Assuring the Safety, Security, and Reliability of MDCPS (Medical Device Cyber Physical Systems)

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NSF CPS Large Meeting
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Team members

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- Penn, Sociology, SAS
  - Ross Koppel
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  - Nicholas Hopper
  - Yongdae Kim
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- Waterloo
  - Sebastian Fischmeister
- Collaborators
  - John Hatcliff, KSU
  - Paul Jones, FDA
  - Sandy Weininger, FDA
  - Zhang Yi, FDA

CPS: Large: Assuring the Safety, Security and Reliability of Medical Device Cyber Physical Systems (NSF CNS-1035715)

Affiliated Project:
- Medical Device NIH/NIBIB Quantum Grant: Development of a Prototype Healthcare Intranet for Improved Health Outcomes (PI: Julian Goldman)
Team Composition

- Outreach
  - Powell

- Medical-domain Expertise
  - Goldman, Hanson, Mullen-Fortino, Park, Rich

- Software Reliability
  - Heimdahl, Whalen

- Software and system certification
  - Heimdahl, Lee, Sokolsky

- Sociology, UI, and human factor
  - Koppel

- Security & Trust
  - Kim, Hopper, Lee

- Real-time systems and communications
  - Lee, Sokolsky, Mangharam, Fischmeister

- Modeling and Analysis
  - Alur, Lee, Pappas, Sokolsky

MDCPS Project Goal

- Develop a new development paradigm for the effective design and implementation of MDCPS that are **safe**, **secure**, and **reliable**:
  - A compositional development framework for safe and secure MDCPS
  - Techniques for rigorous evaluation of clinical scenarios, both operational procedures for caregivers and device systems
  - Control-theoretic methods to the design of physiological closed-loop scenarios
  - An approach to evidence-based regulatory approval and incremental certification of MDCPS
Vision of MDCPS

MDCPS Research Projects

- High-confidence medical software systems
  - Model-based development
  - GPCA (Generic Patient-Controlled Analgesia) infusion pump
  - Pacemaker
- Medical device interoperability
  - MDCF/MIDAS, VMD (virtual medical device)
  - Security and Privacy
- Smart alarms & clinical decision support
- Physiological closed-loop systems
- Assurance and Certification
  - Evidence-based certification
  - Blackbox recorder for medical device
Infusion Pump Safety

- During 2005 and 2009, FDA received approximately 56,000 reports of adverse events associated with the use of infusion pumps
  - 1% deaths, 34% serious injuries
  - 87 infusion pump recalls to address safety problems
- The most common types of problems
  - Software Defect
  - User Interface Issues
  - Mechanical or Electrical Failure

U.S. Food and Drug Administration, Center for Devices and Radiological Health. White Paper: Infusion Pump Improvement Initiative, April 2010

GPCA reference implementation

- FDA initiated
  - GPCA Safety Requirements
  - GPCA Model (Simulink/Stateflow)
- Develop a GPCA reference implementation
- Provide evidence that the implementation satisfies the safety requirements
  - Compositional verification
  - Code generation
- Organize evidence for certification
  - Safety cases
  - Confidence cases
- All artifacts to be available as open source
  - http://rtg.cis.upenn.edu/gip.php3

Model-Based Development of GPCA Reference Implementation
The Pacemaker Challenge

• The formal method challenge problem issued by the Software Certification Consortium (SCC)
  – The system specification for a previous generation pacemaker from Boston Scientific

• Goals:
  – Provide a traceable model-based design path from requirements to executable code
  – Evidence that code adheres to the formal models
  – Study assurance case construction for MDD
  – Heart modeling

Methodology for Safe Medical Device Software

Model-Driven Development + Timing Analysis

<table>
<thead>
<tr>
<th>Software life cycle</th>
<th>Requirement analysis</th>
<th>Design</th>
<th>Implementation</th>
<th>Integration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development process</td>
<td>System spec.</td>
<td>(1) Timed automata model of pacemaker</td>
<td>(3) Synthesis</td>
<td>C code</td>
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<td></td>
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<td>(2) Model checking with UPPAAL</td>
<td>compiled into</td>
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<td>Verification and validation process</td>
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<td>(5) Rechecking with Δ</td>
<td>(4) Measurement based timing analysis</td>
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Medical-Device Interoperability

