Real-Time Challenges and Opportunities in HCMDSS

Insup Lee
PRECISE Center
Department of Computer and Information Science
University of Pennsylvania

CIS 541,Spring 2010

CPS & RTSS

- Cancun Workshop, RTSS 2003
  - Opportunities and Obligations for Physical Computing Systems, IEEE Computer, Nov 2005
- NSF/NCO Sponsored Application Domain/Infrastructure workshops
  - HCMDSS (2005), Aviation Software/Certification (2006), SCADA (2006), HCSP-CPS (2007), Security & Privacy (2008), Transportation (2008), …
  - http://varma.ece.cmu.edu/CPS-Forum/Workshops.html
- CPS Week in 2007 with RTAS, HSCC, IPSN

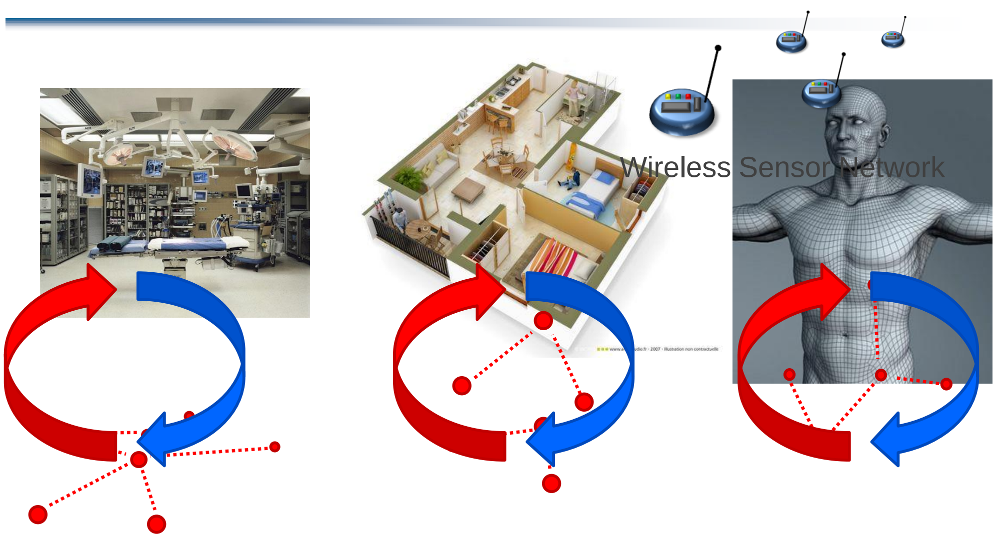
Societal Responsibility/Challenge

- How can we provide people and society with cyber-physical systems that they can trust their lives on?

Trustworthy:
reliable, safe, secure,
privacy-preserving, usable,
etc.

- Partial list of complex system failures
  - Denver baggage handling system ($300M)
  - Power blackout in NY (2003)
  - Ariane 5 (1996)
  - Mars Pathfinder (1997)
  - Mars Climate Orbiter ($125M,1999)
  - The Patriot Missile (1991)
  - USS Yorktown (1998)
  - Therac-25 (1985-1988)
  - London Ambulance System (£9M, 1992)
  - Pacemakers (500K recalls during 1990-2000)
  - Numerous computer-related Incidents wth commer aircraft (http://www.rvs.uni-bielefeld.de/publications/compendium/incidents_and_accidents/index.html)

HCMDSS (High Confidence Medical Device Software Systems)

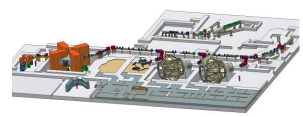


Cyber Physical Systems (CPS)

Key Trends in Healthcare Systems



- System complexity
  - o Increasing functionality
  - o Increasing integration and networking interoperability
  - o Growing importance and reliance on software
  - o QoS is no less important than functionality
- Tomorrow's systems
  - o Dynamic, ever-changing, dependable, high-confidence
  - o System of systems – scale & interoperability
  - o Self-*(aware, adapting, repairing, sustaining)
  - o Personalized medicine



Needs for Healthcare Systems

- Integration techniques for systems of systems
  - o Interoperation of medical devices, EHR systems, ...
  - o High-confidence systems
- Secure, dependable, real-time communication networks with GoS (Guarantee of Service)
  - o Internet service
  - o Interference-resilient wireless networks
- Validation and evidence-based certification

Interoperability

Penn Engineering

Characteristics

- Over the years medical devices gaining communication capabilities
- Devices still operate independently
- Standardized interaction between devices non existent
- Full benefit of communication capabilities not being realize

Current

Future

MD PnP: Interoperable medical devices based on plug-n-play!

