Medical Devices Working Group Update

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ELISA
Enabling Linux in Safety Applications

Aerospace · Automotive · Linux Features
Medical Devices · OS Engineering Process
Safety Architecture · Space Grade Linux · Systems · Tools

Introduction

Use case for investigating Linux as a component in a system.

- First ELISA workshop identified OpenAPS as good candidate as technology
  - Sources were available to hobbyist community, no NDA required
  - Community willing to engage and explain
  - Started analysis of openAPS project
- Group decided to add in analysis on Open Source Medical Ventilator
- Renamed working group to “Medical Devices”
- Investigation on 62304 requirements pertaining to SOUP for openAPS
- Steady progress working on STPA analysis of OpenAPS over time.

IEC 62304

Comparison of results of STPA analysis to 62304 Software of Unknown Provenance (SOUP) was raised during one of the 2021 workshops.

Report on “IEC 62304 requirements pertaining to SOUP” for OpenAPS project and has been moved to github repository: https://github.com/elisa-tech/wg-medical-devices/blob/main/62304-soup/main.md

STPA Approach

“STPA (System-Theoretic Process Analysis) is a relatively new hazard analysis technique based on an extended model of accident causation.”

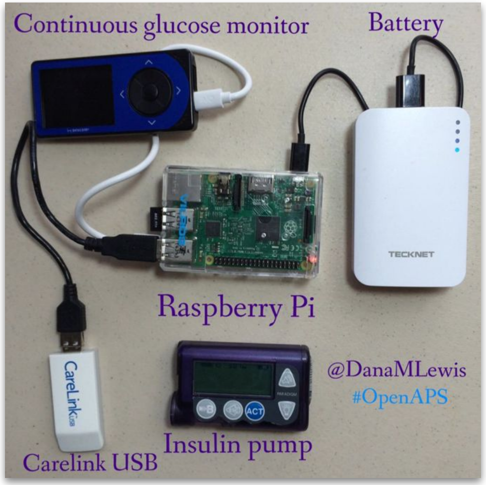
Handbook: http://psas.scripts.mit.edu/home/get_file.php?name=STPA_handbook.pdf

Why?

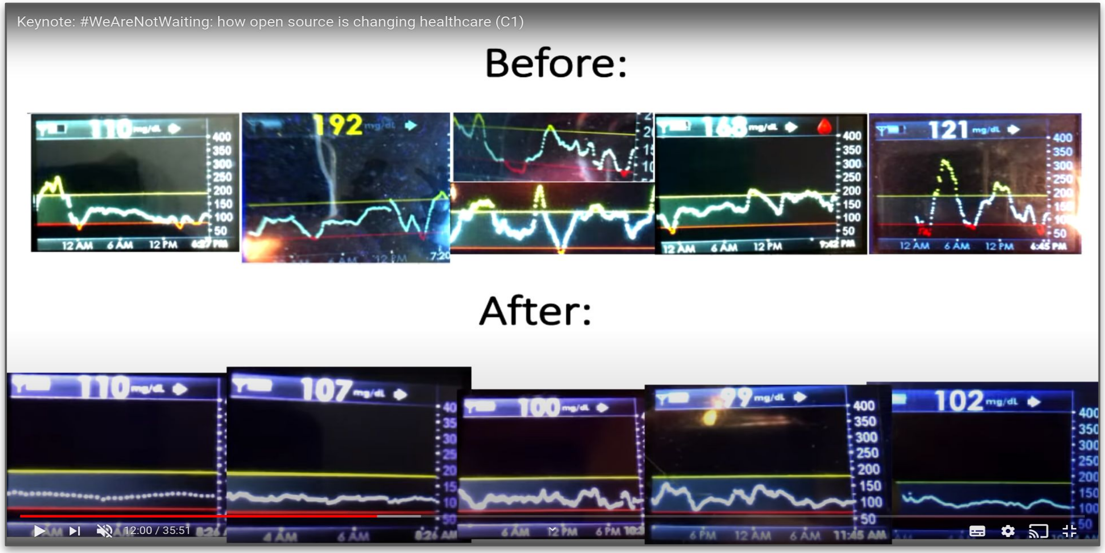
- Takes an iterative approach
- Diagrams and discussions - makes intuitive sense
- Handbook available to guide us, some expertise in methodology available
- Can take analysis all the way down to linux syscalls & interfaces

