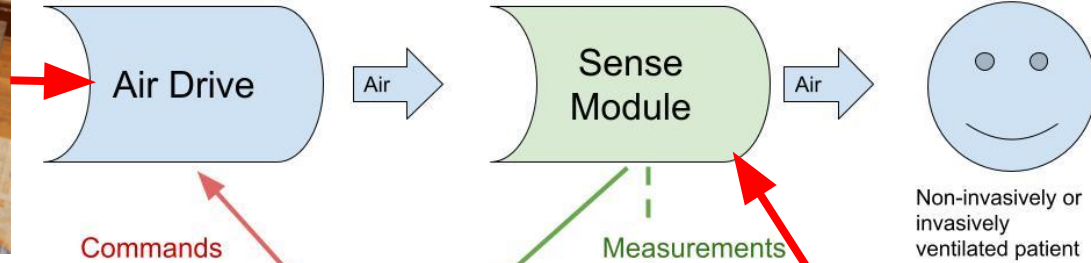
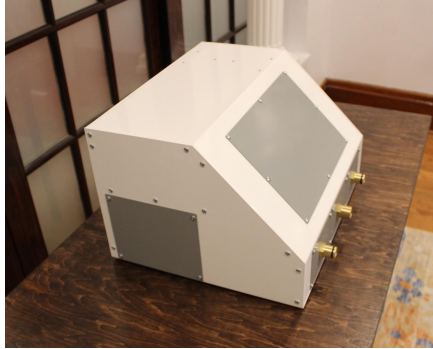
Open Source Medical Devices will not be Free of Regulation.

But they will be Cheaper and more Available.

An Example: A Universal Ventilation Model



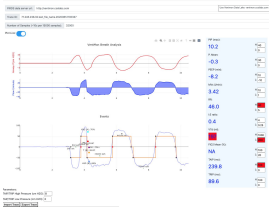
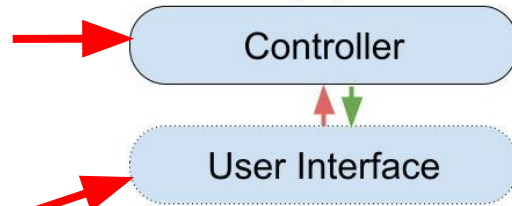
Components in Place



PIRCS - Respiratory Control Standard Commands

PIRDS - Respiratory Data Standard Measurements

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



Copyright Public Invention
License: CC0

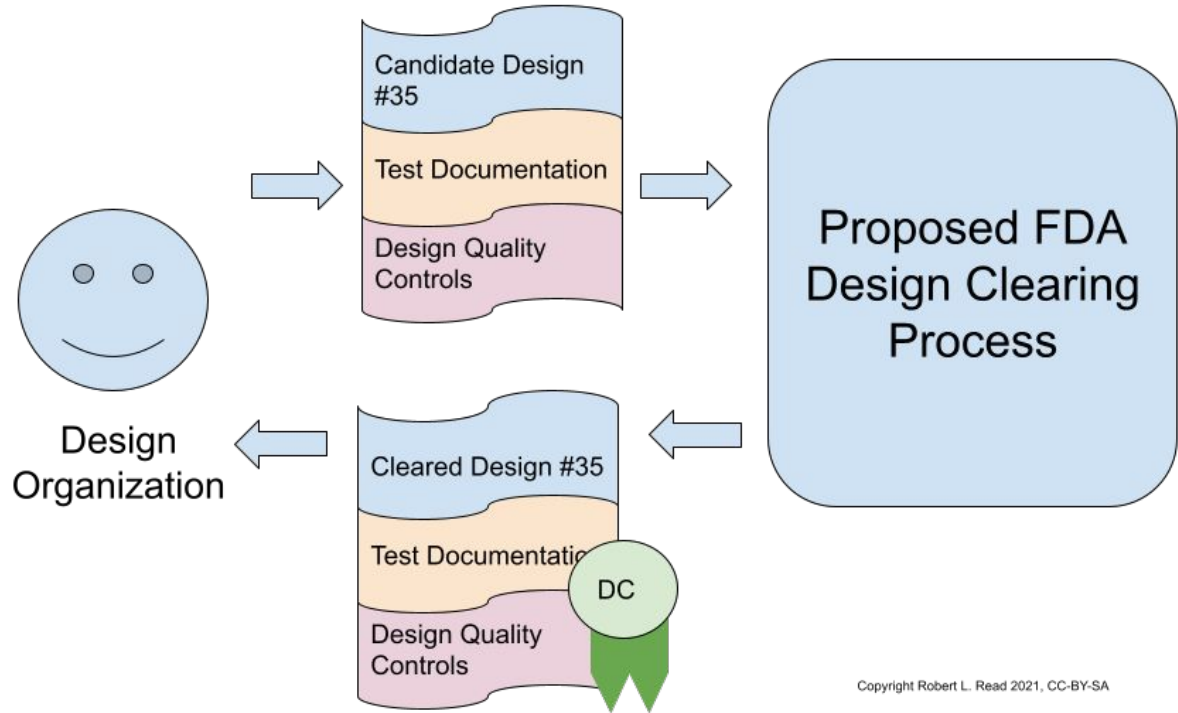
The World need a Reusable Free-Libre Digitally Controlled Air Drive!