Vender neutrality based on virtualization (virtual medical device interfaces)

Advantages

- Improve Patient safety
- Complete, accurate medical records
- Reduce errors
- Context awareness
- Rapid deployment
- Safety interlocks

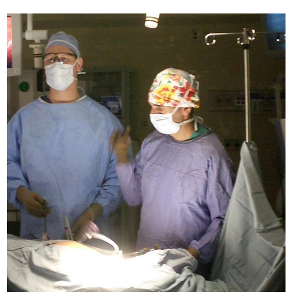
MDPnP Use Case: X-Ray / Ventilator

Penn Engineering

"With the advent of sophisticated anesthesia machines incorporating comprehensive monitoring, it is easy to forget that serious anesthesia mishaps still can and do occur." APSF Newsletter Winter 2005

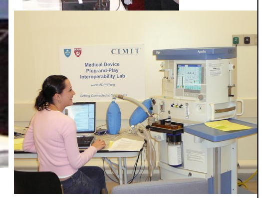
Anesthesia Machine

Portable x-ray machine



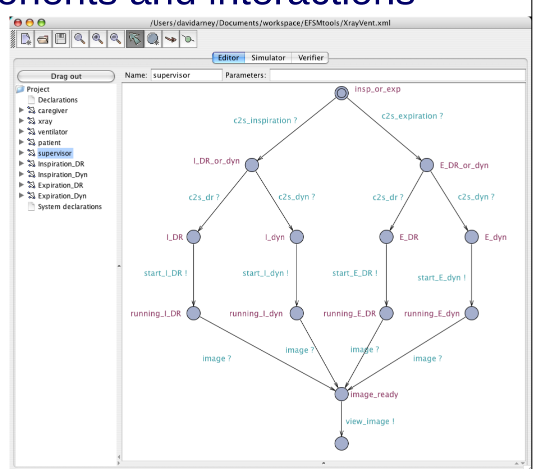
Surgeons

X-Ray / Ventilator Demo Implementation



Modeling MD PnP Systems: Xray/Vent

- Model of system components and interactions
- Model includes:
  - o Xray
  - o Ventilator
  - o Supervisor
  - o Caregiver
  - o Patient



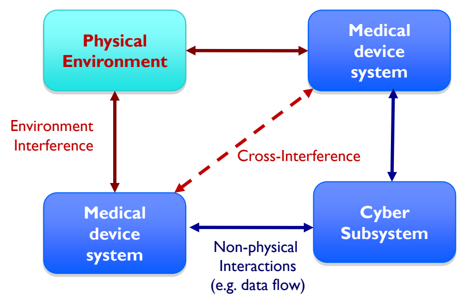
- Verification:
  - o Correctness of inspiration dynamic algorithm
  - o Feasibility of interoperation

Interaction Complexity

- Healthcare systems are systems of systems
- Composition of systems are about the interactions of systems
- “Normal Accidents”, an influential book by Charles Perrow (1984)
  - One of the Three Mile Island investigators
  - A member of recent NRC Study “Software for Dependable Systems: Sufficient Evidence?”
- Posits that sufficiently complex systems can produce accidents without a simple cause due to
  - interactive complexity and tight coupling

Interference Due to Coupling

- MD systems have implanted or worn sensors/devices on the human body
- Interference
  - Explicit resource sharing/synchronization
  - Implicit coupling via shared environment
- Needs:
  - Mixed criticality
  - Mode changes
  - Environment model (e.g., patient model)



Need formal interference analysis methods for medical devices systems

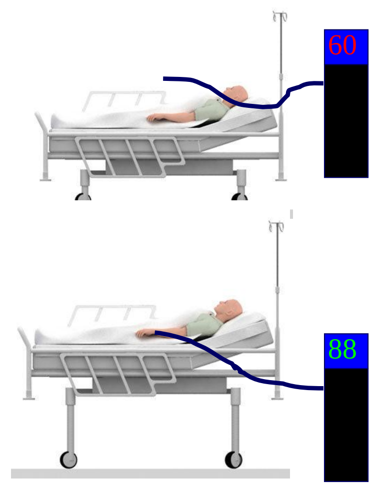
Interference Example: Bed and ABP

A patient's Mean Arterial Pressure (MAP) is measured using a transducer attached to a line in their radial artery. The transducer is mounted next to the patient's bed.

When the bed is raised, the MAP reading increases because the patient is higher than the sensor. The opposite happens when the bed is lowered.

