The Story and The Learnings of The Great Ventilator Rush of 2020

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This time last year...

- In March 2020, LibrePlanet was quickly virtualized in response to the pandemic. This was a hair-on-fire emergency.
- At that time, there was much we didn’t know:
  - We didn’t know that social distancing would work or that people would comply with it.
  - We didn’t know how to treat the disease.
  - Based on Northern Italy, it was entirely plausible that 1.5 million Americans would soon die because of COVID-19.
  - Through a combination of positive action and negligence, we clamped that down to 500,000 fatalities over the last year.

About Ventilators...

- In 2020 there was predicted to be a massive shortfall of ventilators globally.
- Over 100 teams started working on FLOSS ventilators.
- By June, doctors had learned that early ventilation was not as helpful as previous diseases had taught them.
- Ford, Tesla, and Dyson made tens of thousands of ventilators.
- Social impetus began to fade.

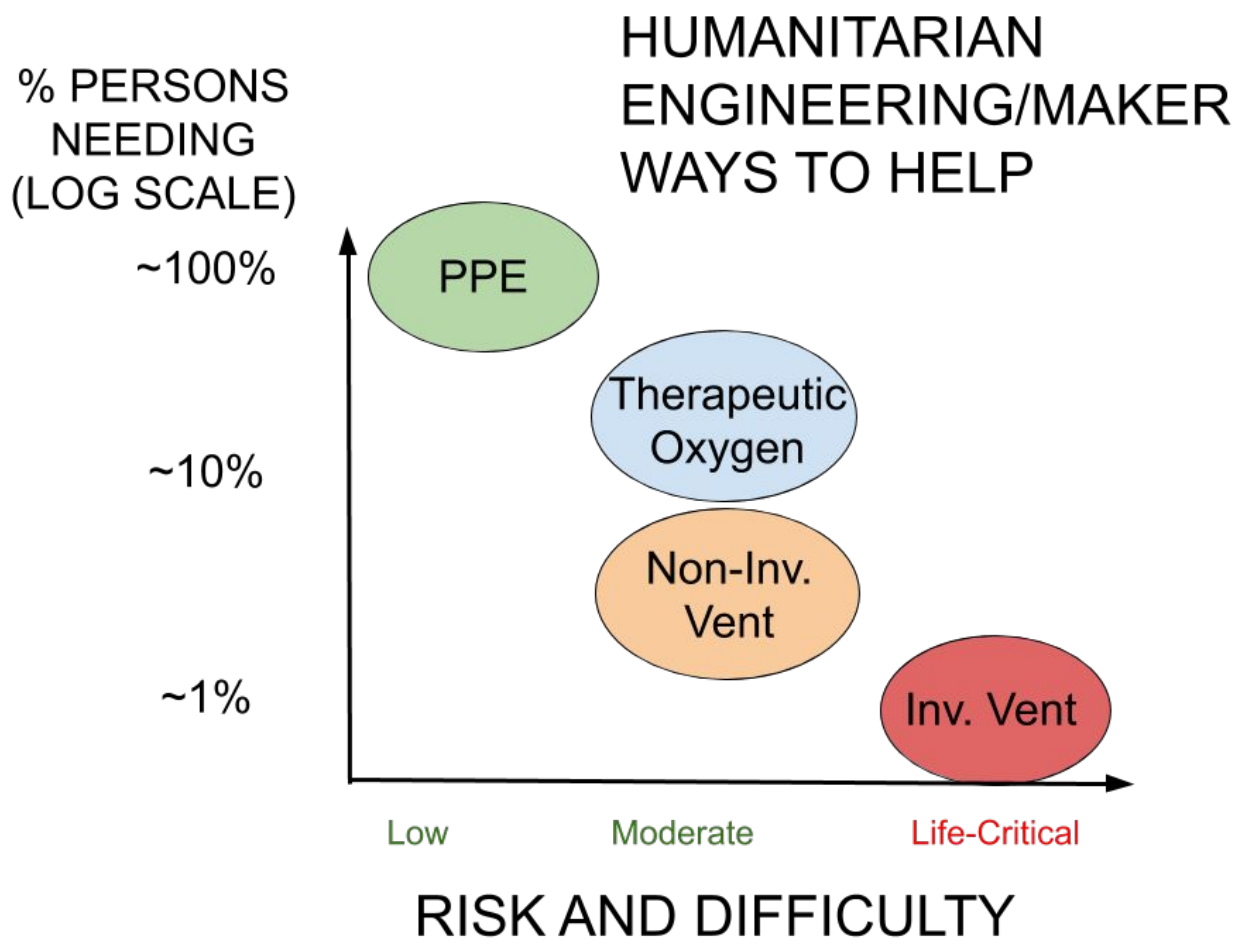
This talk is about what happened in the Free-Libre Open Source Ventilator Rush of 2020 and what we learned from it.

But also about a Vision:

“Twenty years from now, medical devices will be abundant because there will be an internationally distributed supply chain of transparently and publicly testable free culture medical devices.”

Structure of Talk

- The story of Ventilators in the Pandemic
- The learnings for FLOS hardware teams
- The composable approach we are taking
- Introducing the beginning of a new free culture license for medical devices


