Toward Plug-and-play for Medical Devices

X-Ray / Ventilator and PCA Safety Implementations

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Interconnectivity vs. Interoperability

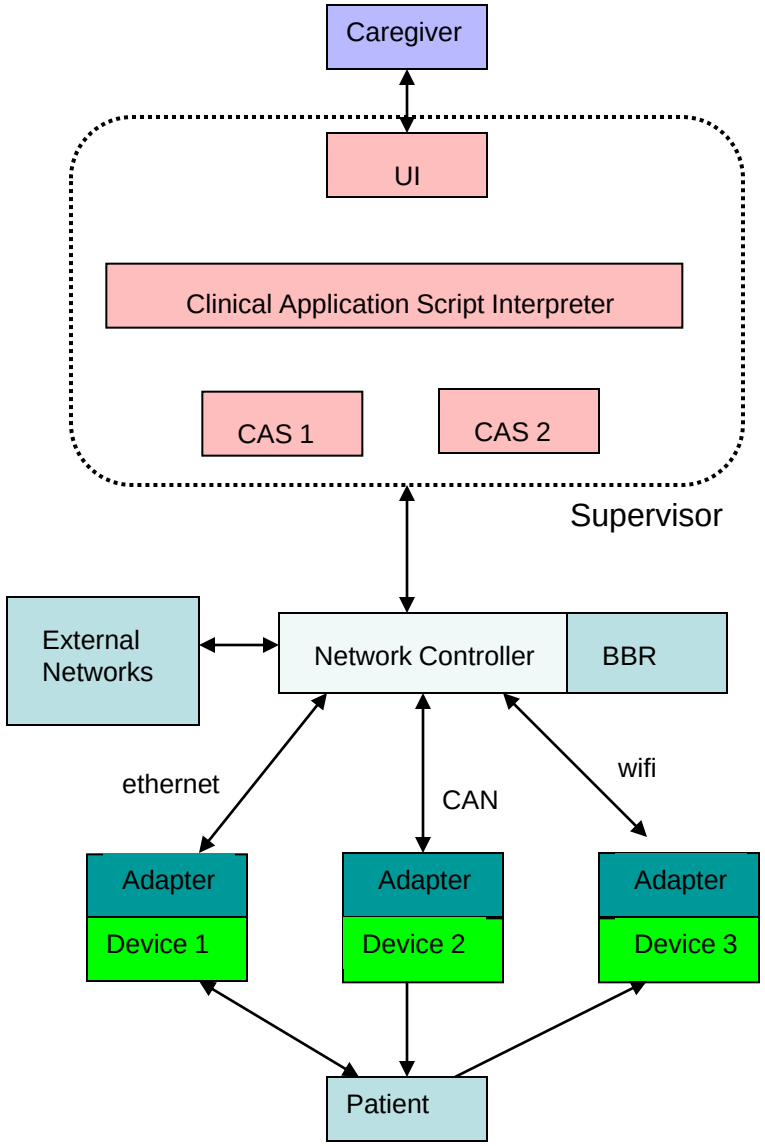
- Interconnected systems:
  - Share data
  - Require drivers for each device
  - Low systems requirements
  - One-off systems
  - May utilize common semantics
  - Avionics examples
- Interoperable systems: Plug and Play
  - Allow seamless addition and removal of components on the fly
  - Requires common semantics
  - Requires stronger device interface descriptions and protocols
  - Can build and immediately start using a system from devices that have never been tested in that combination
  - More complicated under the hood, harder to design the infrastructure, but easier to build implementations / clinical systems

Our Development Process

Workflow:

1. Clinical Use Case
2. Hazard Analysis / FMEA
3. Requirements
4. Formal Model
5. Test Generation
6. Code Generation

Formal Methods based process allows for verification at each step.



Clinical Application Script (CAS) implements a workflow.

CAS includes:

- Executable Program
- Device Requirements
- Safety Properties

"Supervisor" is the physical box with the caregiver UI. CAS Interpreter runs on the Supervisor. Supervisor may be a separate box or be hosted on a device like a ventilator or patient monitor.

Devices transmit a Device Model that describes their capabilities when they connect to the network.

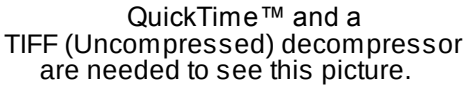
Use Case 1: Synchronizing X-Ray and Ventilator