Characteristics

- Medical devices gaining communication capabilities
- Devices still operate independently
- Standardized interaction between devices non-existent
- Full benefit of communication capabilities not being realized

Advantages

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

MD PnP: Interoperable medical devices based on plug-n-play!
Vendor neutrality based on open medical device interfaces

Compositionality Challenge
Virtual Medical Devices (VMD)

- **MD PnP** (initiative for medical devices interoperability) enables a new kind of medical device, a **Virtual Medical Device (VMD)**.
- VMD is a set of medical devices coordinating over a network for clinical scenario.
- VMD does not physically exist until instantiated at a hospital.
- The Medical Device Coordination Framework (MDCF) is prototype middleware for managing the correct composition of medical devices into VMD.

![Diagram of Device Coordination Algorithm + Medical Device Types = Virtual Medical Device (VMD)]

**Device Coordination Algorithm**

- Clinician selects appropriate VMD
- MDCF binds appropriate devices into VMD instance

**MDCF/MIDAS**

- MDCF displays VMD GUI for clinician

VMD Research Issues

- **Real-time support for VMD Apps**
  - Real-time communication infrastructure
  - Pub/sub programming model
  - Support for programming clinical-algorithms with real-time constraints
  - Event driven & Time triggered
  - Guarantee performance specified by VMD App or prevent clinician from instantiating VMD
  - Temporal isolation guarantees

- **MDCF/MIDAS Platform**
  - Device connection protocols
  - Device configuration protocols
  - VMD setup/tear-down algorithm
  - Verify that platform:
    - Correctly implements protocols
    - Instantiation of VMD is safe
    - Non-interference between VMD Apps
    - Runtime verification

VMD App Validation & Verification

- Generate simulation models directly from executable VMD App specification (for validation)
- Export specification to model-checker for verification

Co-Developed with
NSF CNS-0930647 (PI: John Hatcliff)
Medical Device NIH/NIBIB Quantum Grant (PI: Julian Goldman)
Security

- **Motivation**
  - Devices store personal/sensitive health information
  - Devices are wireless with increasing access range
  - Connecting to existing IT infrastructure (Internet) for easy access
  - Use of COTS software which might not be designed with security in mind
  - Physiologic monitors might be vulnerable to interference
  - HIPAA requirements

**Problem Statement and Approach**

- **Problem Statement**
  - Protect medical devices' data and operation from attackers

- **Approach**
  - **FOUR** broad categories of targets to be protected:
    - **Patient**
      - prevent physical harm to the patient
    - **Data**
      - protect patient data privacy/integrity
    - **Device**
      - prevent denial of service and damage to devices
    - **Institution**
      - prevent targeting of medical institution

**Current Work:** Analysis of the ICE Architecture and its variants' communication stack for potential information security vulnerabilities

**Attacker Categories**

- **Operational Categories:**
  - **Passive**
    - Eavesdrop on communication
    - Do not actively engage in the system's operations
  - **Active**
    - Actively engage in the system's operations
    - Can flood, modify, delay, replay information
    - Can physically compromise systems

- **Contextual Categories:**
  - **Insiders**
    - Attackers that are part of the system and have inside information
  - **Outsiders**
    - Attackers that do not belong to the system

- **Cohesiveness Categories:**
  - **Coordinated**
    - Active attacker nodes that work in a coordinated manner to attack a system
  - **Uncoordinated**
    - Lone-wolf
    - Large number of independent attackers
Smart Alarms

- **VMD of multiple devices and central “smart” controller**
  - Filter, combine, process, and present real-time medical information
  - Suppress clinically irrelevant alarms
  - Provide summaries of the patient’s state and predictions of future trends
- **Benefits**
  - Improves patient safety
  - Reduces clinician workload
  - Facilitates practice of evidence-based medicine