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

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

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

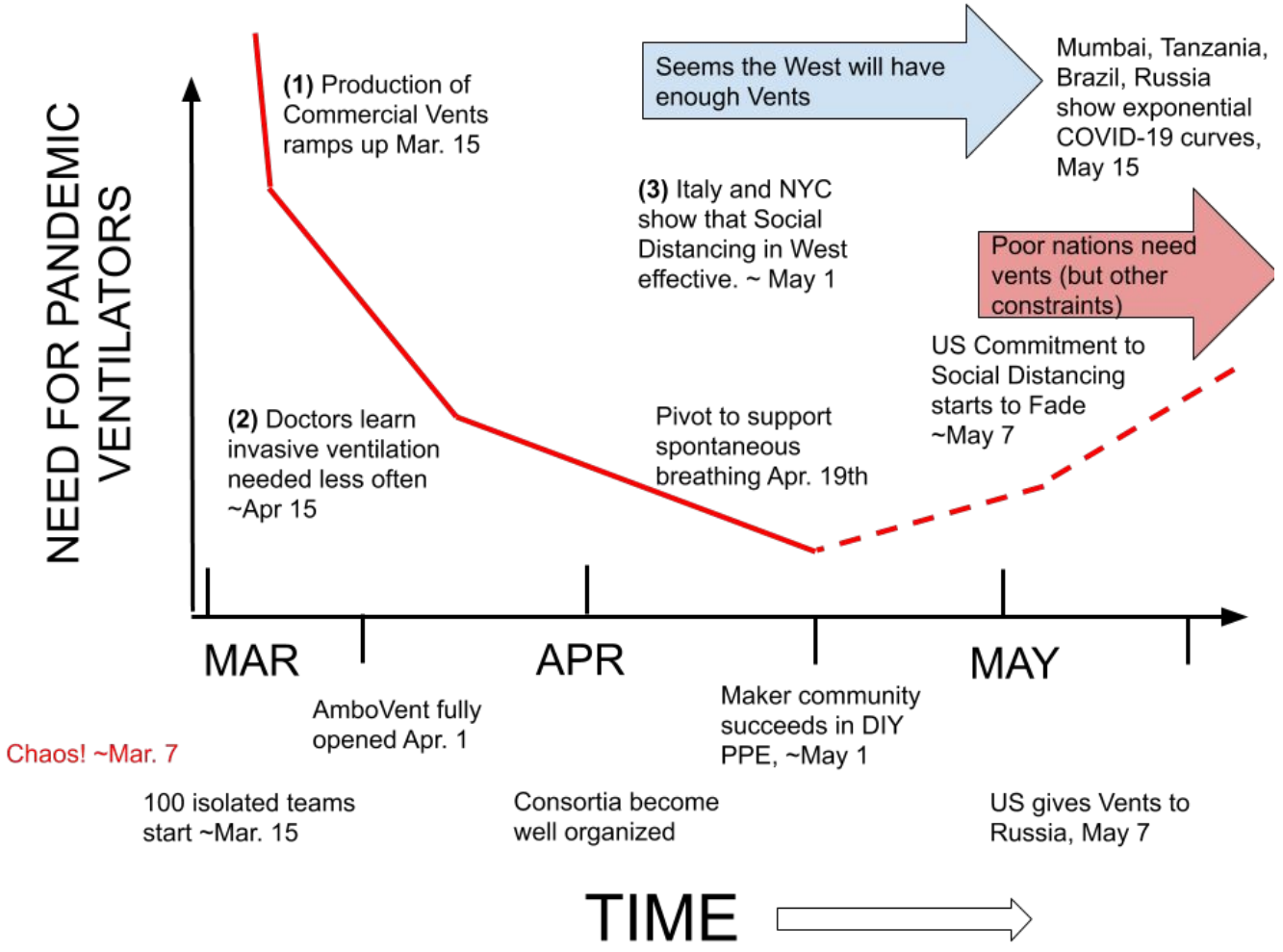
Rank by Average

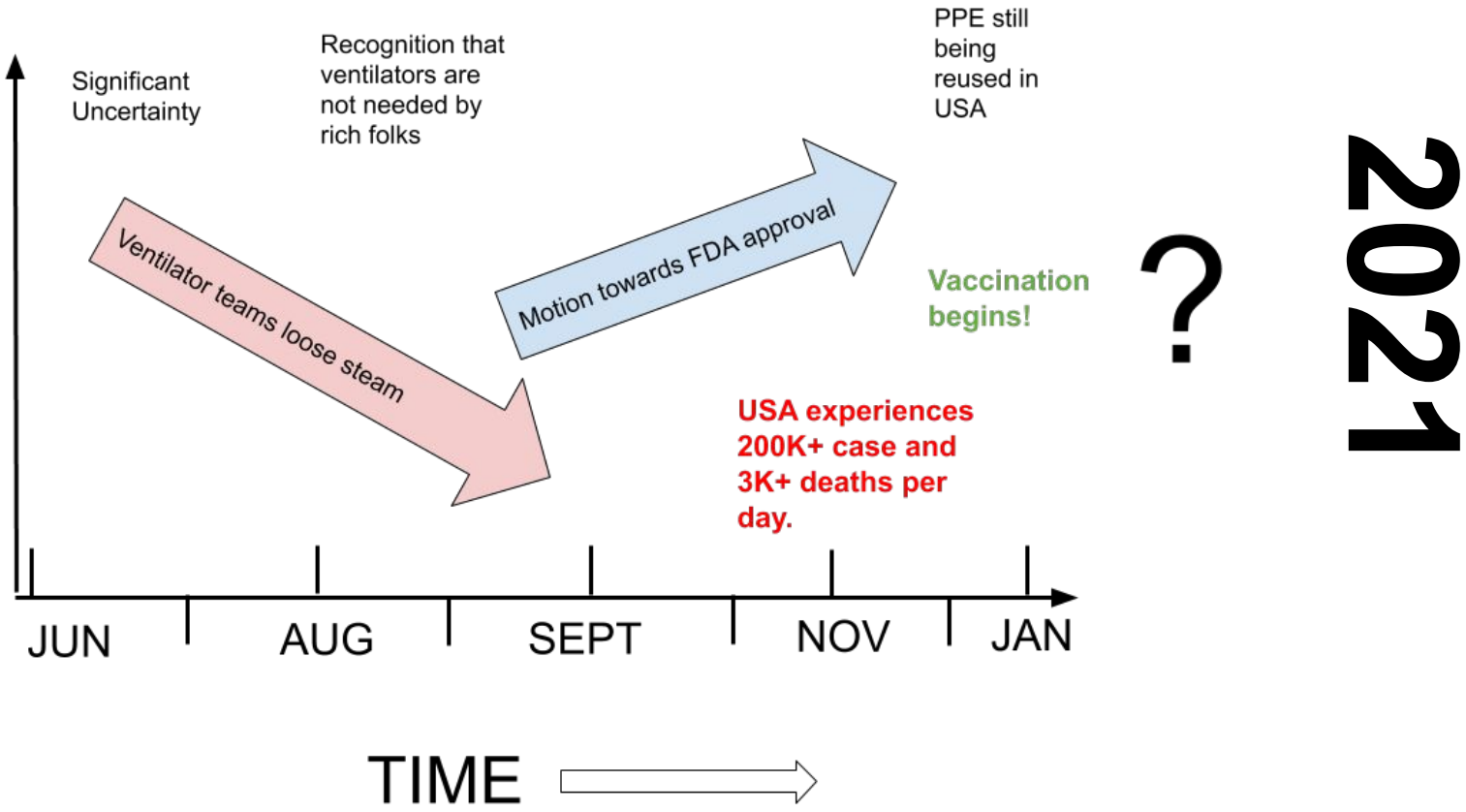
Jan 21, 2021 Public Invention https://www.pubinv.org Home Repo: https://github.com/PubInv/covid19-vent-list

