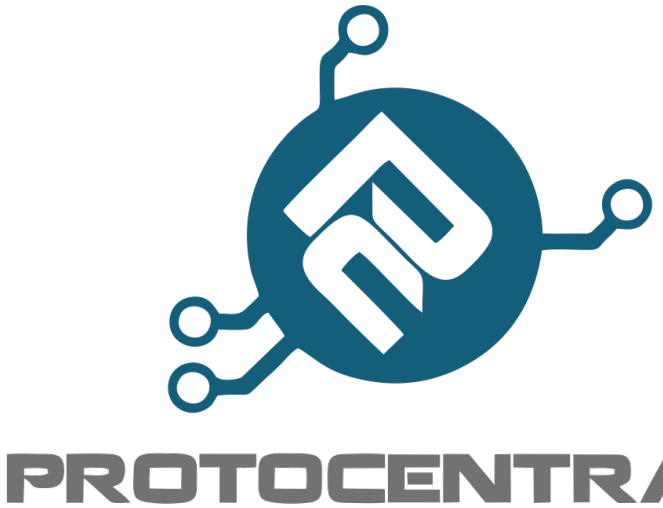
Open source hardware & medical device innovation

Ashwin Whitchurch

UBORA 2018, Pisa



Hello, I am…

- Ashwin Whitchurch
- Founder and CEO of ProtoCentral Electronics, Bangalore, India
- Electrical Engineer with medical devices interests
- Open source hardware supporter and a maker/hacker at heart

The Doctor, Luke Fildes, 1891

What “Patient monitoring” used to look like

What Patient monitoring means now

“We’re in a world today where Google has a lot more relevant medical info about us than our primary care provider.”

But not everywhere…

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What are low-resource settings?

- Lack of funds to cover health care costs, on individual or societal basis
- Less-developed infrastructure
- Fewer or less-trained personnel
- Limited access to maintenance and parts

Source: BIOEN 404 Team Design I, University of Washington

Design constraints for low resource settings

Regulatory standards!= reality

Cost – device, consumables, repair

Medical decisions made **without data**

Donating used medical equipment usually doesn't work

Low income != No income

If we don’t know what they do inside, it’s hard to adapt them to different environments

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Enter open source hardware …

What is real Open Source Hardware?

- **Open Hardware** = some device that you can talk to because it has a well-documented interface.
- **Open Source Hardware** = some device that you can replicate and develop freely because you have access to the source.

Source: Nathan Seidle, Sparkfun Electronics

What is real Open Source Hardware?

… design is made publicly available so that anyone can study, modify, distribute, make, and sell the design or hardware based on that design.

Source: OSHW Statement of Principles 1.0, Open Source Hardware Association (OSHWA)

What is real Open Source Hardware?

… source is available in the preferred format for making modifications to it.

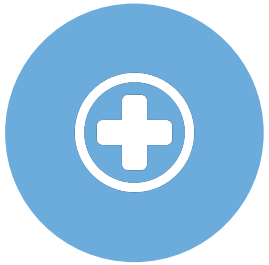
Source: OSHW Statement of Principles 1.0, Open Source Hardware Association (OSHWA)

Open source hardware for medical devices can-

Redefine standards of care for everyone

Re-think the way medical devices are designed

“Standing on the shoulders of giants” Collaborative effort leads to better products



Lead the way for true democratization of medical devices

Open source hardware – a business perspective

When a company relies too much on their intellectual property they become intellectually unfit - they suffer from IP Obesity.

Source: Nathan Seidle, Sparkfun Electronics

Open source hardware – a business perspective

…. anyone can modify, distribute, make, and **sell** the design or hardware based on that design.

Source: OSHW Statement of Principles 1.0, Open Source Hardware Association (OSHWA)

Open source hardware – a business perspective

- Invest in development rather than litigation
- Value of feedback
- Reduced R & D costs
- Crowdfunding is a way to get feedback & funding

Open source hardware – a business perspective

Good

- Faster development cycle
- No chasing patents
- Faster feedback
- Stay ahead of the curve with freedom to innovate

Bad

- IP Protection
- No private VC funding
- Watch out for clones !

