CPS: Collaborative Medium: Infrastructure and Technology Innovations for Medical Device Coordination (NSF CNS-0932289/0930647)

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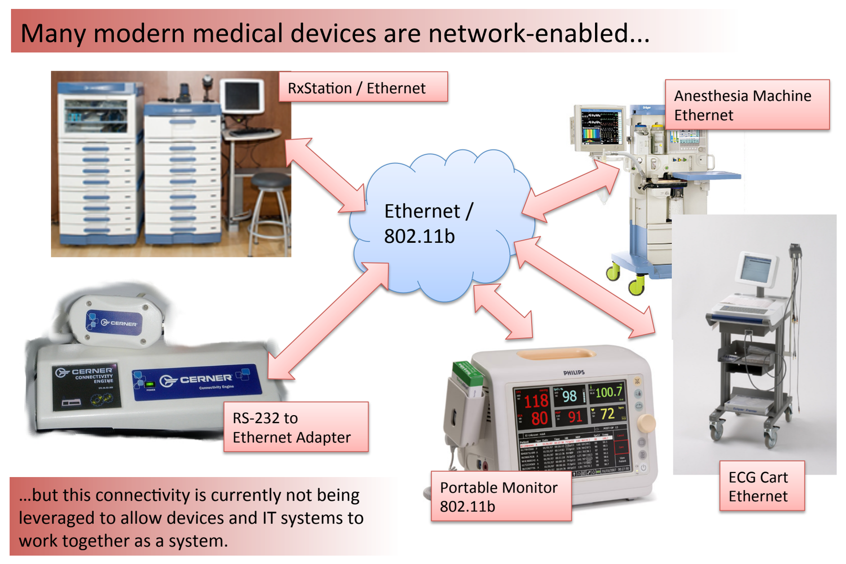
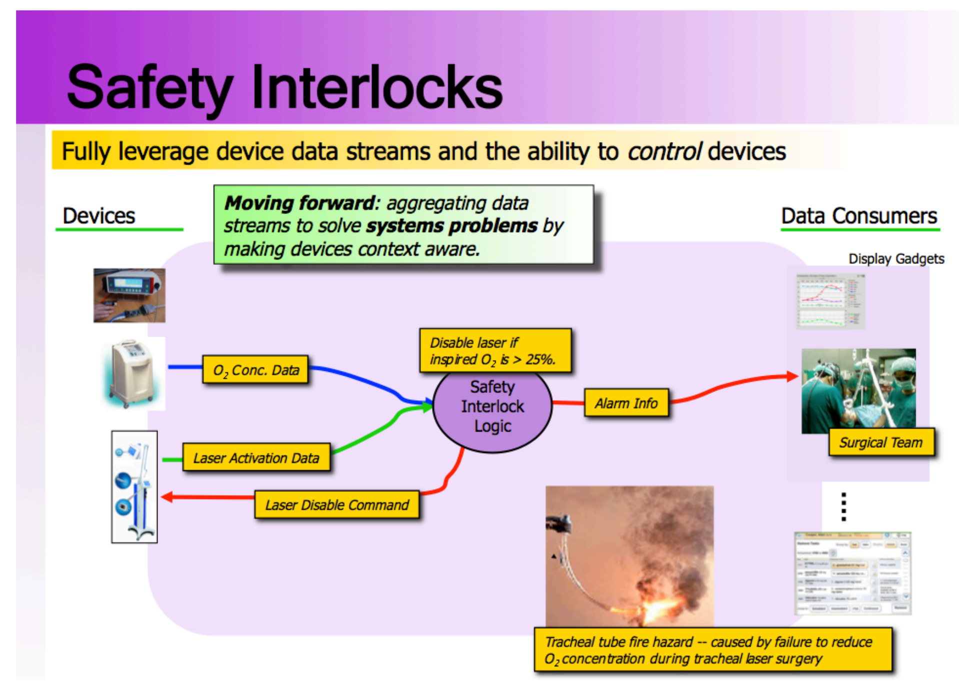
Problems / Challenges