If the production of medical gases were properly modularized, a ventilator could be repaired with multiple air-drives, increasing supply chain resilience.

Low and middle income countries can begin to make medical devices by making modules, rather than entire devices.

The FDA already has notions of “accessories” which make this possible. Even if it requires a complete recertification, the world become less fragile in this model.

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



Large firms will Incorporate and Improve Free Designs.

Sub-components of greater and greater complexity will become commodities.

Large firms will be free to focus on adding improvements.

Example:

Medical devices already use commercial off-the-shelf (COTS) parts. These parts can become free-design modules of considerable complexity, decreasing the design cost and increasing overall safety.

How do we make this real?

- A Library of Proof-of-Concepts Designs (existing already)
- Funding for creating and documenting manufacturing plans to the point of being “start-up ready” (SUR)
- A third-party testing organization
- A culture of publishing test data
- A license that forces publication of (some) regulatory application documents at the time of regulatory request (Sunlight regulatory)
- Standards, standards, standards! (Physical, electrical, and data)
- Emphasis on modularity for repairability and supply-chain robustness

A Library of Proof-of-Concept Designs

- This already exists and is growing, but is not organized and standardized across organizations ([OSMS](#), others)

Proof-of-Concept << Start-Up-Ready

- Few incentives for taking the next steps (as shown by Kiliszewski)
- NGOs should have a strong incentive for doing this – we need to convince them to financially support this.

A third-party testing organization

Note: this idea is from Joshua Pearce, Rohith Malya, Sabia Abidi, but let me articulate it.

We need a financially supported, professional, third-party, impartial “consumer reports” (distributed) laboratory capable of producing accurate test reports of open-source medical devices.

This will make use of open-source designs for components and machines 10x more easily used.

A Culture of Publishing Test Data

Established best practice for software is to use automated unit tests.

Best practice for open hardware is not yet established, but must become, the publishing of clear test data.

A Sunlight Regulatory Licence

(<https://github.com/PubInv/RegulatorySunlight>)

Legal theory of licenses: hooks and triggers

Trigger: Applying for Regulatory Approval

Hook: Forces publication of some (not all) of Regulatory Application (e.g. FDA)

Purpose: Create a cultural commons of sharable, open FDA applications

Sunlight Regulatory License gives and demands...

What you get:

The right to copy the design.

What you have to do:

Give back your improvements and (part of) your regulatory application.

Note: This project needs legal scholars as volunteers!

The Open Secret

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

MAKE OPEN STANDARDS!

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.

IEEE SA (Standards Association) Open...

I learned of them just yesterday; hope to submit the PIRDS and PIRCS standards to them.