Open source hardware – a safety & security perspective

Open source hardware – a safety & security perspective

- Implicit trust in brand name devices
- In medical devices, Safety == Security

Open source hardware – a safety & security perspective

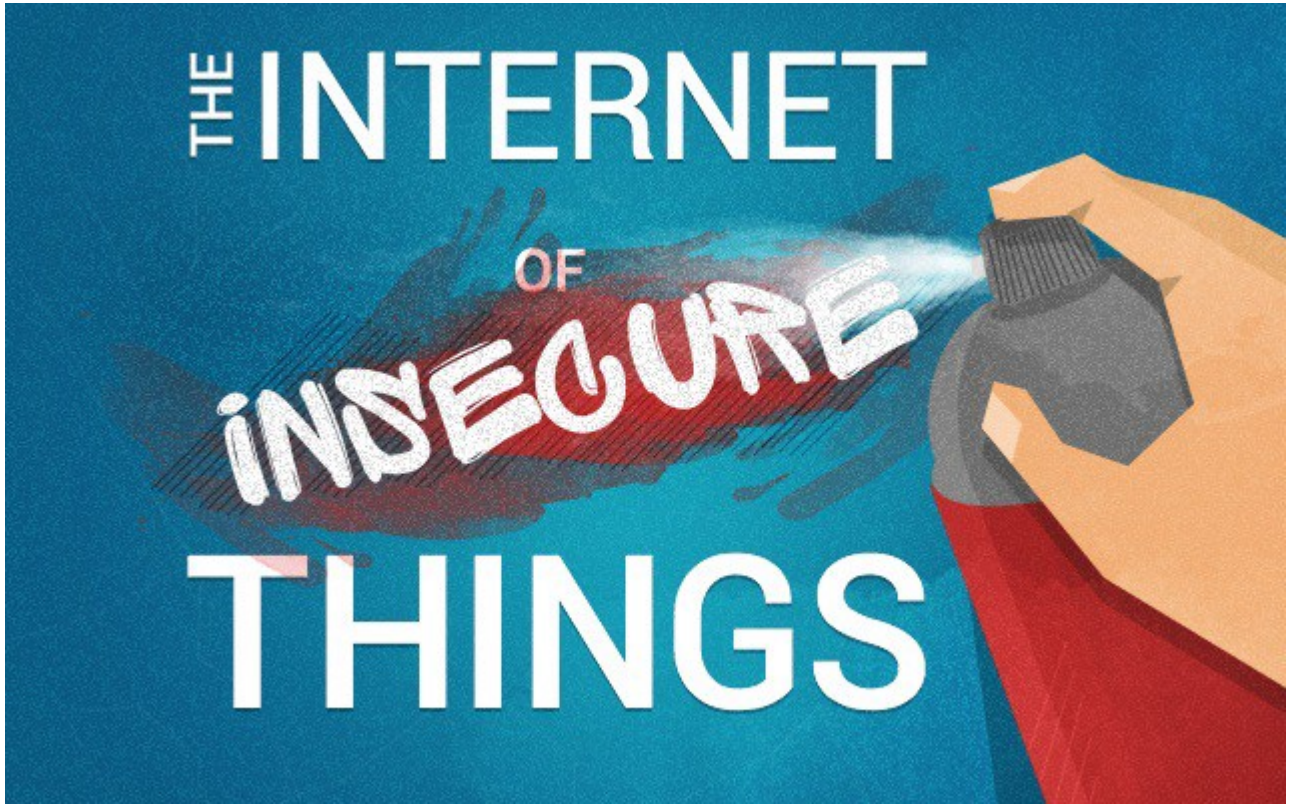
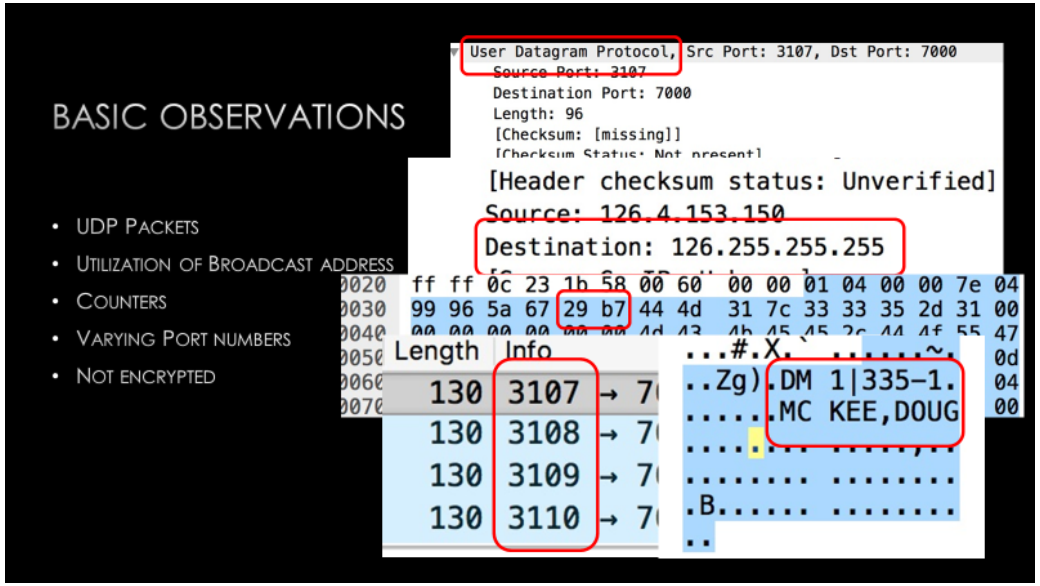