This can mask a problem by making the pressure look OK when it's low, or cause false positive alarms.

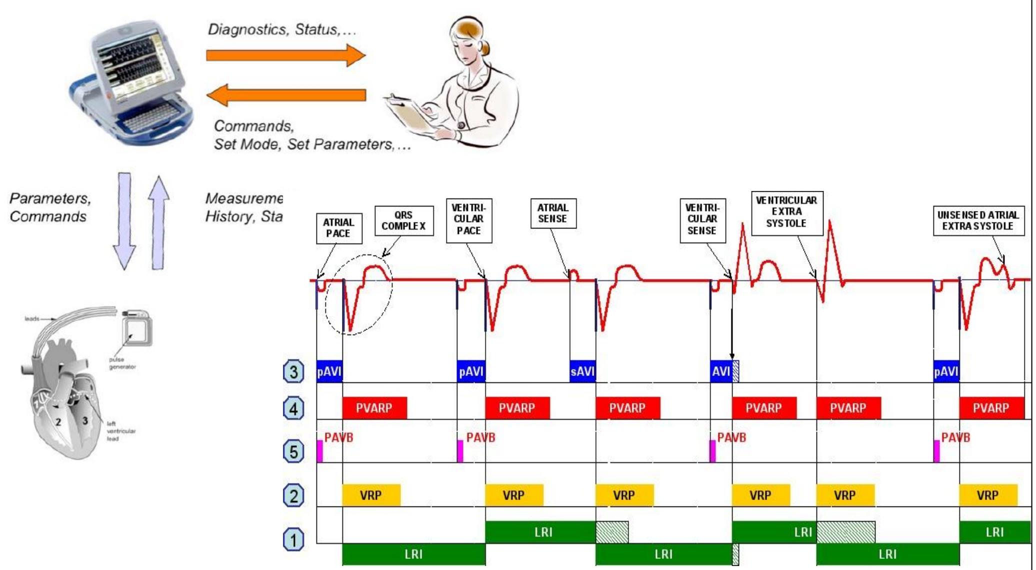
UNH page on MD PnP project:
http://www.ece.unh.edu/biolab/hof/



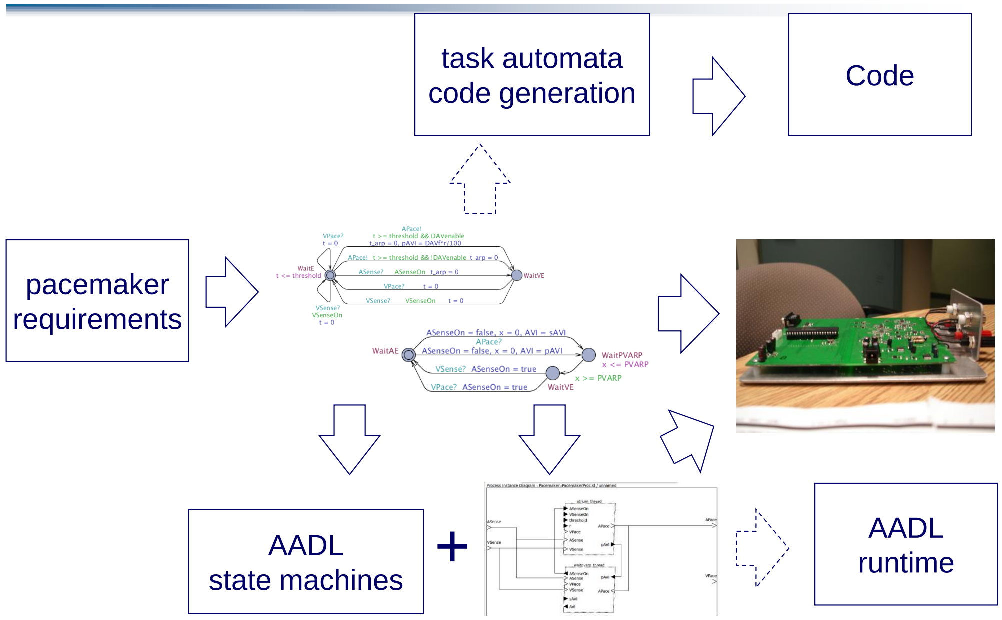
The Pacemaker Challenge

- The formal method challenge problem issued by the Software Certification Consortium (SCC)
- Given:
  - The system specification for a previous generation pacemaker from Boston Scientific
- Goals:
  - From requirements to code
    - Provide a traceable model-based design path from requirements to executable code
    - Evidence that code adheres to the formal models
  - Heart modeling
    - Capture precise but high-level heart operation
    - Provide means of realistic testing
    - Both model and implementation levels