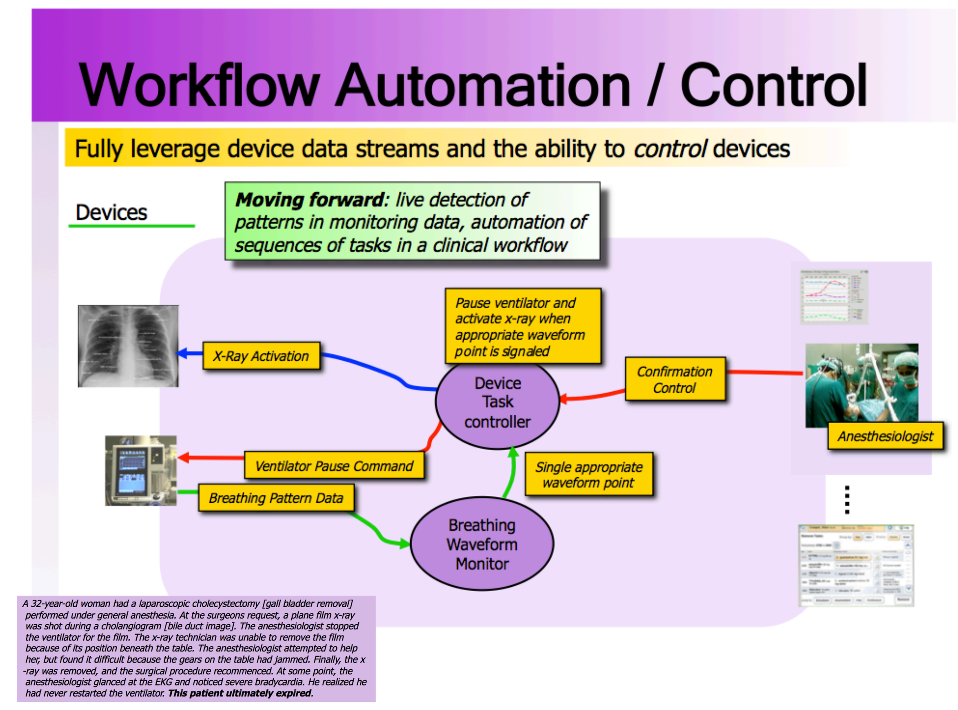
Unleveraged Device Connectivity

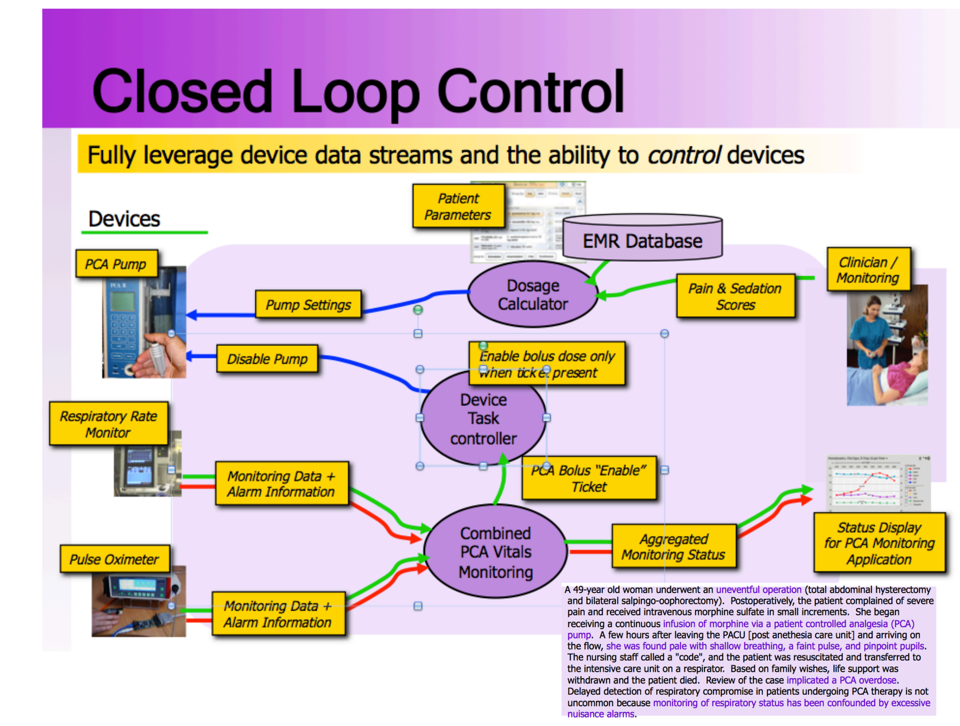
- Delivering modern medical care involves complex cyber-physical systems…
  - many medical devices, electronic medical records, clinicians/care-givers …all working together to achieve a goal
- Although most modern medical devices have some form of connectivity, they are not integrated so that they can work together as a system
  - devices are "unaware of their context", e.g., details of patient parameters, history, current procedures they may impact/distort readings
  - data from multiple devices is not combined to produce more meaningful information to clinicians
  - actions of multiple devices cannot be automatically coordinated to achieve greater safety and efficiency