Image courtesy: toptal.com

Medical device security myths



- Proprietary devices are secure
- Open Source devices are more vulnerable

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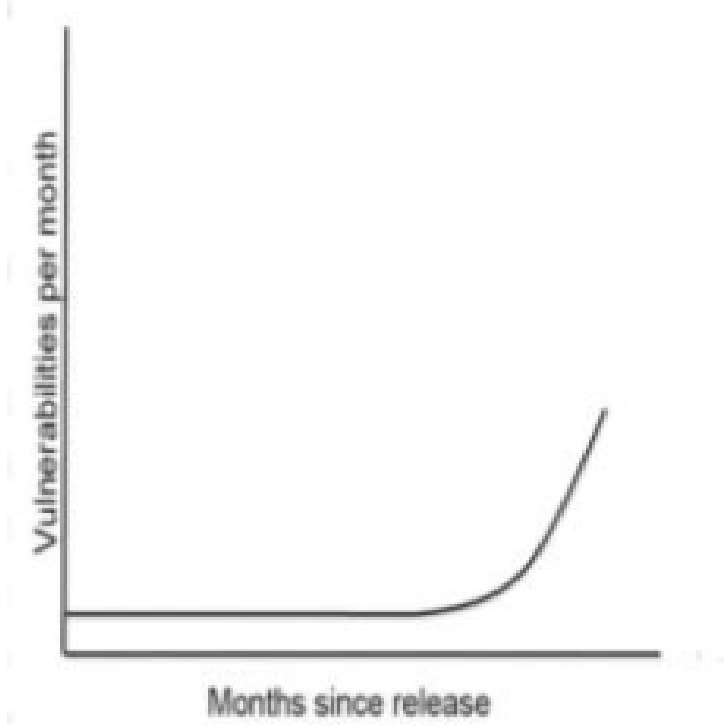
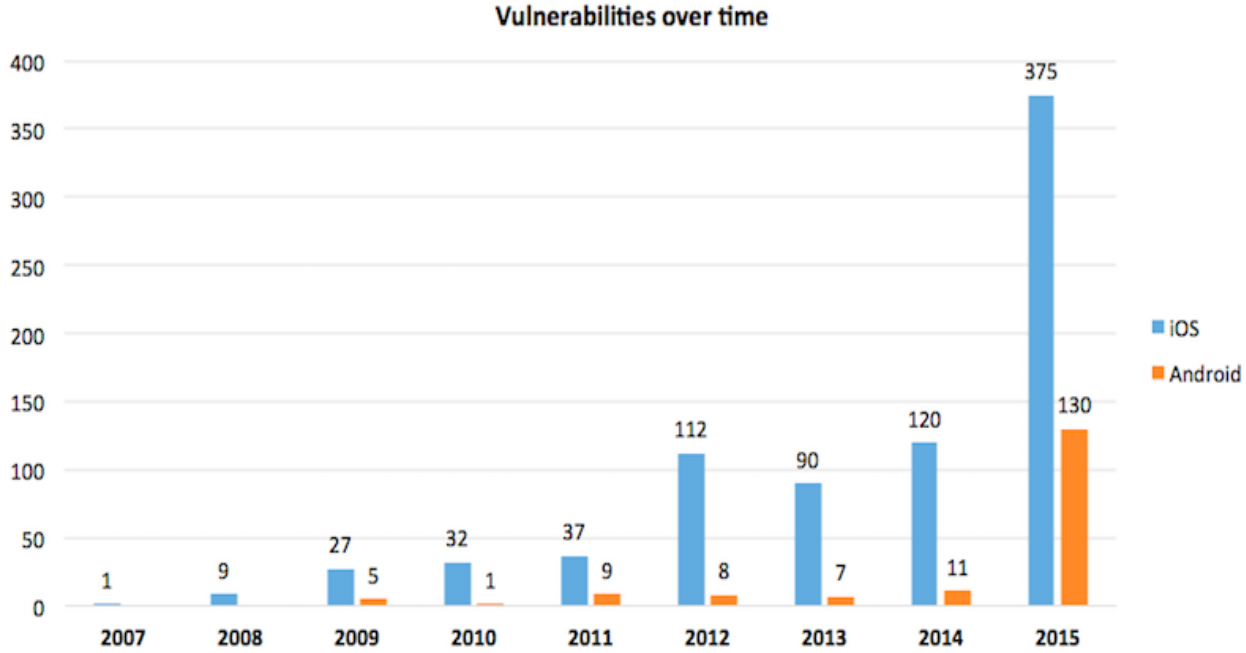