**Challenges**
- Filtering and combining data streams from multiple devices (clock synch?)
- Developing context-aware patient models
- Encoding hospital guidelines, extracting experts’ models, learning models statistically
- Presenting data concisely and effectively

G-CDS Architecture

- **Generic Clinical Decision Support Architecture**
  - Modular: flexible and configurable
  - Preprocessing, inference, visualization
  - 3-pronged approach
- **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
  - Vasospasm decision caddy
  - Sepsis early warning system
- **Issues**
  - Simplify design to ease workflow integration
  - Understand and establish safety in these systems
PCA Closed-loop System

- **Goal:** Improve the safety of PCA uses
- **Approach:** Integrate monitors with an intelligent "controller" to:
  - Detect respiratory disturbance
  - Safety lock on over infusion
  - Activate nurse-call

Networked Physiological Closed-Loop Systems

- **Benefits**
  - Improved patient safety
  - Improved clinical outcomes
  - Reduced deployment cost
    - Networking existing medical devices

- **Clinical Use Cases**
  - Closed-loop PCA
  - Closed-loop Blood Glucose (BG) Control
  - Ventilator weaning procedure

- **Challenges**
  - Hazard identification and mitigation
    - Network packet delay/drop, sensor disconnection, out-of-sync between controller and devices
  - System modeling and analysis
    - Hybrid (continuous physiology + discrete controller) system simulation & formal verification
## Certification

- In the U.S., FDA approves medical devices for specific use
  - Safety and effectiveness are assessed
  - Evaluation is process-based: ISO 9001 (quality management) and ISO 14971 (risk management)
  - FDA's 510(k) requires "substantially equivalent" to devices on the market

- Process standards are just one part of the picture
  - Evidence about the product should play a larger role, which provides a reasonable assurance of safety and effectiveness

- Certification of interoperable medical devices in MDCPS
  - Currently, each collection of interconnected devices is a new medical device to be approved. Unsustainable!
  - Can we approve virtual medical devices or clinical scenarios?

## Assurance and Certification

- In search of an evidence-based regulatory regime
  - Assurance cases have been suggested as the basis for evidence-based certification
    - Means of organizing argument
    - Goal-Structured Notation
  - Assurance cases
    - Safety cases
    - Confidence cases
    - Security cases
  - Industry day on assurance cases for medical devices, U. Minnesota, July 28, 2011
  - Incremental and compositional assurance and certification
Compositional Certification?

- A collection of interconnected medical devices is a new medical device
  - Reuse assurance cases for individual devices and concentrate on safety of interconnection?

- Interoperability enables *ad hoc* device assemblies
  - Approve clinical scenarios and interoperability infrastructure?

Life Data Recorder

- Life Data Recorder (LDR)
  - Blackbox for medical device
  - Proposed by FDA researcher
  - Preliminary prototype design for evaluation
  - Highly configurable
  - Multiple purposes
  - Compact data format design
  - Adaptation to existing or new devices

- Trade-offs and Challenges
  - Timing uncertainty
  - Space limitation
  - Interleaving information about events unknown
  - How to check if a system property is true?
  - How to capture and analyze interactions between medical devices?
Posters during lunch

- Safety-Assured GPCA Reference Implementation
- From Verification to Implementation: A Model Translation Tool and a Pacemaker Case Study
- Closed-Loop Pacemaker Testing and Verification Test-Bed Real-Time Heart Model on a Chip
- Middleware Assurance Substrate
- Medical Device Dongle: An Open-Source Standards-Based Platform for Inter-operable Medical Device Connectivity
- Model-Driven Safety Analysis of Closed-Loop PCA Systems
- Modeling and Analysis of Closed-loop Glucose Control Systems
- A Safety Case Pattern for Model-Based Development Approach
- Life Data Recorder and Three-Valued Runtime Checking Semantics