What Could be Achieved if Devices formed a System of Systems (SoS)?





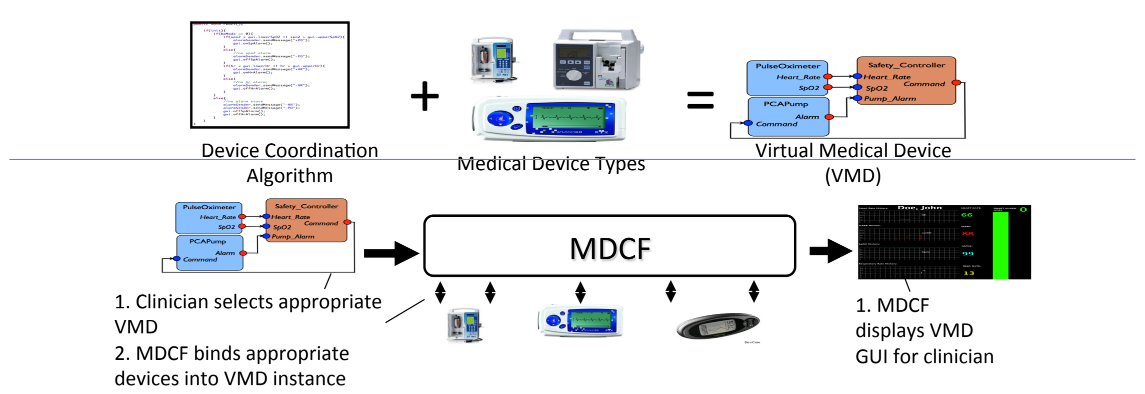


Technology Solutions

Middleware for Device SoS Integration

The Medical Device Coordination Framework (MDCF)

- Our project is developing an open source *Medical Device Coordination Framework* – a platform for integrating medical devices into systems
- The MDCF provides…
  - Publish-subscribe middleware for integrating devices
  - A component-based application (app) environment for developing and running algorithms that coordinate the device data flows and actions
- Together the platform, app, and connected devices form a Virtual Medical Device – a composite system device composed of individual devices

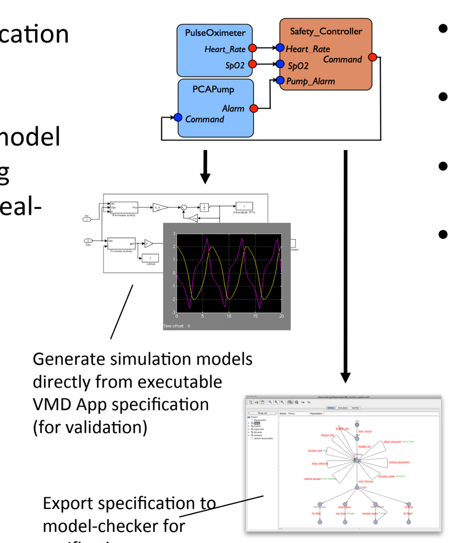


Research Issues

Real-time support for VMD Apps

- Hard real-time communication infrastructure
- Light-weight
- Pub/sub programming model
- Support for programming clinical-algorithms with real-time constraints
- Event driven
- Time triggered
- Admission control
- Guarantee performance specified by VMD App or prevent clinician from instantiating VMD