Source: Familiarity Breeds Contempt The Honeymoon Effect and the Role of Legacy Code in Zero-Day Vulnerabilities, Sandy Clark, et. al.,



Martin Janek and Sieuwert van Otterloo, ICT Institute

The Honeymoon effect

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If the Trojan Horse was made of glass, would the Trojans have rolled it into their city?

Bill Vass, Sun Microsystems on FOSS

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Some devices that we made

Funded on CROWD SUPPLY

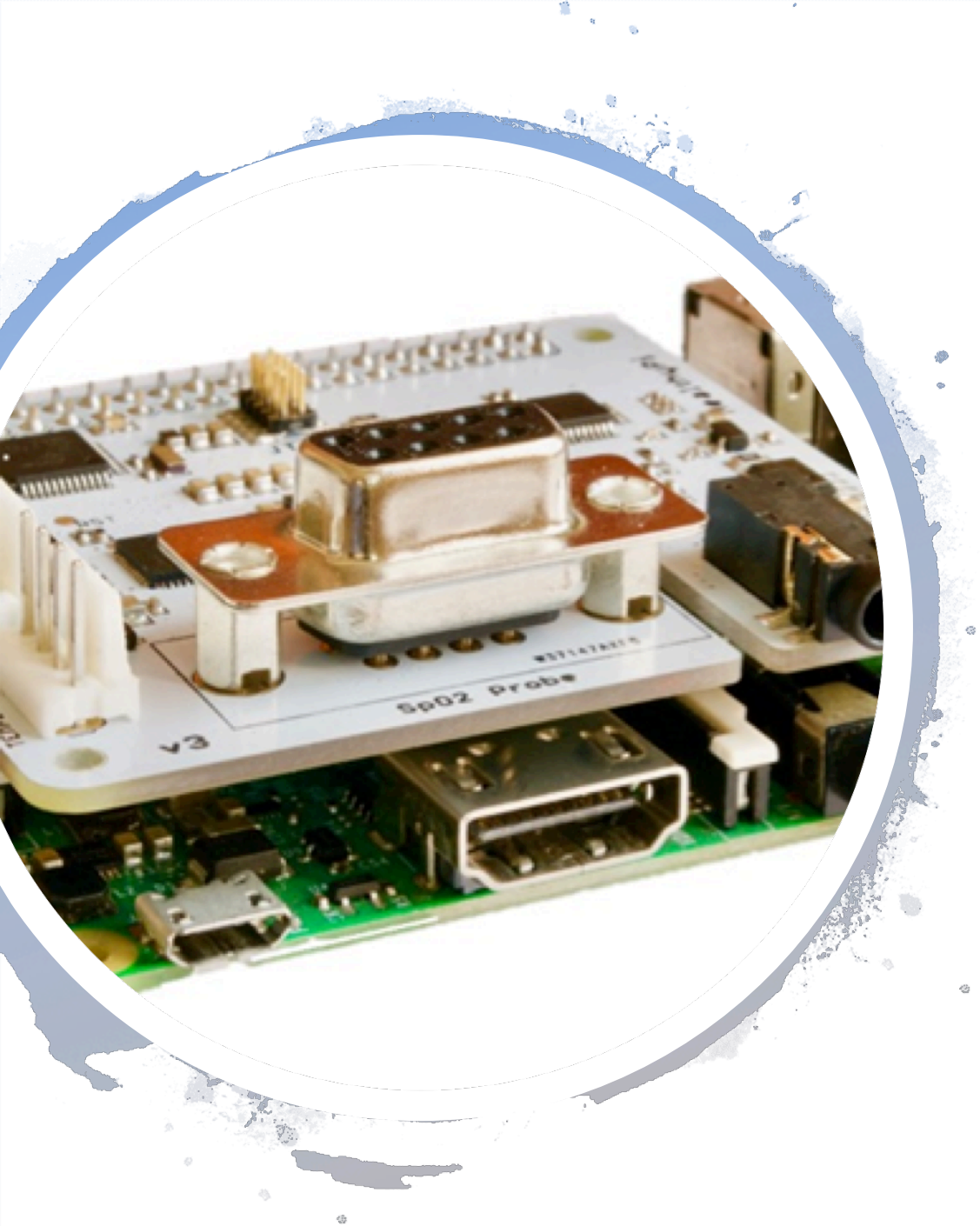
HackadayPrize2017

HealthyPi 3 – an open source patient monitor

- **Vital parameters monitored:**
- Electrocardiogram (ECG)
- Respiration using impedance pneumography
- Photoplethysmogram (PPG) and SpO2 (Pulse-ox)
- Skin temperature
- Blood Pressure

BOM Cost < $100 (without Raspberry Pi or display)

All sources available at: https://github.com/Protocentral/protocentral-healthypi-v3



HealthyPi 3 – Why did we make it?

- Build low-cost, usable, customized patient monitors
- Help device designers build new products using HealthyPi as a reference