Why Study OpenAPS? Community & Open

- https://openaps.org/
- https://github.com/openaps



Source: https://diyps.org/2016/09/15/openaps-rigs-are-shrinking-in-size/

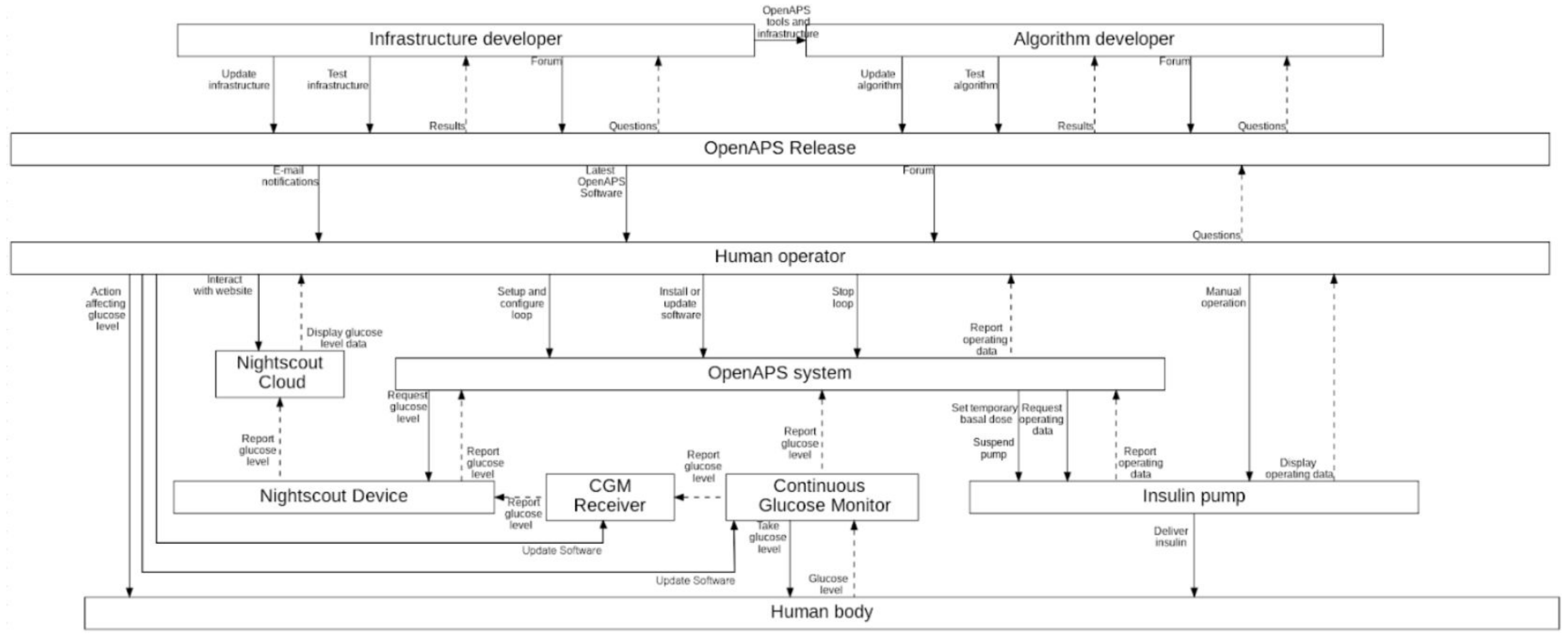


Keynote: #WeAreNotWaiting: how open source is changing healthcare (C1)
Before:
After:
12:00 / 35:51