VMD App Validation & Verification

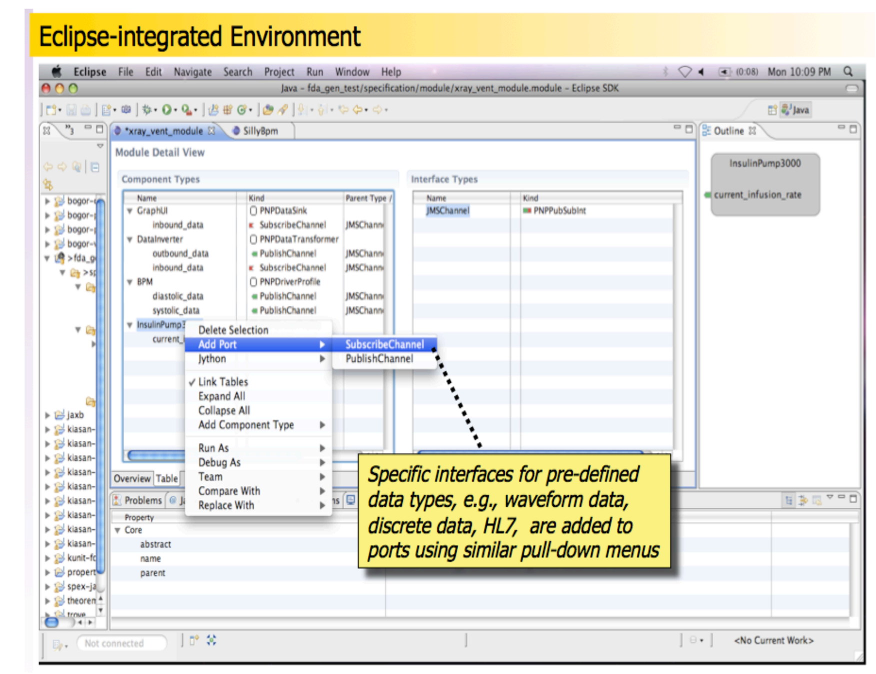


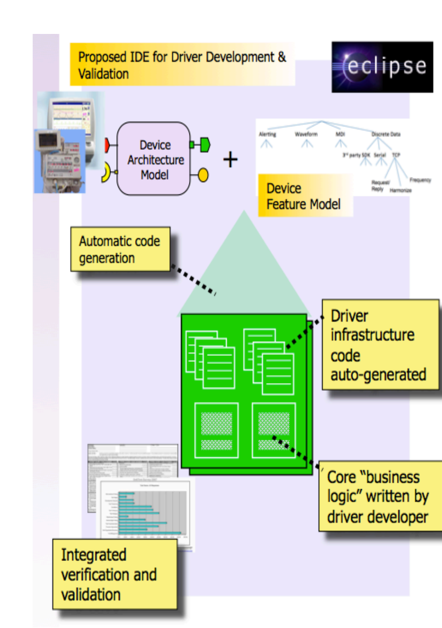
MDCF Platform Verification

- Device connection protocols
- Device configuration protocols
- VMD setup/tear-down algorithm
- Verify that platform:
  - Correctly implements admission control
  - Correctly implements protocols

The MDCF conforms to the ASTM standard for an *Interoperable Clinical Environment* (ICE) developed by the CIMIT MDPnP project.