- Educational value of tearing-down clinical grade components and acquiring clinical grade data without the price or NDAs

Innovate new products that have not thought about, but now possible because of a lower entry barrier

So we can do this ….

Which can lead to this !

TocoPatch

Monitoring Solution Optimized for Nurse-Midwives in District Hospital Settings

Technology developed in collaboration with D-tree International under sponsorship of Saving Lives at Birth Consortium / USAID Seed Grant

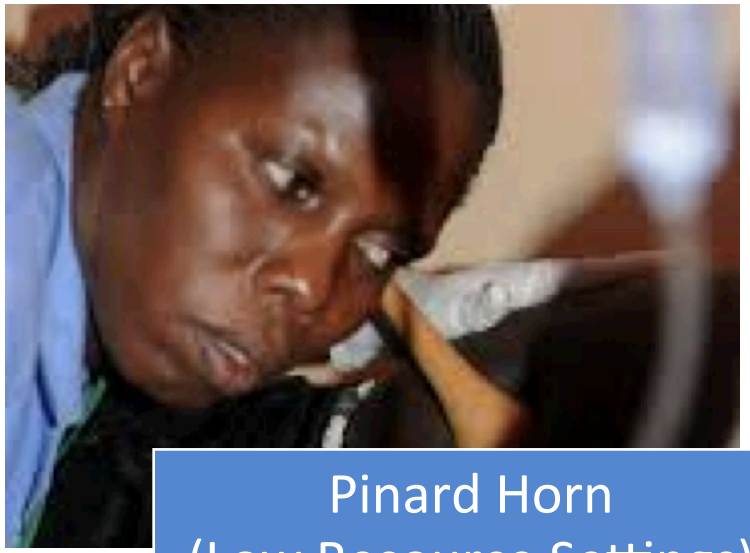
Fetal Distress During Labor and Delivery

- Interruptions in flow of oxygen and exchange of CO2 during labor can lead to fetal death or severe complications
- Causes: Umbilical cord occlusion, Placental abruption, Maternal hypotension
- May be mitigated through timely therapeutic and/or aggressive intervention

Courtesy: Doug Williams (doug.Williams@alum.mit.edu)
Note: Technology developed in collaboration with D-tree International under sponsorship of Saving Lives at Birth Consortium / USAID Seed Grant

Current Intrapartum Fetal Monitoring Approaches

Cardiotocograph
(High Resource Settings)



Pinard Horn
(Low Resource Settings)