Link to definition of evaluation criteria: https://docs.google.com/document/d/e/2PACX-1vRl9yZ27KvsIftcNvweHgH1A81pO8gHL62TWpY_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 compatibi	National Agency / EUA	Usage in Field	Average	Financing	Manufacturability (1000s)	U
Medtronic Puritan Bennett (PB) 5	http://newsroom.medtronic.cor	4	2.5	4	5	5	4	5	5	5	5	4.45	0	4	
Ambovent	https://1nn0v8ter.rocks/AmboV	5	5	5	5	5	5	4.5	5	3.5	1.5	4.45	1	5	
CoroVent	https://www.corovent.cz/	3.5	2.5	4	4	3	5	5	5	5	1	3.80	2.5	5	
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	1.5	5	
Rice OEDK Design: ApolloBVM	http://oedk.rice.edu/apollobvm	5	5	4	3	5	3	3	1	5	1	3.50	5	5	
RespiraWorks	https://respira.works/	5	4	5	3.5	3.5	4	4.5	2	2	1	3.45	1.5	4.5	
MakAir	https://github.com/makers-for-	5	3	5	4.5	3	4.5	3.5	1	0	5	3.45	1		
SmithVent2020	https://drive.google.com/drive/	5	4.5	5	4.5	1.5	4.5	5	1	2	1	3.40	0	3.5	
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	1		
CAM Ventilaor	https://github.com/Arcus-3d/co	5	2.5	4	3	3.5	3.5	5	1	3	3	3.35	1	3	
VentilAid	https://www.ventilaid.org/	5	4	4	3	4	4.5	3.5	1	2.5	1.5	3.30	1	5	
Respirador-DQ3D-NICA	https://github.com/DQUEROL/	4	4	2.5	3.5	5	3.5	3.5	2	1	3	3.20	0	5.0	
LEITAT1 Respirator	https://www.3dnatives.com/en	1	2	2	4.5	5	5	0	5	2	5	3.15	0	5	
Open Source Ventilator Project	https://simulation.health.ufl.ed	4	3.5	5	3.5	2.5	4	3.5	1	3.5	1	3.15	1	4	
Protofy Team OxyGEN	https://oxygen.protofy.xyz/	5	4	4	3	1	2	1	2.5	4.5	2.5	2.95	2.5	3	
The Open Ventilator	en.theopenventilator.com	3	2	3	2	0	2.5	2	5	5	5	2.95	0		
OpenVent-Bristol V3.0	https://docs.google.com/sprea	4	4	3.5	3.5	2	3.5	3.5	1.5	2.5	1	2.90	1	4	

Over 100 somewhat free hardware ventilator projects right now... a better way to use thousands of skilled engineers is to modularize the problem.


NEED FOR PANDEMIC VENTILATORS
(1) Production of Commercial Vents ramps up Mar. 15
Seems the West will have enough Vents
Mumbai, Tanzania, Brazil, Russia show exponential COVID-19 curves, May 15
(3) Italy and NYC show that Social Distancing in West effective. ~ May 1
Poor nations need vents (but other constraints)
US Commitment to Social Distancing starts to Fade ~May 7
(2) Doctors learn invasive ventilation needed less often ~Apr 15
Pivot to support spontaneous breathing Apr. 19th
MAR
APR
MAY
AmboVent fully opened Apr. 1
Maker community succeeds in DIY PPE, ~May 1
Chaos! ~Mar. 7
100 isolated teams start ~Mar. 15
Consortia become well organized
US gives Vents to Russia, May 7
TIME


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

?

2021

The Results: Mixed.

- FLOS PPE was a successful (> 5 million pieces delivered)
- FLOS Ventilators mostly failed to have impact:
  - Some designs went closed-source and went dark
  - Some achieved Emergency Use Authorization
  - None have been used?

But…

- New communities created
- Enormous spread of medical knowledge to engineers
- ...and an idea emerging of a libre respiration device ecosystem

New Communities Created

- Approximately 90,000 lightly involved volunteers
  - 70,000 at OSMS
  - 18,000 at Helpful Engineering
  - 100 active at COSMIC (but active)
  - 30 (active) at Public Invention