Pacemaker & Heart: Time Driven Systems

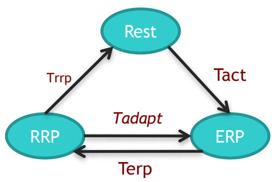


From Requirements to Code (and Back)

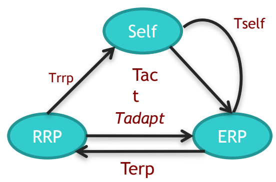


Heart Modeling

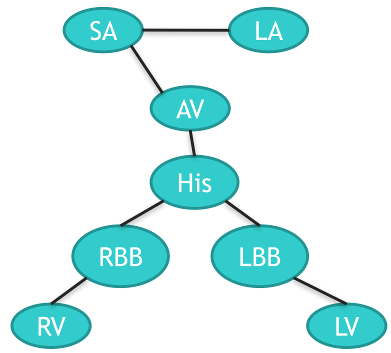
- Goal: simulate electrophysiology of the heart
  - Impulse formation and propagation
  - Response to pacing events
  - Tunable parameters
- Nodal and muscle tissue as timed automata



Muscle tissue element



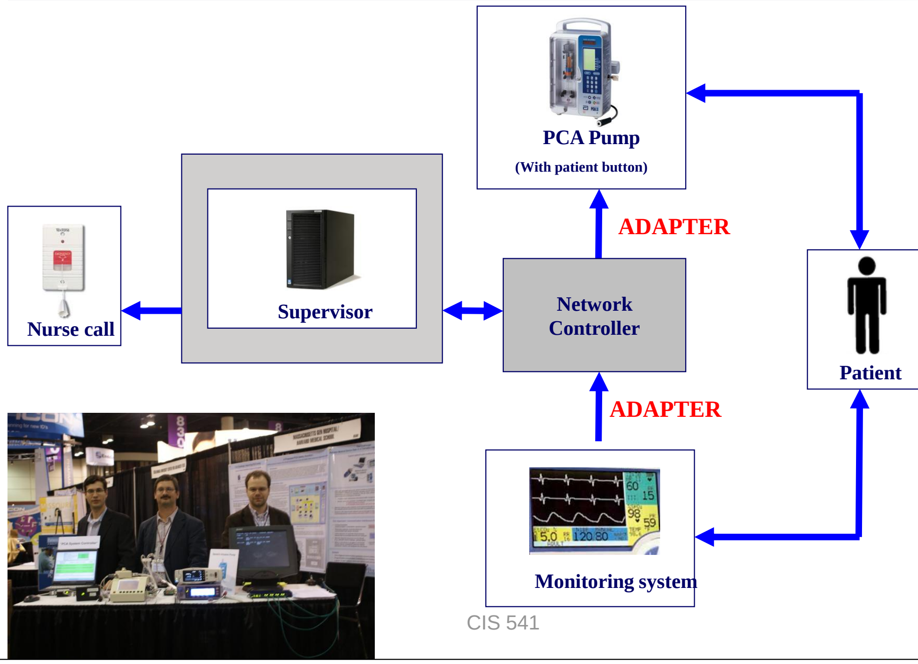
Nodal tissue element



PCA Monitoring: Closing the Loop

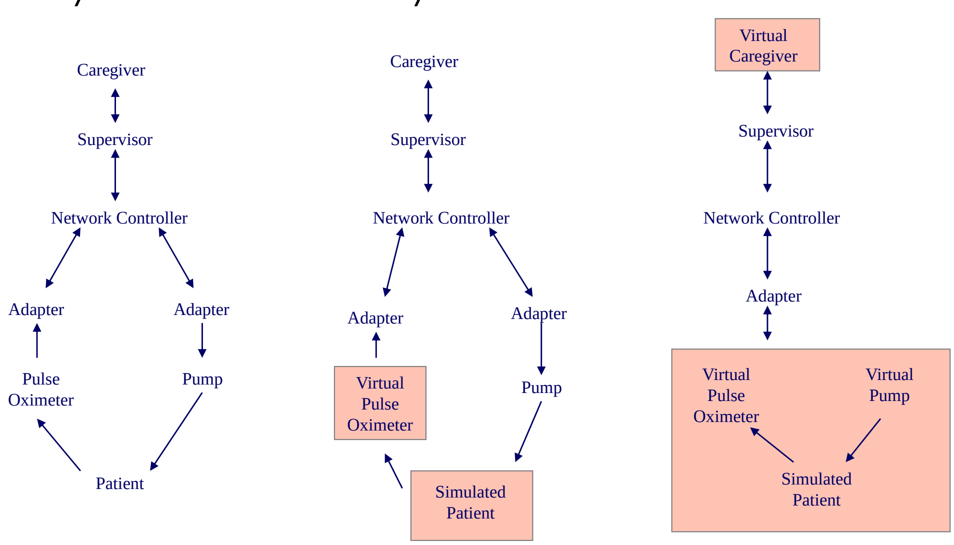
- PCA (Patient Controlled Analgesia) infusion pumps are used to administer pain medications such as Morphine to conscious patients after surgery
- Can we use pulse oximeters and capnometers already in the hospital to monitor PCA opioids?
- Goal: Integrate monitors with an intelligent "controller" to:
  - Detect respiratory disturbance
  - Lock-out infusion
  - Activate nurse-call