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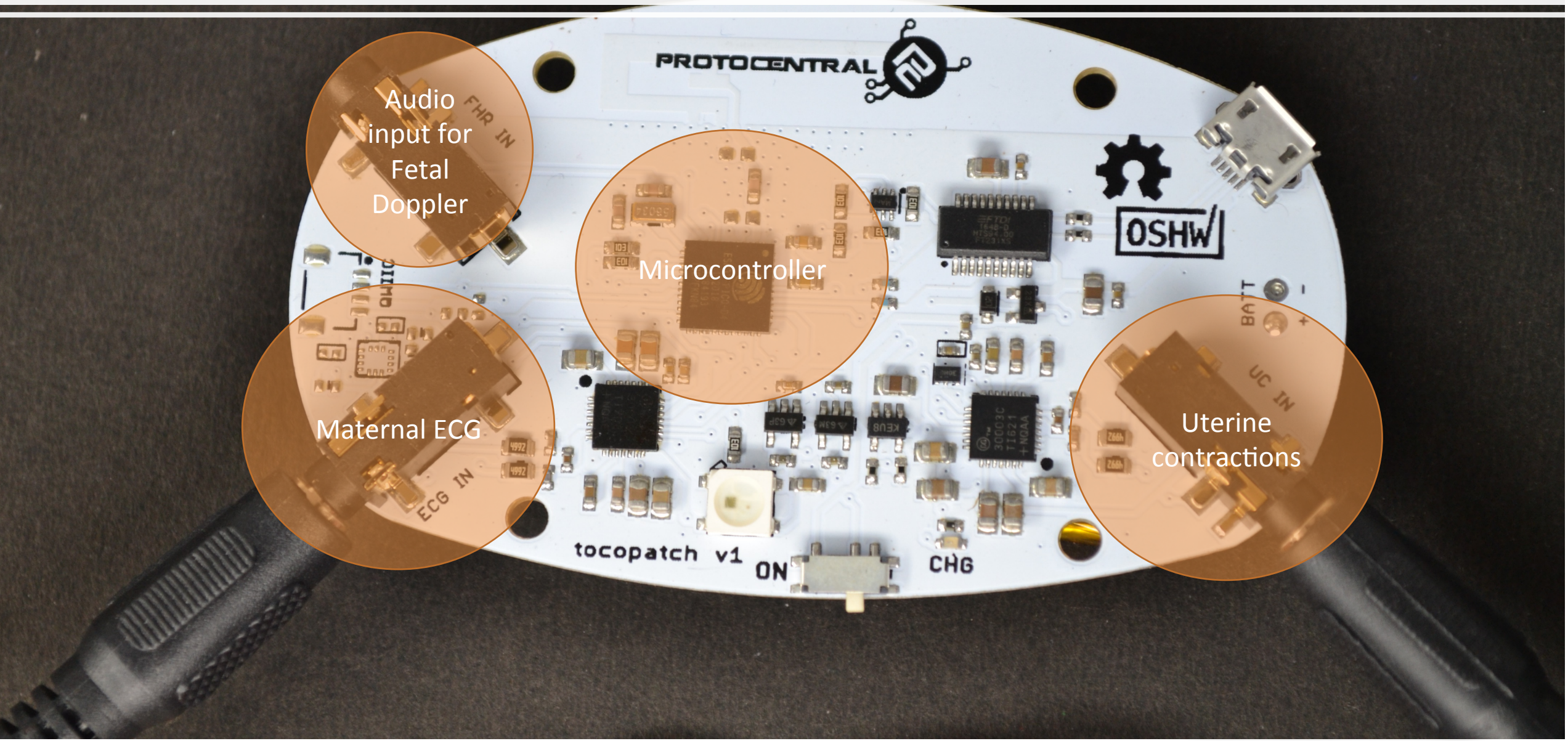
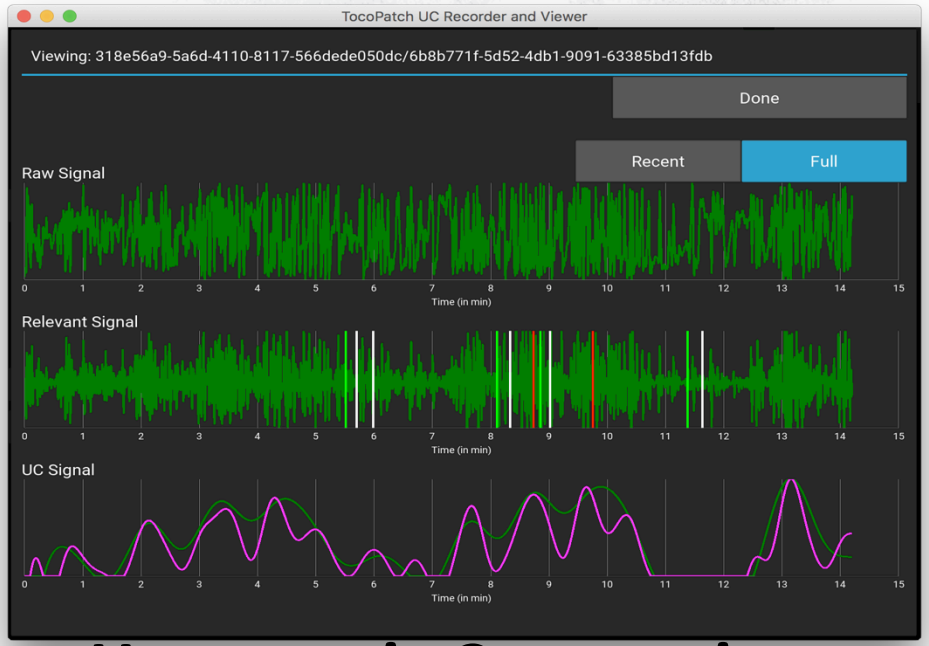
The Tocopatch