Helpful Engineering
https://helpfulengineering.org/

Open Source Medical Supplies
https://opensourcemedicalsupplies.org/

COSMIC
https://cosmicmedical.ca

Public Invention
https://www.pubinv.org/

JOGL - Just One Giant Lab
https://jogl.io/

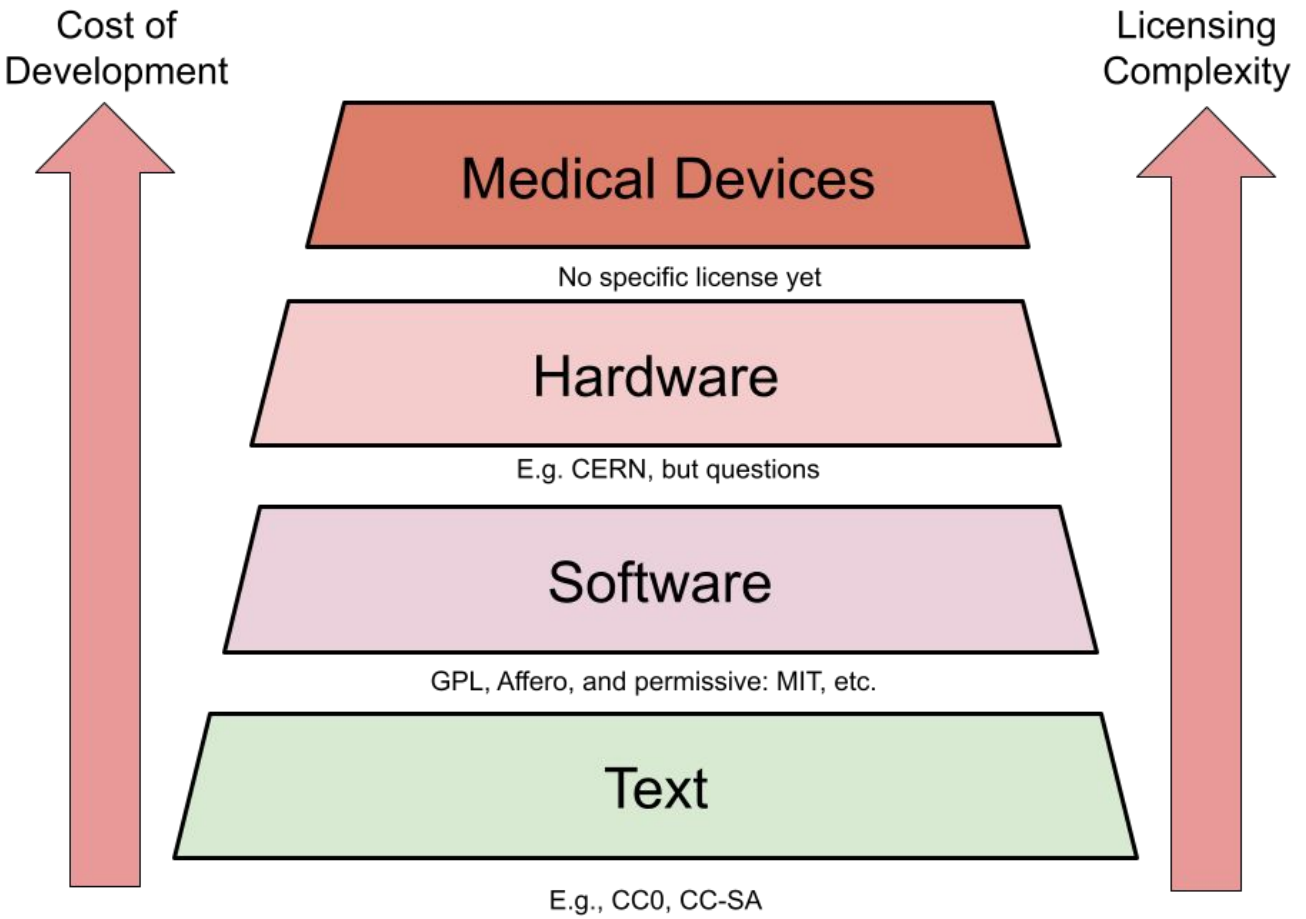
Enormous spread of knowledge to engineers

- About 100 engineers now fully understand mechanical ventilation
- Significant spread of knowledge about licensing, but still tremendous confusion
- Many hardware engineers learned about remote team organization and agile techniques pioneered by software engineers

(Over to Marc.)

Why Free-libre Medical Devices?

- Eventually, a Free-libre medical device should be MORE trustworthy because all of the testing is transparent.
- The expensive research capital for basic medical devices has long since been the basis of sunk business costs and profits.
- Commoditizing medical devices reduces costs and increases access



Things that were bad

- Great confusion about FLOS licensing
  - Persistent and groundless fear of liability based only on design
  - Much confusion on copyleft vs. permissive licensing
  - Multiple licenses create paradox of choice
- FLOS/Public -- but not right now...and then it is too late!!
  - Tremendous duplication of effort due to lack of transparency
  - Being free and community based from day one would have helped this
- Benefits of FLOS community slow to be evidenced…
  - Reuse of hardware a little bit harder than software
  - Everyone wanted to be “the” solution

Lessons of the Great Ventilator Rush

1. Think not of being THE solution, but A PART of the solution.
2. Be modular as the Free Software community is.
3. Learn from the Free Software team organization techniques.
4. Engineering is not enough on a hardware team; organization, fundraising, management, and user experience is even more important than on a software team.
5. The communication burden is about three times that of a pure software team.
6. A free culture medical device movement is born and growing.
7. Licensing and liability require some thought; we advocate separating development from manufacturing.
8. Respect the FDA (and other) regulatory processes.

(Over to Rob)

1. Think not of being THE solution, but a PART of the solution.

In the 2020 ventilator rush, **100** teams worked almost in isolation.

The “We’ll eventually be open” mindset is a terrible mistake that I heard on many occasions.

Be humble.

Buckminster Fuller:

“Tell the truth, tell the whole truth, and tell it right now.”

Me (and Eric Mill):

“Be free and open from the first day of the project.”

2. Be composable as the Free Software community is.

- AFAIK, the UNIX design principle started it: your write small programs (filters) which can be composed to do useful things.
- This is NOT true of medical devices, and is only partially true of microelectronics in general.

Composability >> Modularity

3. Learn from the Free Software team organization techniques.

- Source control systems most of all---from day one!
- Unit testing.
- Automated Tests and Continuous Deployment.
- Agile development beats big design up front---even for medical devices.

The Difficulty of Measuring Impact: Even worse in Hardware.

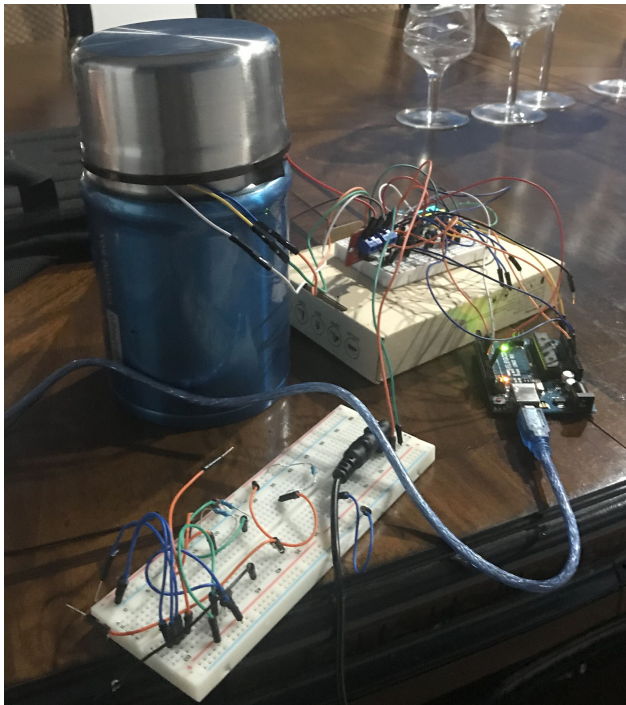
4. Free Hardware demands:

- organization,
- fundraising,
- management, and
- user experience

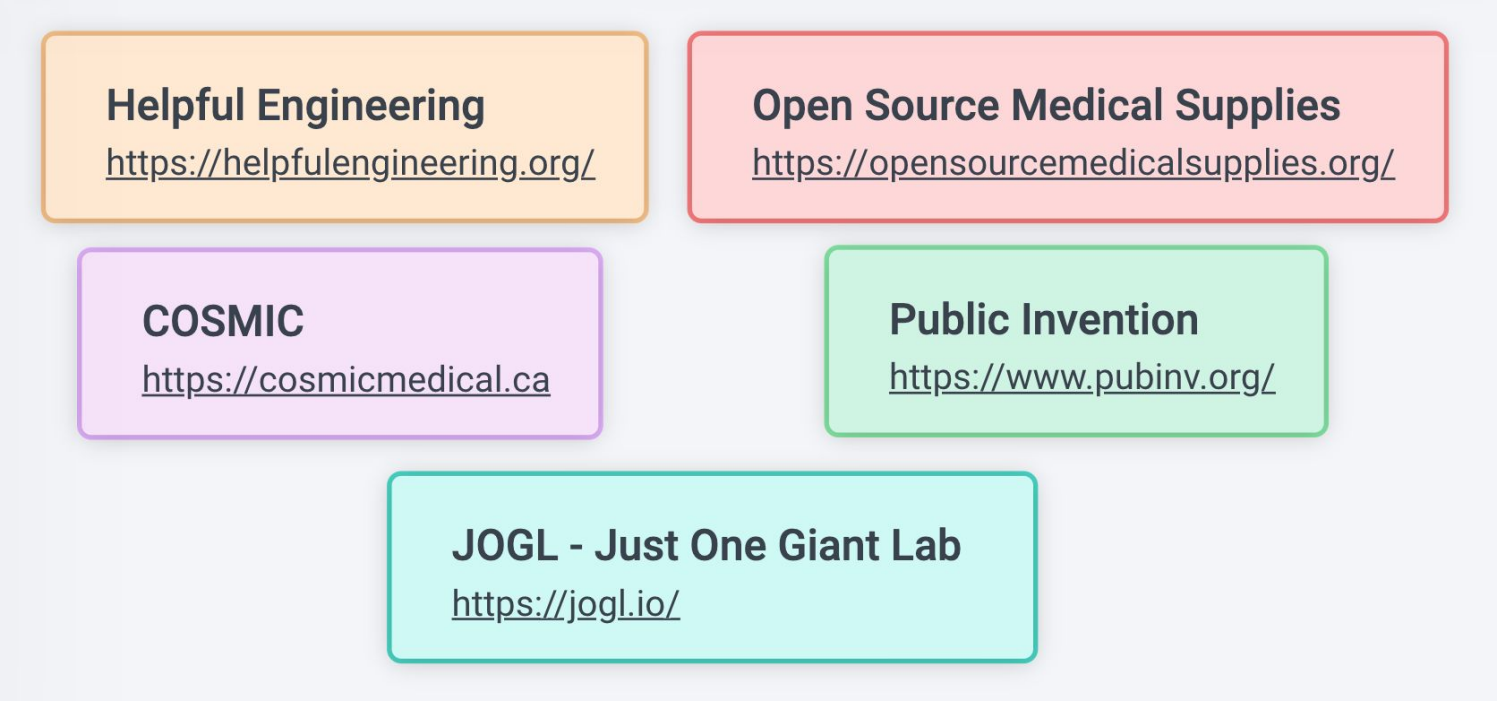
is even more important than on a software team.

5. The communication burden is about three times that of a pure software team.

- Even with video chat, text chat, etc., communication is much harder on a team building a physical device.
- Teaching students to debug a circuit with a multimeter over video chat is non-trivial.



Good news: there is a tiny but growing Free Culture medical device movement.



6. Licensing and liability require some thought; we advocate separating development from manufacturing.

Deployment:

Medical devices >> hobby devices >> software.

7. Respect the FDA (and other) regulatory processes.

There are no shortcuts.

A regulatory environment imposes additional burdens which are time-consuming.

My suggestions:

- Plan on it taking more time.
- Plan on having to learn the rules.
- Do not exaggerate the cost of the paperwork: it is expensive but not prohibitively so.
- But, we currently have no established Free-libre community and culture that knows how to do this.

Done with Lessons.

A Personal Idea: Respireco

“**Resp**iration **Eco**system” of “**Re**search A**spir**ation **Co**mpany”

Complete Free-Libre Modular Respiration System

Goal is to obtain the “net effect” on the components: total value is the square of the number of complete components. This is harder to do in hardware than software, but not impossible.

This makes it easier for free culture software and hardware engineers to contribute, because there are many composable projects.