PCA Monitoring System



Virtual Medical Device Scenarios

All Physical Devices | Mixed Physical and Virtual | All Virtual Devices



Penn Engineering

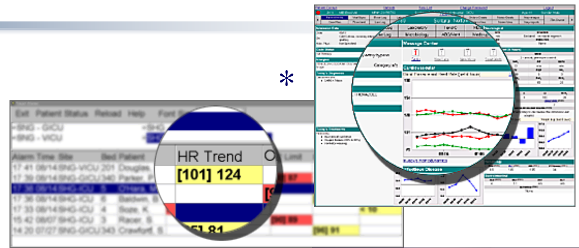
Centralized Monitoring: System of Systems

Applications

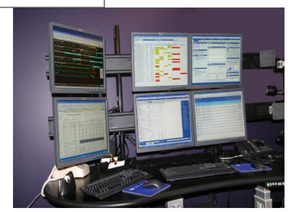
- Hospital based monitoring
- Secondary monitoring infrastructure

Features

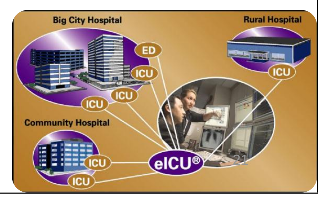
- Patient Care Tools*
  - o Patient Profile
  - o Treatment Plan
  - o Event Log
  - o Physician note-writing capability
- Remote Health Management Tools*
  - o Video-assessment
  - o Remote Bedside Monitoring



- Alerts*
  - Types
    - Patient Status Alerts
    - Care Issue Alerts
    - Process Reminder Alerts
    - Daily Management Reports
  - Patient Parameters monitored include:
    - Heart rate (value, trend)
    - Mean Arterial Pressure (value, trend)
    - Inter-beat Interval (EKG)
    - O2 Saturation



Penn E-lert eICU®

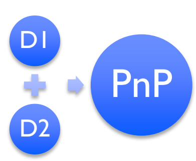


* Source: Visicu Inc.'s eICU system (http://www.visicu.com/products/index.html)

Penn Engineering

Assurance and Certification

- Assurance case
  - o All assurance is based on arguments that justify certain claims based on documented evidence
  - o Two approaches: implicit (standards based), and explicit (goal-based)
- Evidence-based Certification
  - o Certification is a judgment that a system is adequately safe/secure/correct/timely for a given application in a given environment
  - o The judgment should be based on as much explicit and credible evidence as possible
- Incremental certification based on evidence
- Blackbox recorder for medical device



Opportunities for Real-Time Research in HCMDSS

- System integration and interoperability
  - Mixed critical systems, mode change protocols
  - Compositional methods with GoS (Guarantee of Service)
  - Real-time interfaces for components
  - Virtualization
- Model-based development
  - Patient modeling and simulation
  - Closing the loop
  - Modeling of caregivers
  - Resource-aware design
- Adaptive patient-specific algorithms (e.g., smart alarms)
- Incremental validation and certification
  - Evidence based
  - Metrics for certifiable assurance and safety
  - Blackbox recorder

Additional Information

- HCMDSS workshop, 2005 (www.cis.upenn.edu/hcmdss)
- “High-Confidence Medical Device Software and Systems,” Insup Lee et al., IEEE Computer, April 2006, pp. 33-38.
- Joint HCMDSS/MD PnP Workshop, 2007 (www.cis.upenn.edu/hcmdss07/)
- High-Confidence Medical Devices: Cyber-Physical Systems for 21st Century Health Care, NCO/NITRD, Feb 2009
- MD PnP (www.mdpnp.org)
- The edge of medicine: the technology that will change our lives, W. Hanson, M.D., 2008