Sample TocoPatch Output
Uterine contractions

Routine Contractions



Hypertonic Contractions

Courtesy: Doug Williams (doug.Williams@alum.mit.edu)
Note: Technology developed by ProtoCentral in collaboration with D-tree International under sponsorship of Saving Lives at Birth Consortium / USAID Seed Grant

Sample TocoPatch Output
Fetal Heartrate

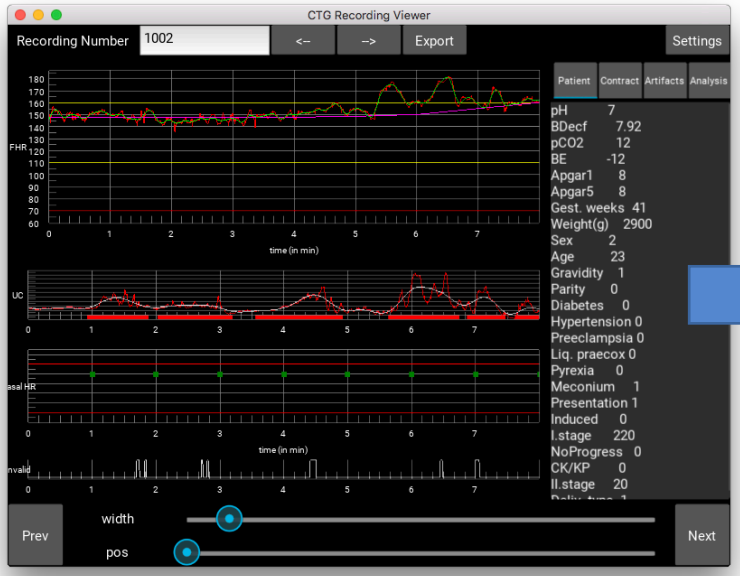
Automated detection of key FHR patterns per FIGO standards:

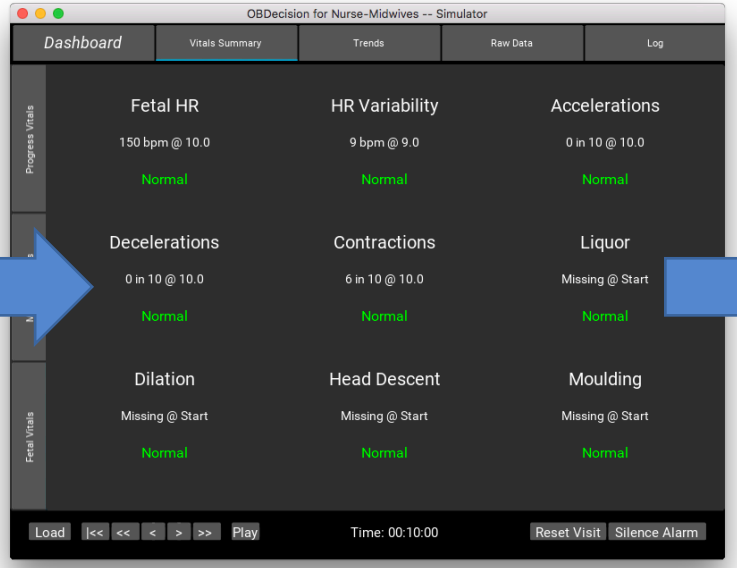
- Prolonged Decelerations (p)
- Late Decelerations (r)
- Periodic Variable Decelerations (o)
- Accelerations (g)