Component-based Development for Coordination Apps

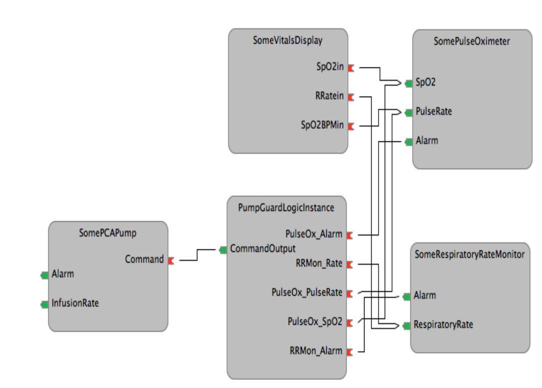




Solution Strategy

- **Vision:** Integrated Development Environment for driver development & validation
- Model/Aspect-based
  - provides high-level abstractions that make it easy to configure new drivers
  - enforces regular architecture
  - focuses developer concerns on important domain issues and hides mundane coding issues
- Code generation from models/aspects
  - speeds development & reduces opportunity for errors
- Integrated & automated verification /validation
  - allows validation tasks to be more easily pushed to others beyond MDCF provider
  - allows MDCF provider to rapidly certify drivers when submitted by external developers

Components are composed to form coordination apps



Applications

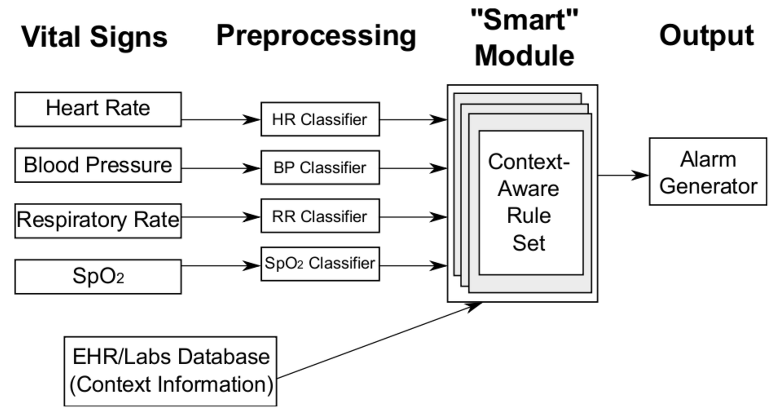
Smart Alarms and Decision Support

Definition

- MCPS of multiple devices and central "smart" controller
  - Filter, combine, process, and present real-time medical information
  - Suppress irrelevant alarms
  - Provide summaries of the patient's state and predictions of future trends

Benefits

- Improve patient safety
  - More accurate than current alarms
  - Provide pertinent contextual information
- Reduces clinician workload
  - Reducing high number of false alarms, which reduces caretaker fatigue
  - Eliminates need for periodic hand-recording of data
- Facilitates practice of evidence-based medicine



Challenges

- Filtering and combining data streams from multiple devices
- Developing context-aware patient models
- Encoding hospital guidelines, extracting experts' models, learning models statistically
- Presenting data concisely and effectively

Approach

- Generic Smart Alarm Architecture
  - Modular: flexible and configurable
  - Preprocessing, inference, visualization

Case Studies

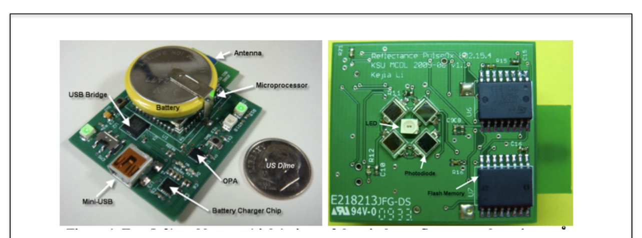
- Smart alarm for CABG patients
  - Post-CABG surgery patients produce many false alarms
  - Simple classification with nurse-generated rules: 57% reduction in false alarms
- Seizure smart alarm
  - Brain tissue oxygen alarm threshold unsubstantiated in regards to seizure
  - Investigating multiple vital sign alarm to detect seizure
- Vasospasm smart alarm
  - Post-SAH surgery patients at risk for vasospasm
  - Clinical suspicion factors for vasospasm are subtle, definitive measure is invasive
  - Working to analyze multiple vital signs to produce risk assessment for vasospasm

Future Work

- Expand number of vital signs considered
- Simplify design to ease workflow integration
- Understand and establish safety in these systems

Reconfigurable Families of Medical Devices

MDCF enables what we call "medical platform-oriented devices" (MPODs) – "headless" devices with very small form factors consisting primarily of "raw" sensors and actuators – the device UI and primary computation are implemented via apps on the MDCF platform.



