MDCF Tutorial
-- Introduction

http://mdcf.santos.cis.ksu.edu/

Kansas State University
University of Pennsylvania

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Medical Device Coordination Framework

Open experimental ICE-compliant platform to bring together academic researchers, industry vendors, and government regulators

- **Goals**
  - Open source infrastructure
  - Meet performance requirements of realistic clinical scenarios
  - Provide middleware with reliability, real-time, security
  - Provide an effective app programming model and development environment with integrated verification/validation support and construction of regulatory artifacts
  - Support evaluation of device interfacing concepts
  - Illustrate how to support real and mock devices
  - Illustrate envisioned regulatory oversight and 3rd party certification

- **Non-goals (at the moment)**
  - Not trying to redo the whole body of work on physiological signal ontology (we want to message content agnostic, import “types” from previous work)
  - Not trying to build a communication protocol from the ground up
  - Not trying to provide a realistic clinician interface
Research Teams / Funding

**NSF Cyber-physical Systems Program**
- KSU & U Pennsylvania ($1.5mil total)
- Funding runs through August 2012

**NIH/NIBIB Quantum Grant**
- High profile grant ($10mil total over five years)
  - Program for “medical moon shots”
  - Affiliated with the NSF SHARP grants
- Funding runs through August 2015
- Prime is Julian Goldman, Mass General / CIMIT
- Academic team members include:
  - KSU, U Penn, UIUC
- Other team members include a couple of small device manufacturers/integrators (Anakena, DocBox, Moberg Research) and consultants (e.g., Tim Gee)
- Strong ties to NIST, Veterans Affairs, FDA
FDA Collaboration

- Project originated as a request from FDA to build a prototype
- Have had two FDA NSF Scholar-in-Residence grants
  - Current: Brian Larson (former senior engineer / pacemaker developer from Boston Scientific) is working for us as a research associate
  - Spending time at the FDA working on the MDCF app development and certification framework
- Co-authoring papers with FDA engineers on MDCF concepts and proposed safety evaluation / regulatory structure
  - We are aiming for MDCF to be used to illustrate important device interoperability/coordination concepts within the FDA
- Weekly teleconferences with FDA and others from industry
  - AdvaMed, CapsuleTech, Phillips, Underwriters Lab, Roche Diagnostics, etc.
  - Working on developing safety evaluation and regulatory submission prototypes based on a “compositional” regulatory approach to medical interoperability platforms – illustrated using the ICE ASTM standard
  - The MDCF will likely be released to this community within the next several months to illustrate aspects of the long-term vision
Tutorial Topics

Communication Infrastructure

App Development Environment

Mapping to ICE Architecture

Mock Devices
Develop a bus-based app for implementing a safety interlock by coordinating monitoring of vitals with pump control...

Pulse ox, respiratory rate monitor, infusion pump with hand-held control are connected to the patient.
Develop a bus-based app for implementing a safety interlock by coordinating monitoring of vitals with pump control...

An app library holds apps that automate a variety of workflows including “closed loop” scenarios.

A Coordination Supervisor module calls the app launcher to create instance of app classes and make pub/sub connections to the bus.

An app may acquire exclusive access to relevant devices and sends/receives information to those devices during execution.
Develop a bus-based app for implementing a safety interlock by coordinating monitoring of vitals with pump control...

“Begin monitored PCA infusion”

Clinician uses MDCF Clinician console to interact with the app supervisor, select apps, and to respond when human input is requested.
Currently the primary usage mode of MDCF is “developer centric” – server, mock devices, etc. are typically launched through Eclipse.
Demo
Conclusion

- MDCF continues to evolve
  - If a capability that you are interested in is missing from the current code base, that doesn’t mean that we haven’t thought about it and aren’t planning for it

- Current goals
  - Provide a sand-box for technology exploration related to app development, device interfacing, security, and real-time middleware

- Priorities for upcoming development
  - Much more robust app development environment
  - Prototype of ICE Device Model concept
  - Completion of security framework
  - Scaling up of data logging framework
  - Transitioning to real-time framework