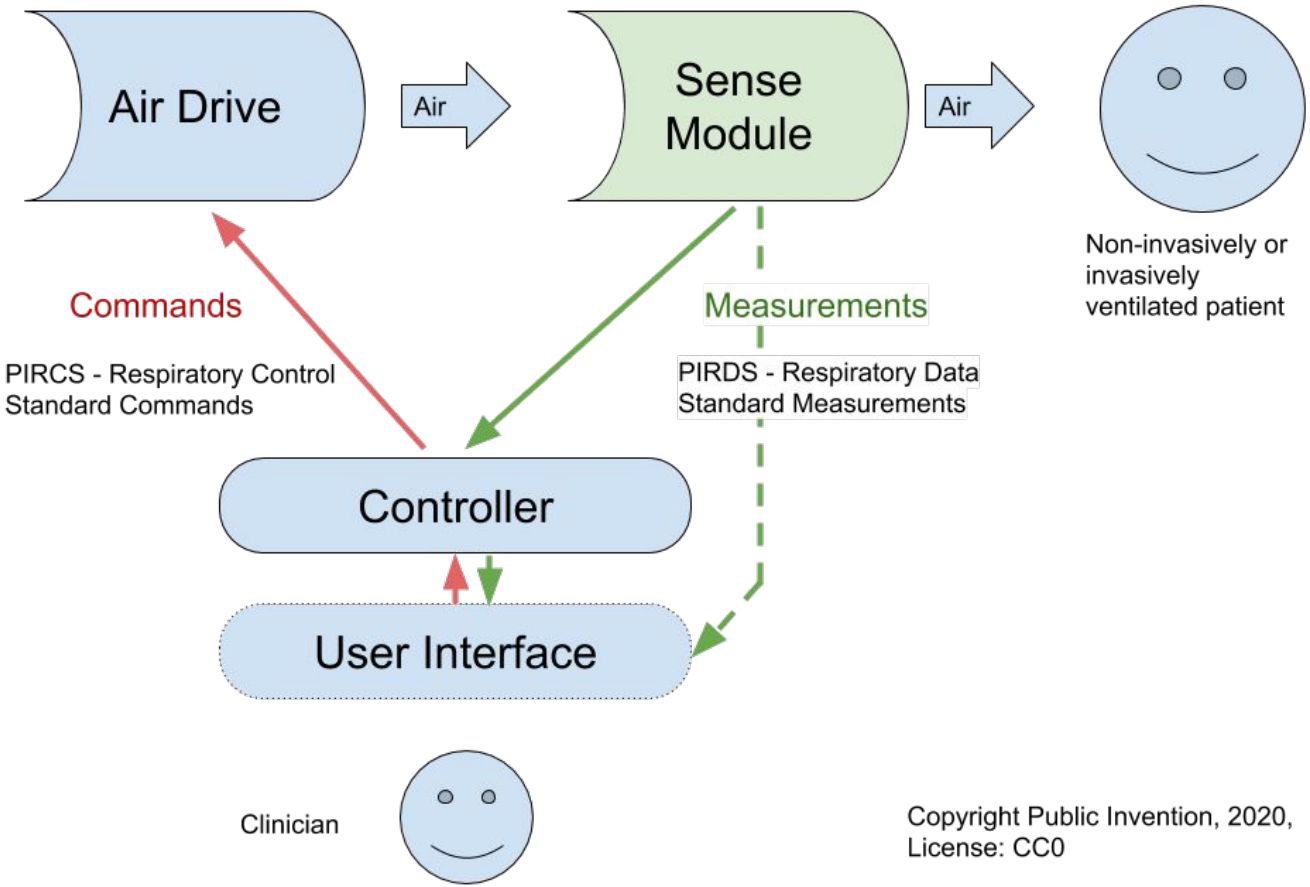
"If something is easy to repair, it is easy to construct." - Leo Fender