A tiny platform-based reflectance pulse oximeter developed at KSU EECE Device Component Lab

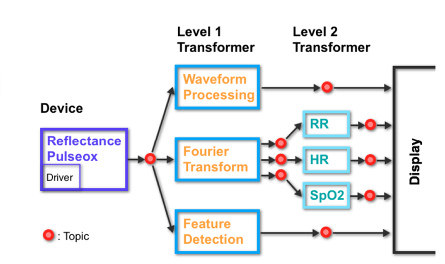
Although only two physiological parameters, HR and SpO_2, are reported by a conventional pulse oximeter, the photoplethysmograms (PPGs) acquired by the pulse oximeter's light-based sensor offer other clinical parameters (at right)

Additional clinical parameters that can be extracted from PPGs

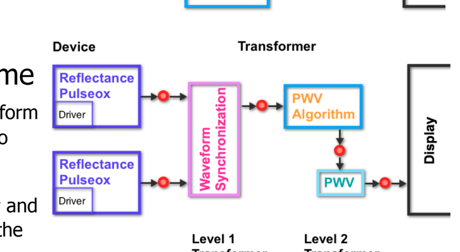
- Systolic, diastolic, blood pressure (BP)
- Stroke volume (SV)
- Cardiac output (CO)
- Respiration rate (RR)
- Peak-to-peak time (PPT)
- Pulse wave velocity (PWV)
- Arterial elasticity (AE)
- Stiffness index (SI)
- Reflection index (RI)
- Perfusion index (PI)
- Patient activity/motion
- Patient identity
- Ambient light information

MDCF apps allow the allows the sensors of the pulse ox MPOD to be rapidly reconfigured into different medical devices

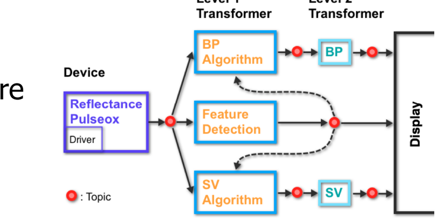
Example 1: App to extract HR, SpO_2, and RR with moving averages, display smoothed waveforms.



Example 2: App using two MPOD POs (positioned at the wrist and finger of the same hand) to extract pulse wave velocity. The Waveform Synchronization transformer aligns the PPGs received from the two devices using timestamps in the messages. The synchronized waveforms are then streamed to the central PWV Algorithm transformer, which internally employs a linear-phase lowpass filter and signal differentiation method as in. The PWV transformer reports the final PWV value, e.g., after applying a moving average filter.

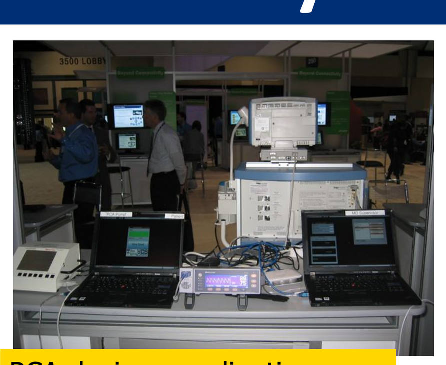


Example 3: App uses feedback from feature (noise, ambient light) detection to attach viability ranking to components producing physiological parameters BP and SV.



Outreach/Impact

Industry Collaboration



PCA device coordination demo at Cerner Health Conference October 2009

U Penn Ph.D. student Andrew King explains demo scenario to Paul Jones from FDA

Regulatory Policy

We are actively engaged with FDA engineers to develop science-based inputs for forming regulatory policy for interoperable medical systems

- Safety evaluation eco-system for medical device interoperability platforms
- Example hazard analyses, mock 510(k) regulatory submissions for apps and other MDCF components
- Guidelines for development of third-party certification regime

Educational Material

The MDCF is open source and is designed to support a variety of interesting class projects and graduate research projects

- A collection of mock (software simulated) medical devices including blood pressure monitor, pulse oximeter, infusion pump, electrocardio-gram (ECG)
- A collection of example apps illustrating how to use the MDCF app development environment
- Illustrations of how to interface with real medical devices
- Suggested student projects

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