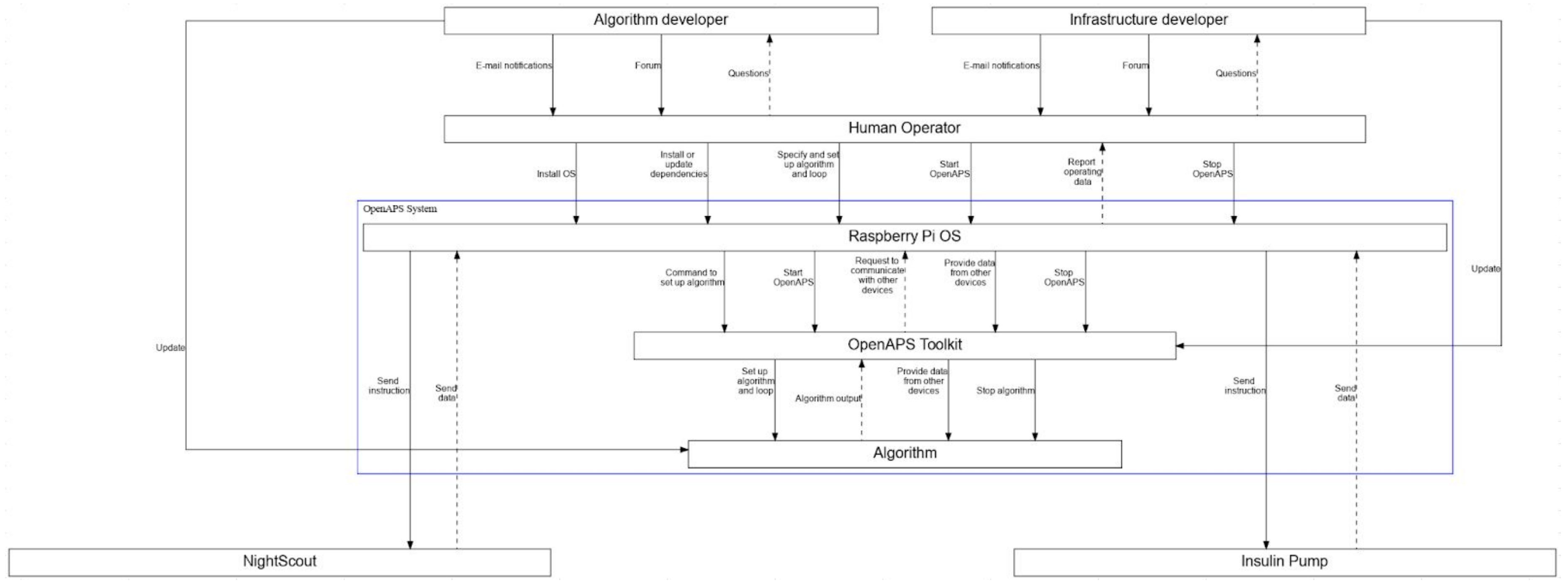
Source: blood glucose graph picture was a screenshot from https://www.youtube.com/watch?v=p76hGxv3-HE

More research studies at:
https://www2.diabetes.org/newsroom/press-releases/2022/new-study-shows-open-sourced-autmoated-insulin-delivery-safe-effective-treatment-option-type-1

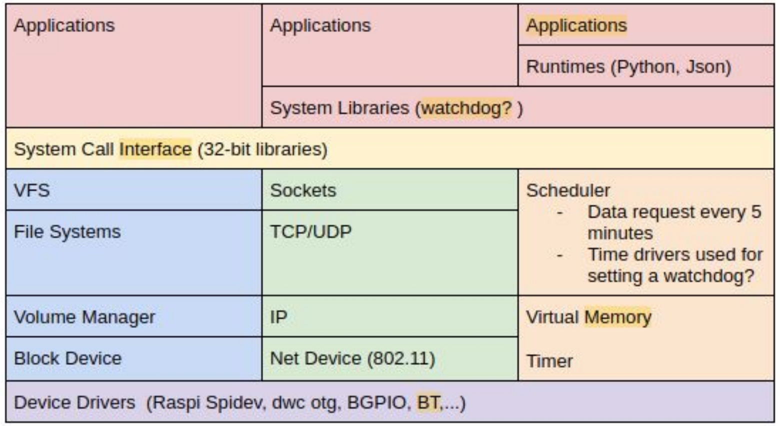
L1 Control Diagram: Interaction with Environment