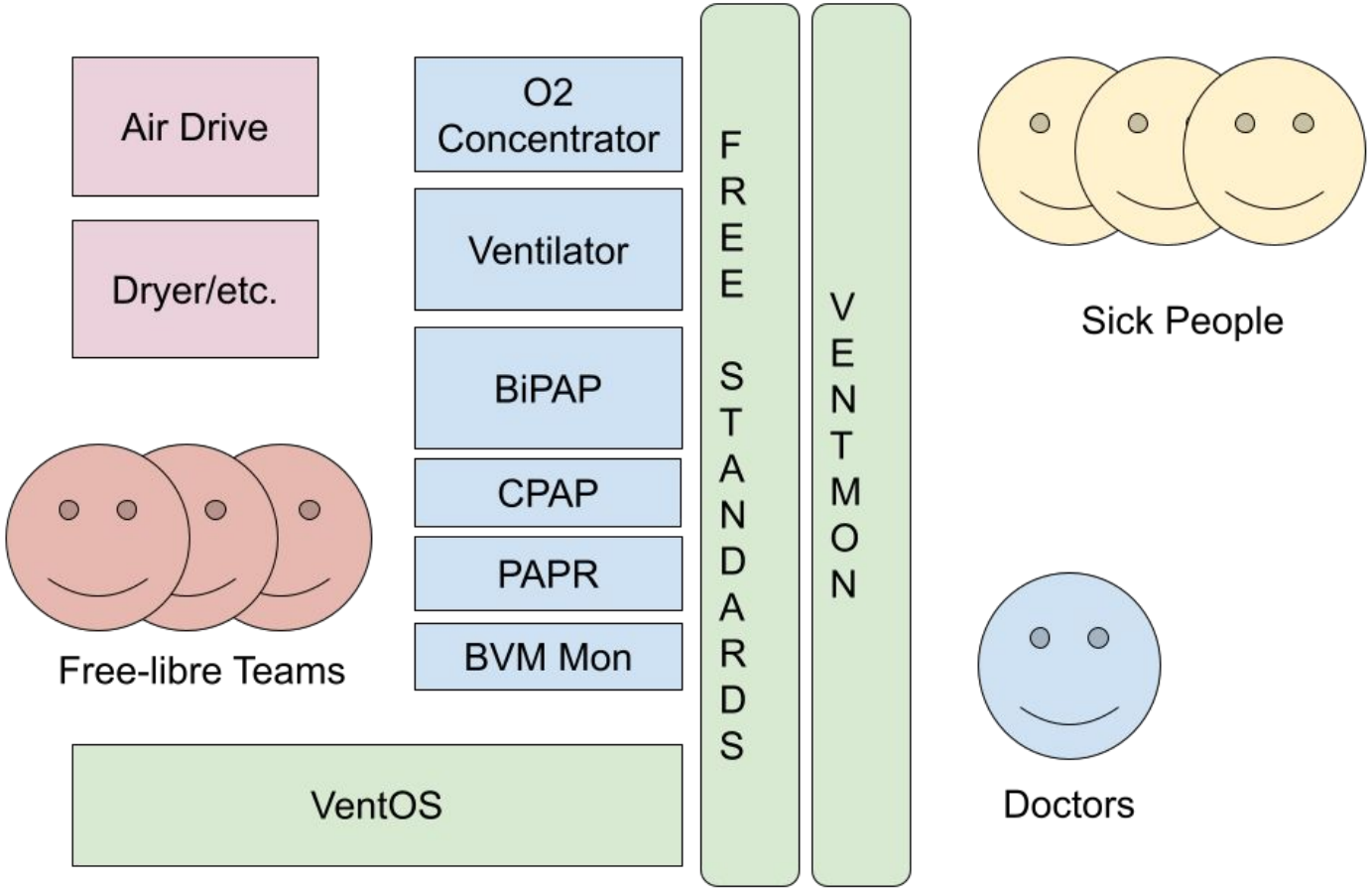
Composability >> Modularity

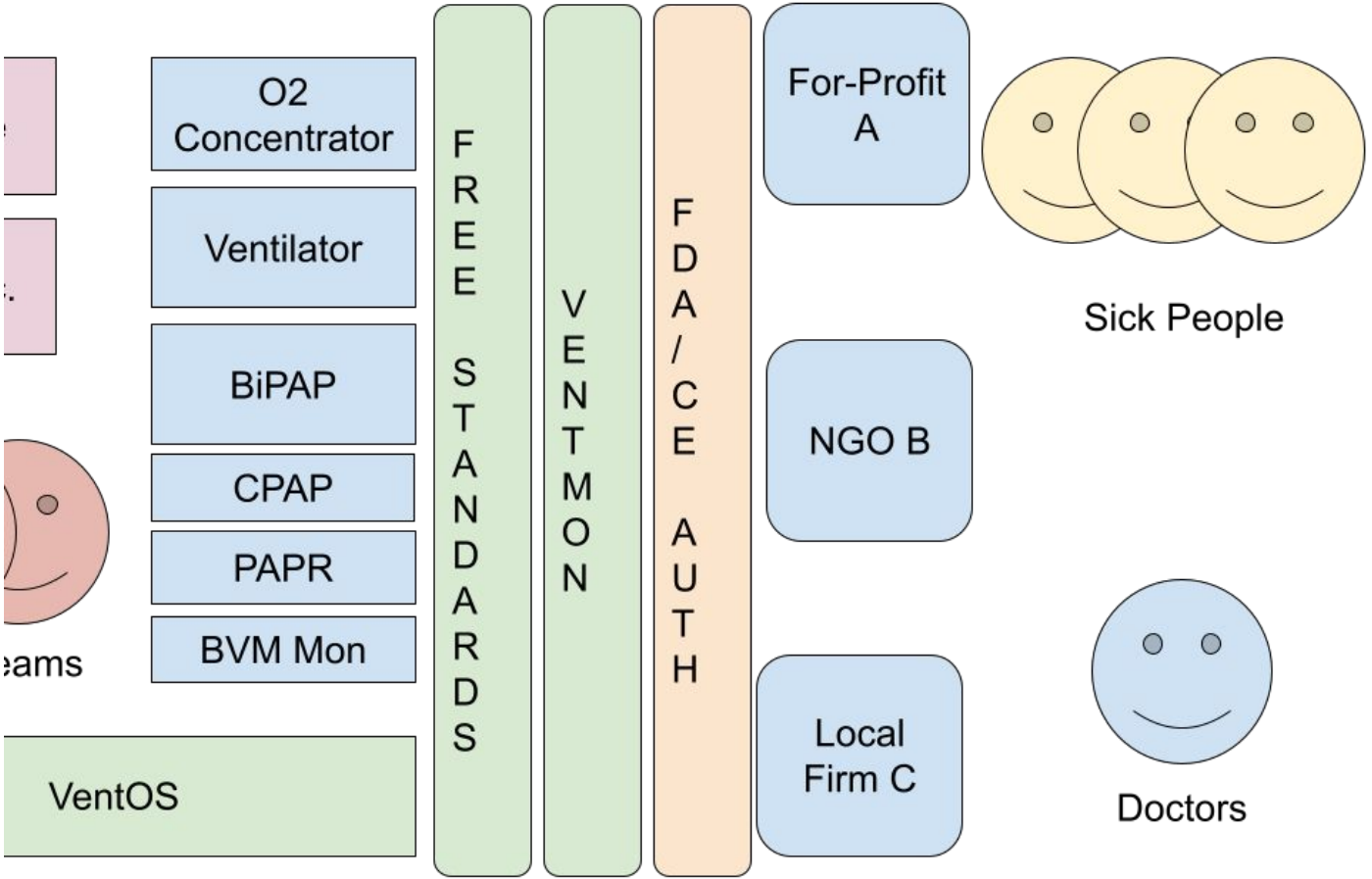
&&

((TCO && Logistics) >> Price)

This matters more in low-resource communities and during crises (Kyle Wiens iFixIt.)