Anesthesia Machine

Portable x-ray machine

Surgeons

X-Ray / Ventilator Implementation



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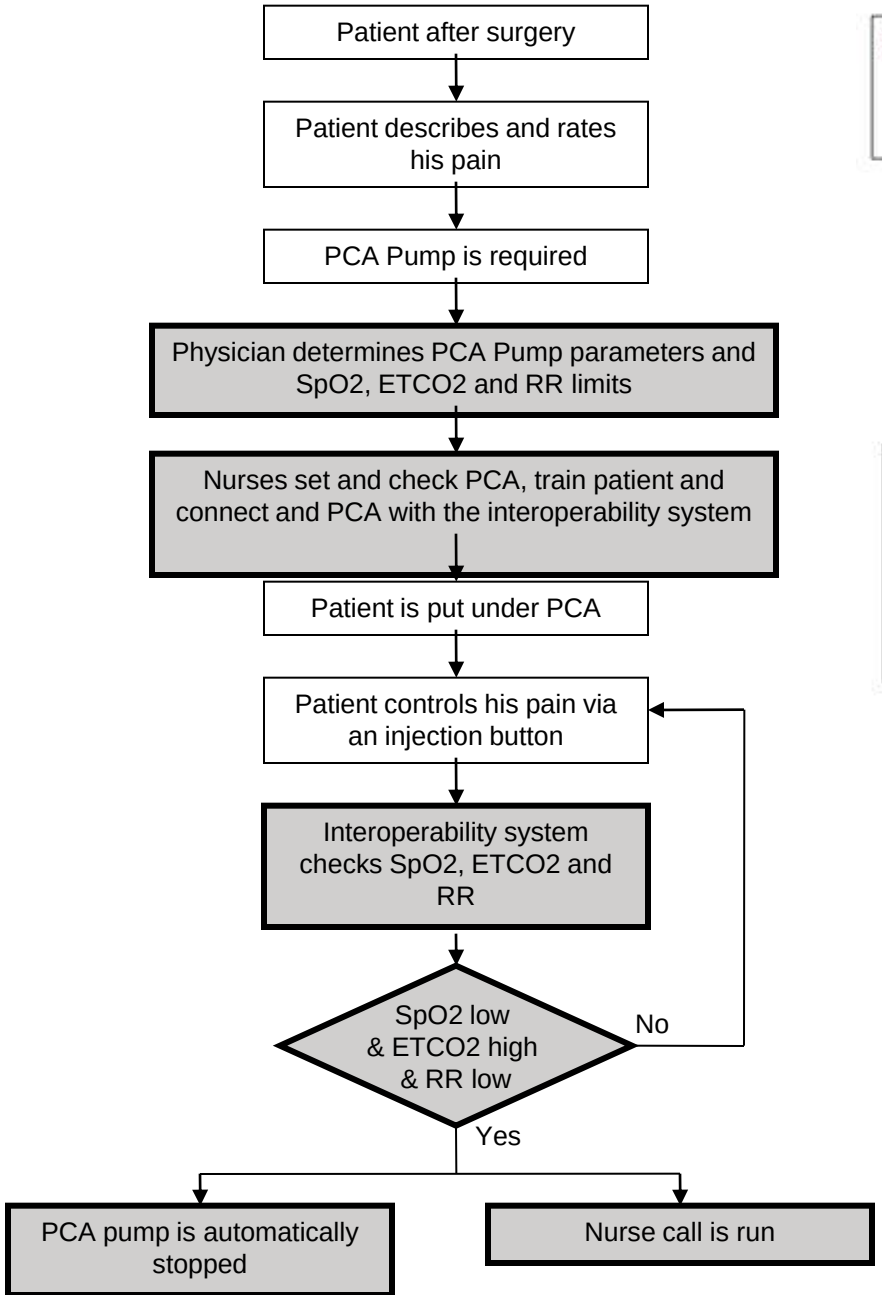
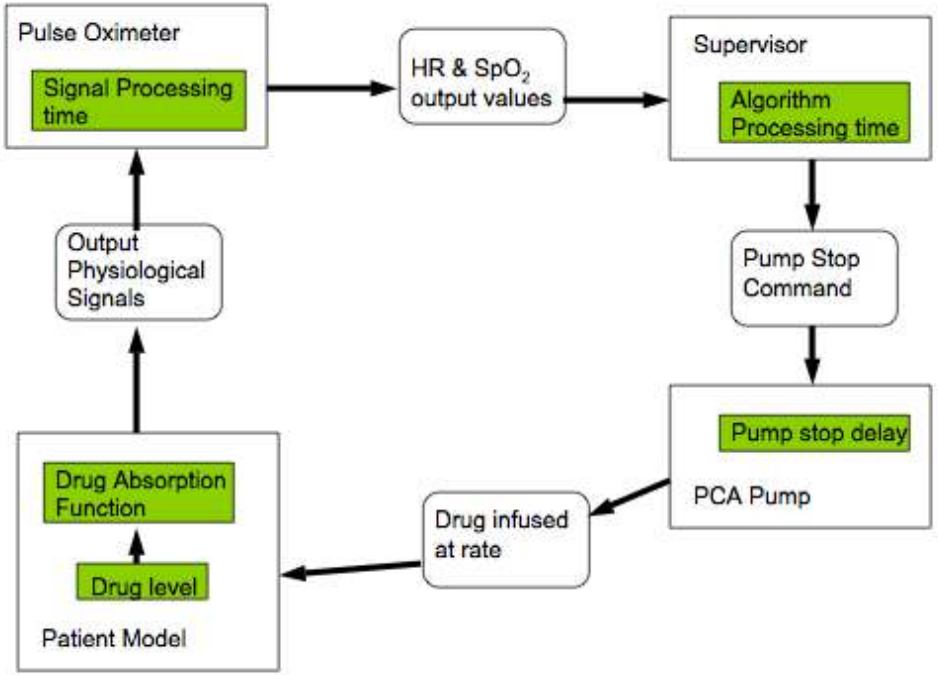
PCA Monitoring

- Can we use pulse oximeters and capnometers already in the hospital to monitor PCA opioids?
- Goal: Integrate monitors with an intelligent “controller” to:
  - Detect respiratory disturbance
  - Lock-out infusion
  - Activate nurse-call





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Challenges

- Network Requirements are not monolithic
  - Wired vs. Wireless
  - Real-time vs Best-effort
- Patient Model
  - People are unpredictable
  - 80% Solution
- Control Program Compatibility
  - Conflicting Controllers
  - Resource Contention
- Verifying Safety Properties
  - Safety properties of the whole system
  - Safety properties of the devices
- Regulatory Challenges
  - Pairwise verification is not feasible
  - Who is the manufacturer of the composed system?