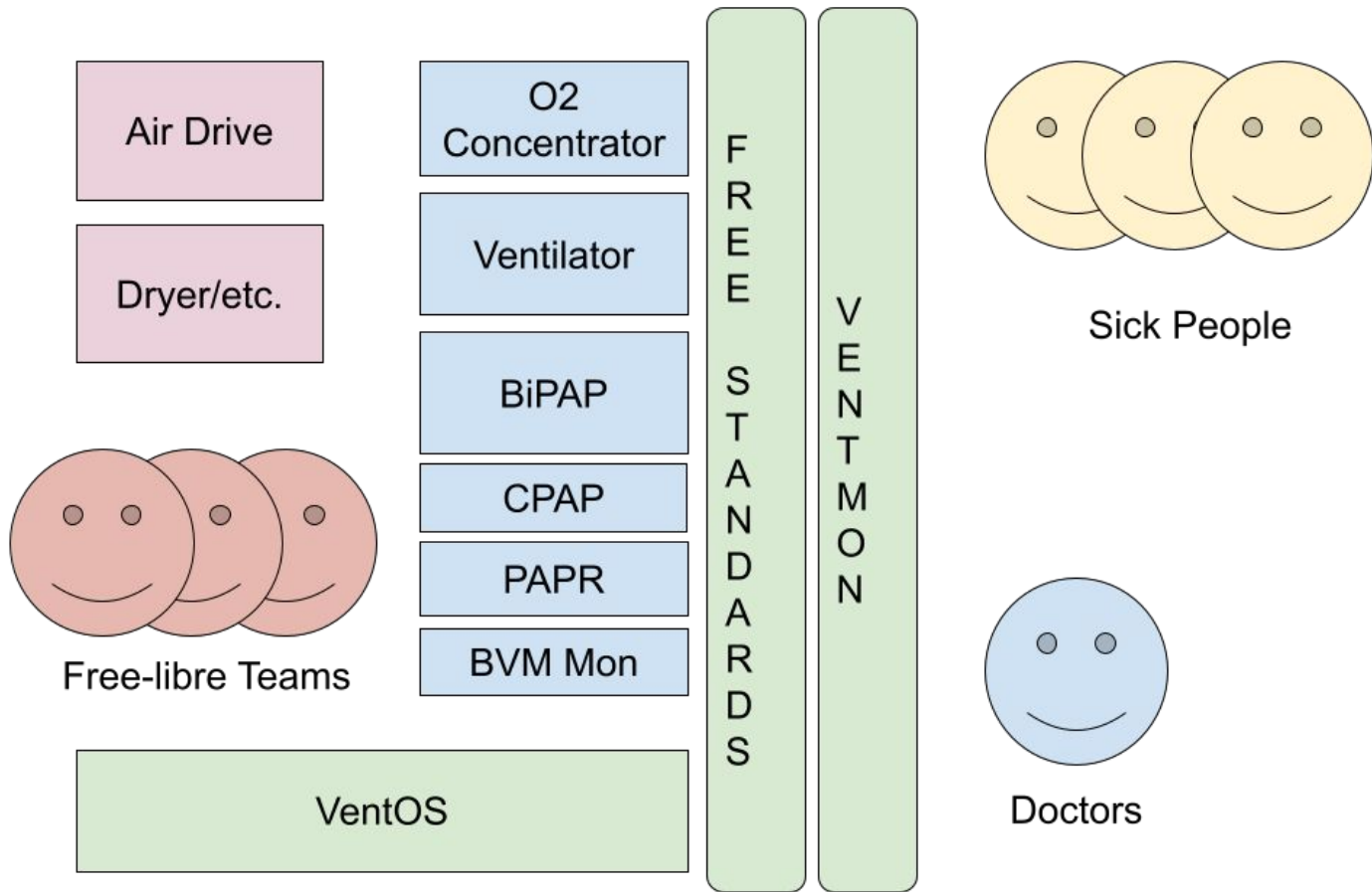
- <https://github.com/PubInv/PIRCS-pubinv-respiration-control-standard>
- <https://github.com/PubInv/PIRDS-pubinv-respiration-data-standard>

What standards for Respiration?