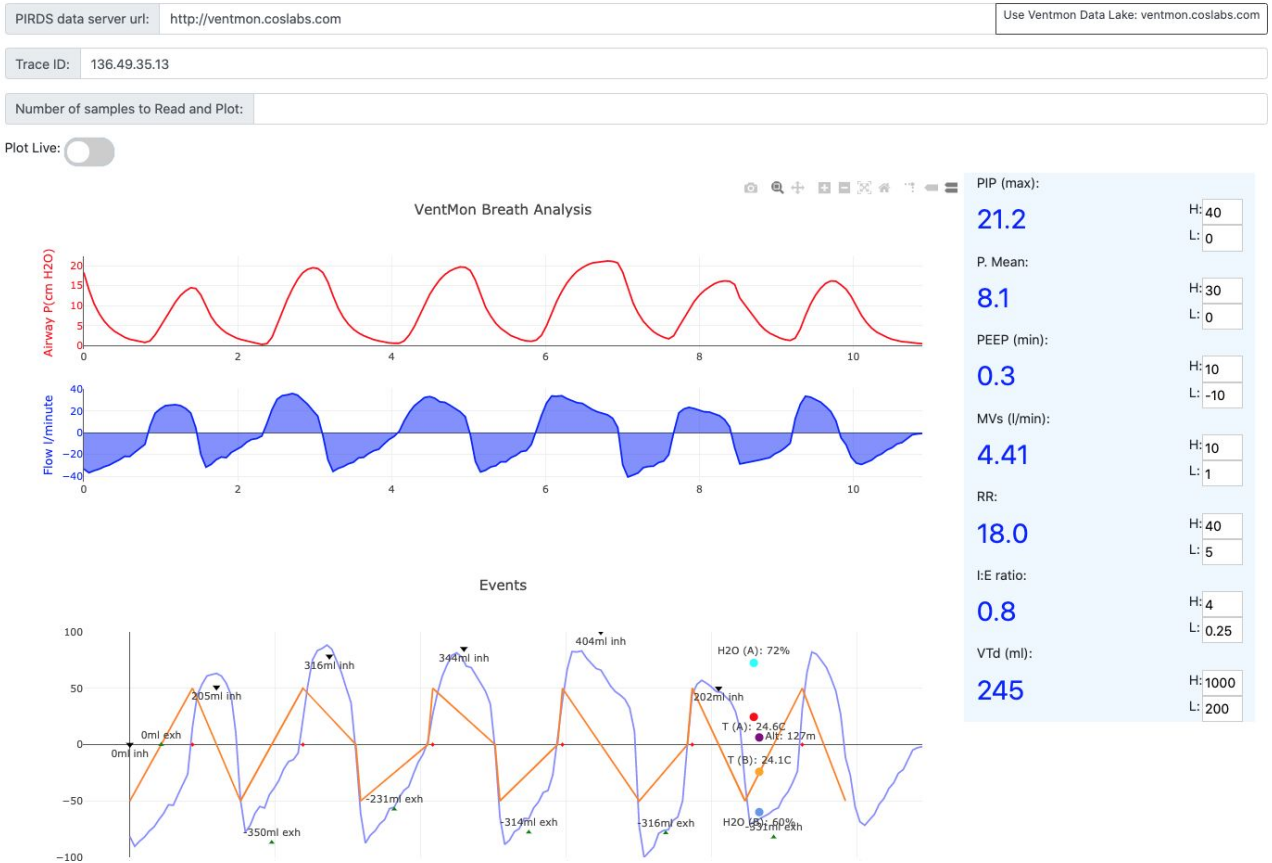




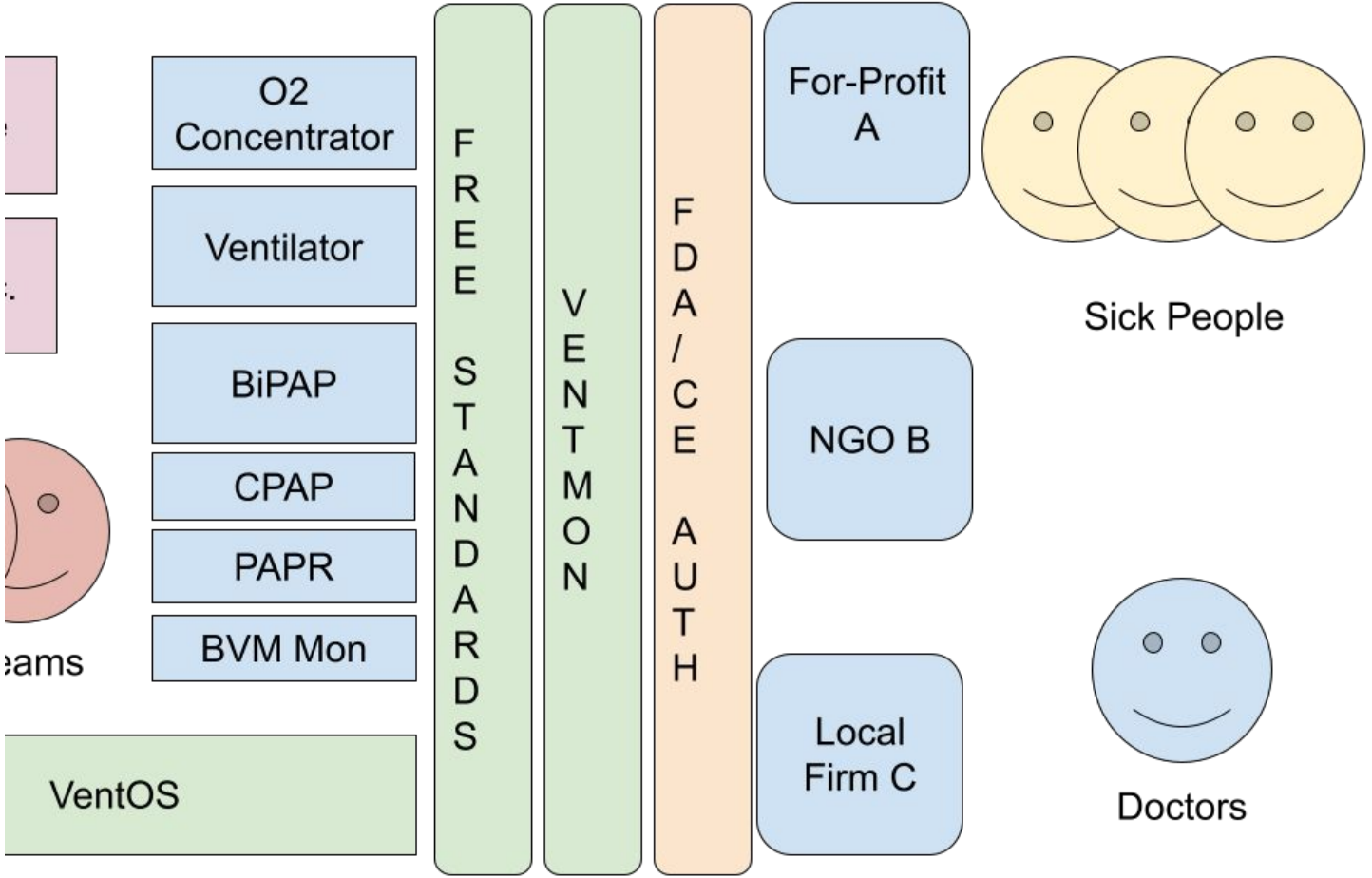
Pandemic Projects as Part of the Ecosystem

1. VentMon
2. Public Invention Respiration Data Standard
3. VentDisplay
4. VentMon Data Lake
5. VentOS (a Helpful Engineering Project)
6. Public Invention Oxygen Concentrator
7. SFM3X00
8. Patient Inflating Valve
9. Regulatory Sunlight License

Standards (PIRDS) and VentDisplay allow teamwork.



VentMon T0.4 shipping! Gratis to Libre teams!



Regulatory Sunlight License:
A new kind of Free Culture License

- Experiment to use FDA approval instead of copyright as the basis
- Covers ALL documentation sent to the FDA
- Allows reuse of that documentation
- Triggers on application to regulatory body
- Goal is to (over decades) create a shared public commons of reusable device designs, documentation, tests, risk analyses, manufacturing plans, incident reports, etc.
- We could use competent legal, political economy, graphic art, and scholarship help:
- https://github.com/PubInv/RegulatorySunlight

We ask you to reify this Vision:

“Twenty years from now, medical devices will be abundant because there will be an internationally distributed supply chain of transparently and publicly testable free culture medical devices.”

“Invent in the public, for the Public.”

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