Medical Cyber-Physical Systems:
Data-Driven Resiliency Assessment and Design

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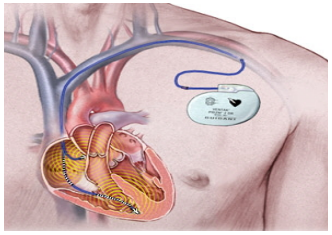
Medical Cyber-Physical Systems

Pacemakers



Insulin Pumps

Wearable Monitors

Patient Monitors

Infusion Pumps

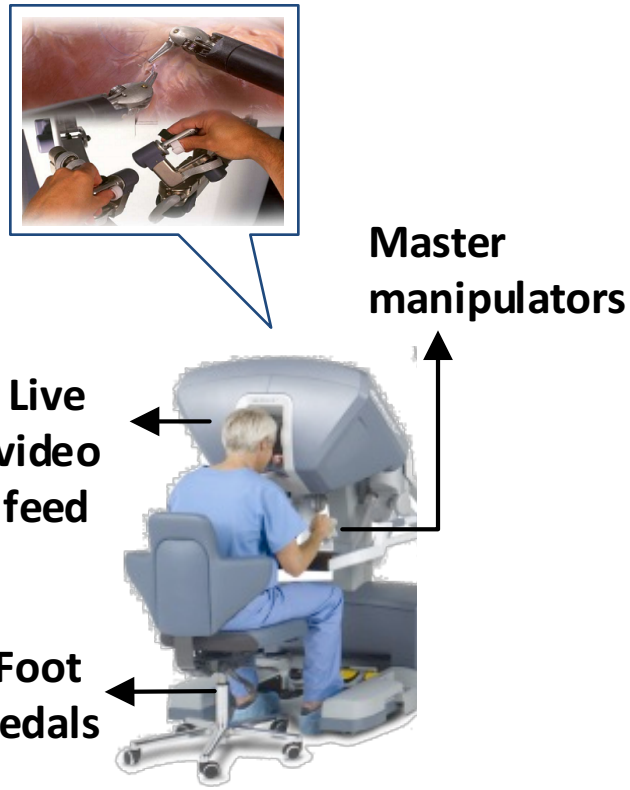
Defibrillators

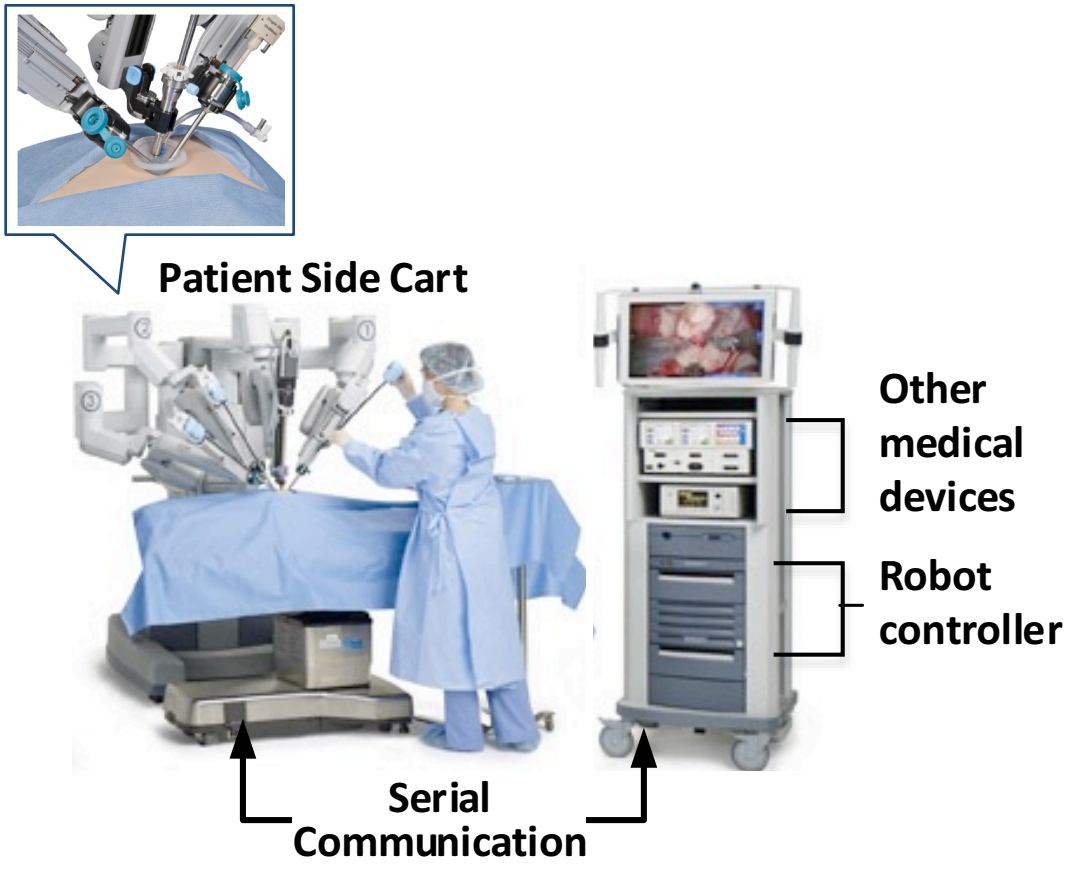
Surgical Robots

Imaging Systems

Linear Accelerators

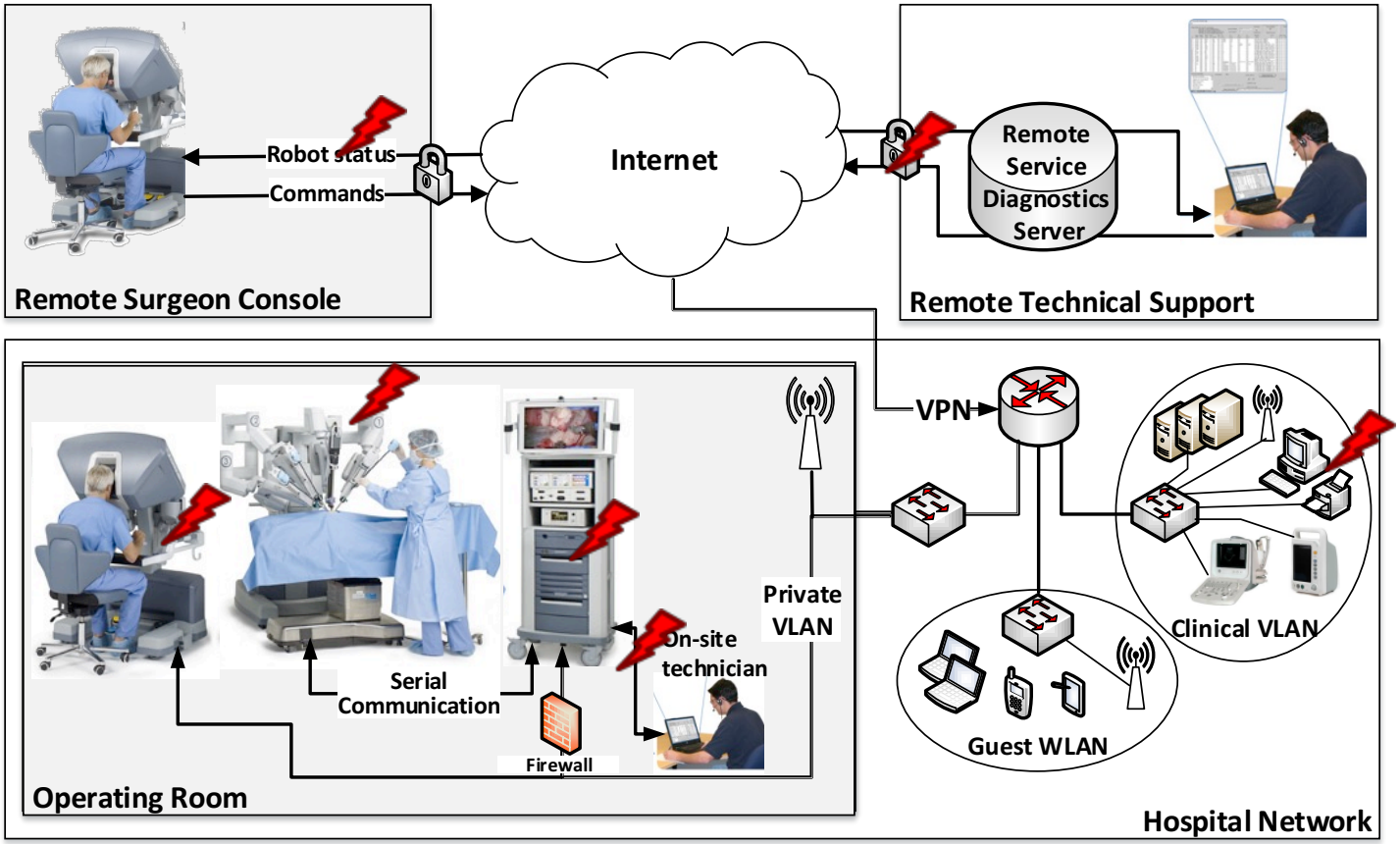
Human-Cyber-Physical Systems





da Vinci Surgical System, Intuitive Surgical, Inc.

Human-Cyber-Physical Systems



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Catastrophic Events

Accidental Failures

GE Healthcare - Telemetry Monitoring Systems
Did not recognize a patient's telemetry rhythm.
Did not alarm a series of ventricular fibrillation events.
Patient Outcome: Death

FDA Adverse Event Report - 2010

Malicious Attacks