Also includes computation of basal HR and heart rate variability

Note: Technology developed by ProtoCentral in collaboration with D-tree International under sponsorship of Saving Lives at Birth Consortium / USAID Seed Grant

TocoPatch /LowCostCTG UI for specialists and simplified UI for nurse-midwives





Courtesy: Doug Williams

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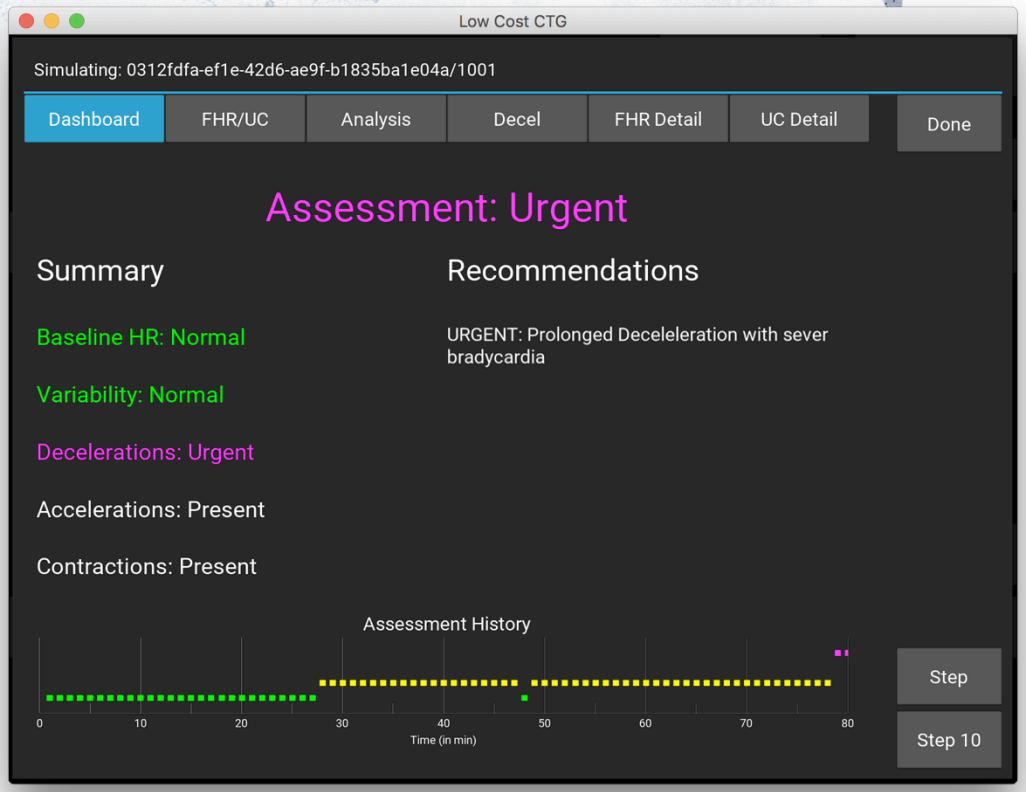
TocoPatch /LowCostCTG Dashboard and Decision Support



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TocoPatch /LowCost CTG Project Status

- Recipient of 2-year USAID /Saving Lives at Birth Seed Grant . Testing in collaboration with Queen Elizabeth Central Hospital in Blantyre Malawi.
- LowCostCTG sensor technology currently undergoing patient testing since January 2018
- Decision support technology functional, with patient testing expected to start in October 2018
- Extended testing by midwives outside of direct development team scheduled to start in January 2019

Note: Technology developed in collaboration with D-tree International under sponsorship of Saving Lives at Birth Consortium / USAID Seed Grant

Open To Collaboration

We are very open to collaborations, either with overall solution (LowCostCTG) and individual technologies (TocoPatch)

Technologies are collaboration friendly: Hardware and Software to be licensed as Open Source

Contact me or Doug Williams (doug.williams@alum.mit.edu)

Note: Technology developed in collaboration with D-tree International under sponsorship of Saving Lives at Birth Consortium / USAID Seed Grant

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Why?

People cannot choose not to need Healthcare

Conclusion

- Improve and **equalize** standards of care with technology
- 90% of the world's investment in medical research benefits only the most affluent 10 % of its population
- With great power comes great responsibility. Use responsibly !!

Collaborators or partners who wish to contribute their work to these projects are welcome!

Write to me!

ashwin@protocentral.com / @ashwinkw

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