On-going Collaborative Projects

- GPCA (Generic Infusion Pump)
  - Lee, Jones, Whalen, Koppel
- Pacemaker
  - Alur, Mangharam, Heimdahl, Lee, Sokolsky
- Infrastructure of MD PnP (MIDAS, MDCF, RT communication, security)
  - Lee, Goldman, Hatcliff, Fischmeister, Kim, Hopper
- Smart Alarms and Clinical Decision Support
  - Lee, Mullen-Fortino, Park, Lee, Koppel
- Closing the loop
  - Pappas, Lee, Sokolsky, Mangharam, Goldman, Mullen-Fortino, Park
- Assurance cases
  - Sokolsky, Heimdahl, Lee
Collaboration & Outreach

• Collaboration
  – Regular virtual meetings
    • Biweekly meetings
  – Regular physical meetings
    • Exchange of researchers, students
    • CPSWeek 2011,
    • Joint workshop in HCMDSS/MDPnP 2011
• Outreach
  – Minnesota Summer software symposium
  – Healthcare IT (Cerner) and medical device industries (St Jude, Medtronic, Boston Scientific)
  – Interaction with FDA approval process
  – Research exchange with S. Patek, J. Lach, J. Stankovic at Virginia
  – Collaboration with U. Mass, Amherst and South Carolina on medical device security

More Outreach Activities

• Co-Chair, joint workshop on High-Confidence Medical Device Software & Systems and Medical Device Plug-n-Play, CPSweek 2011
• Co-Chair, Analytic Virtual Integration of CPS Workshop, RTSS 2011
• Demonstrated Real-Time Heart Model at CPSWeek Demos
• Talk Modeling and verification of embedded software at Programming Languages Mentoring Workshop, POPL, Jan 2012 (Audience: 150 students from undergrads at community colleges to PhD students at research universities)
• Co-Program Chairs, ICCPS 2011, CPSWeek 2011
• Co-General Chairs, ICCPS 2012, CPSWeek 2012
• Co-Organizer, Workshop on Systems of Systems of Medical Devices, SoSMD 2012
• Chair, CPSWeek Steering Committee
• Leader, CPS-VO Medical Cyber-Physical Systems
invited/keynote talks

- R. Alur, Formal verification of hybrid system, EMSOFT, Taipei, Taiwan, October 2011
- R. Alur, Interfaces for control components, FORMATs, Aalborg, Denmark, September 2011
- M. Heimdahl, Model Based Development (MBD) for Medical Devices: Promises and Pitfalls. LifeScience Alley, Minneapolis, March 2011.
- I. Lee, Medical Cyber-Physical Systems, EU-US Workshop on Networked Monitoring & Control/CPS, Brussels, Belgium, June 2011
- I. Lee, Compositional scheduling and analysis techniques for real-time embedded systems, CPS Day @DGIST, Deagu, South Korea, May 2011
- I. Lee, Medical Cyber Physical Systems, Dept. of Computer Science, Washington University, Dec 2010
- R. Mangharam, Computer Methods for Medical Devices: Validation of Computer with Nonclinical Models, FDA/NHLBI/NSF Workshop, September 2011
- M. Whalen, Proving the Shalls in Practice: Experience with Industrial Formal Analysis, Keynote address at the 19th Annual Requirements Engineering Conference, August, 2011
- M. Whalen, Next-Generation V&V Techniques for Medical Devices, OPAL MedicalDevice Summit, March, 2011

recent publications

More Publications (2011)

• R. Alur, Formal verification of hybrid systems. 11th International Conference on Embedded Software, 2011.
• R. Alur and A. Trivedi, Relating average and discounted costs for quantitative analysis of timed systems. 11th International Conference on Embedded Software, 2011.
• Z. Jiang and R. Mangharam, Modeling Cardiac Pacemaker Malfunctions with the Virtual Heart Model. 33rd Annual International Conference of the IEEE Engineering in Medicine and Biology Society, 2011.

More Publications (2010)

The rest of the day

http://rtg.cis.upenn.edu/MDCPS/2012jan_meeting.html