L2 Control Diagram: Focus in on OpenAPS



L3 System views



Applications	Applications	Applications
		Runtimes (Python, Json)
	System Libraries (watchdog?)	
System Call Interface (32-bit libraries)		
VFS	Sockets	Scheduler - Data request every 5 minutes - Time drivers used for setting a watchdog?
File Systems	TCP/UDP	
Volume Manager	IP	Virtual Memory
Block Device	Net Device (802.11)	Timer
Device Drivers (Raspi Spidev, dwc otg, BGPIO, BT,...)		

Static System View

- Supported system calls
- Static modules
- Dynamic modules
- Kernel Config options

Dynamic System View

- System calls invoked
- ioctls invoked
- Subsystems use

Tracing openAPS workload

Thank you to OpenAPS community for providing real workload traces!

- **Methodology**
  - Discover Linux kernel subsystems used by openAPS
  - Enable event tracing before starting the workload.
  - Extract system call numbers from trace and map them to system calls
    - Collect supported system calls using auditd package tool: ausyscall --dump
  - Trace openAPS application (kernel tracing & strace)
  - Gather static and dynamic module information
- **Tools employed**
  - ausyscall --dump
  - Kernel tracing
  - Lsmod
  - scripts/checksyscalls.sh (Linux kernel script)

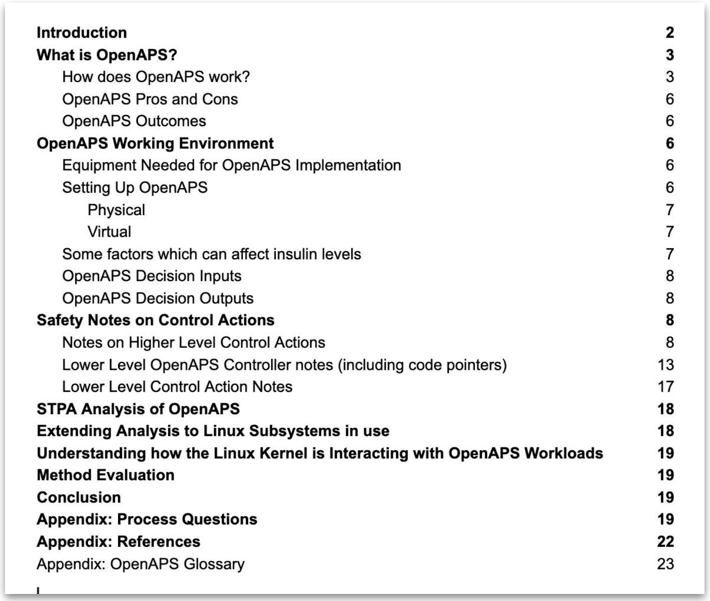
Methodology upstreamed to: https://docs.kernel.org/admin-guide/workload-tracing.html

2024 Update

- Updated SPTA results in github repository with results from reviews
  - Removed redundant L1 & L2 requirements in set generated from STPA methodology
- Refined tool to convert STPA analysis spreadsheet requirements into machine readable YAML format. https://github.com/elisa-tech/wg-medical-devices/tree/main/applying-stpa
- Moving OpenAPS to build with Yocto, and generating SBOM
  - Ran into issues with porting OpenAPS to Yocto
  - Unable to identify mentor to help with work. Efforts shelved.
- Looking for other open medical device application to compare & contrast
  - No additional use cases identified.

2024 Update

- Summary of the analysis for OpenAPS effort over the years.
  - L1 & L2 analysis wrapped up at this point
  - Results committed to github
  - White paper cleanup to summarize efforts in progress



2025 Plans

- Finish white paper summarizing efforts
- Suspended working group meetings until new use case identified.
  - Mail list (medical-devices@lists.elisa.tech) will remain active for discussion, and proposals of new use cases.
  - Ad hoc meetings will be called for final passes on white paper

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Thank you

Milan Lakhami
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Nicole Pappler
Jeff "Jefro" Osier-Mixon
Shuah Khan