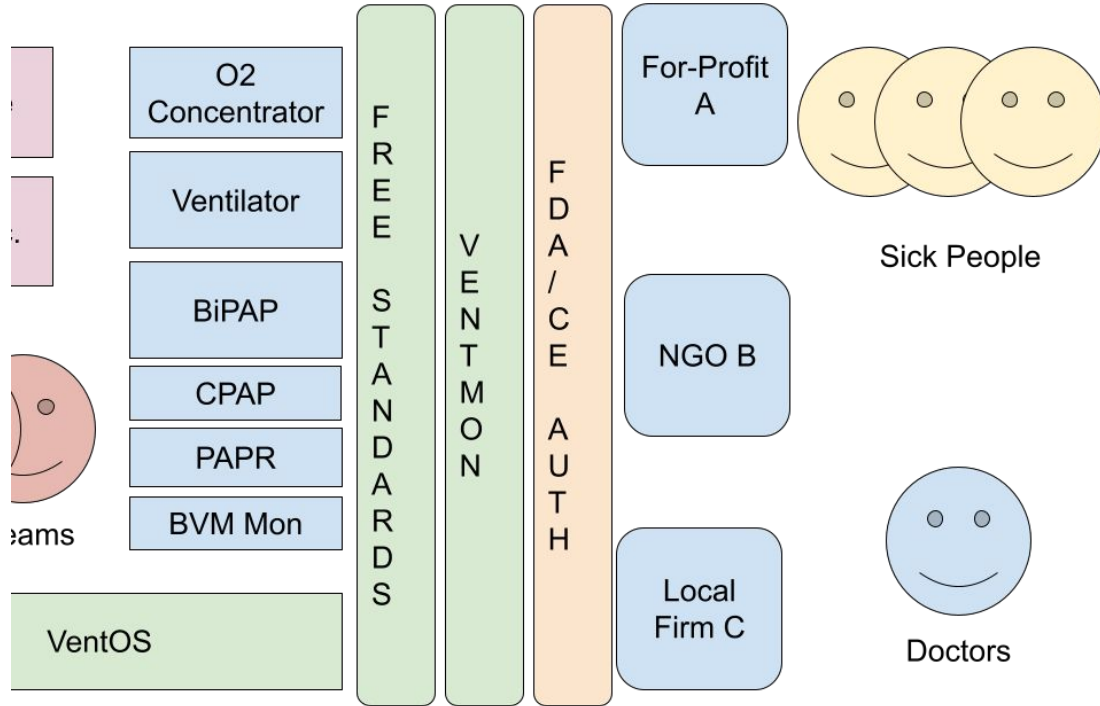
- 22mm/15mm adult/neonatal airway physical connectors (existing physical)
- Public Invention Respiration Data Standard ([PIRDS](#)) — representing breath (existing data standard)
- Public Invention Respiration Control Standard ([PIRCS](#)) — control of breath/ventilators (existing API standard)

But more needed—can we create:

- A standard for air drives themselves? (underway)
- A standard for O2 concentrator performance study?
- Standards for full test suites (i.e., British MHRA RMVS standards)



Freespireco creates business opportunities...



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.

Videos of Demos of Hardware

- PolyVent ventilator dem:

<https://www.youtube.com/watch?v=4cNxsxGG3SU&list=PL9nAioXQFIE6OBPzdT58ey-rnCFJlofM2&index=8&t=4s>

- VentMon: (Live demo starts at 11:30):

<https://www.youtube.com/watch?v=OV9MrMjVOCI>

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Summary

We can do this! We can:

- Create and establish standards
- Create libraries
- Create designs for Manufacture
- Create a free-culture of FDA applications

...and thereby, over a decade, create a culture of open source medical devices which truly democratize important therapies and create universal business opportunities.

What Public Invention needs...

- Highly skilled volunteers for 6 hours a week
- Especially volunteers who can lead whole teams
- \$400,000

What the world needs...

- **Cooperation!** Stifle the “Not invented here” syndrome.
- **Technical Leadership!** We need dedicated leaders who can devote time and energy.
- **Policy Leadership!** We need grantors to step up giving and policymakers to become aware