Philips Medical Systems – XCELERA Imaging System
Due to a virus infecting several computers at a hospital, the XCELERA software could not be used from time to time.
Potential Patient Outcome: Death, health deterioration

FDA Adverse Event Report - 2009

- **Over 17,000 recalls, more than 18 million devices**
- **2.4 million adverse events, 923K injuries, 49K deaths**

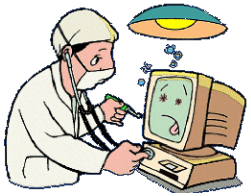
U.S. FDA, 2006-2013

Safety Challenges

- **Causes and impacts of incidents not well studied**
  - **Causal analysis:** HW/SW interactions, physical system dynamics, humans in the loop, and context

- **Safety mechanisms not rigorously validated**
  - **Assessing resiliency** against realistic safety hazards

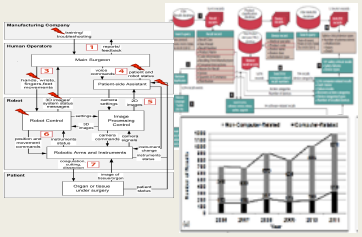
- **Passive monitoring and recovery mechanisms**
  - **Real-time** detection and mitigation of system hazards



- **System operators not well trained for incidents**
  - **Safety training** by hazard simulation

Analyzing Data on Past Safety Incidents

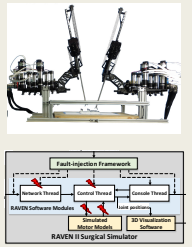
- **Automated analysis** of incident reports
- Systems-theoretic **causality modeling**



IEEE Security & Privacy, 2013
IEEE CBMS, 2014
STS, 2014 (*Memorial Paper*)
PLOS ONE, 2016

Assessing Resilience to Safety Hazards

- Hazard analysis to identify causes for **unsafe scenarios**
- Software fault-injection to **create realistic hazards**

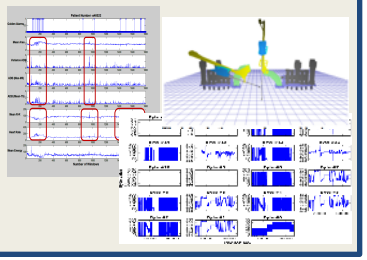


ACS Meeting, 2015
Medical CPS, 2015
SafeComp, 2015
IROS, 2016

Resilient Medical Cyber-Physical Systems

Designing Resilient Systems

- **Real-time detection** and **mitigation** of safety hazards
- **Safety validation** in presence of **accidental failures** or **malicious attacks**



IEEE DSN, 2016
HotSoS, 2016

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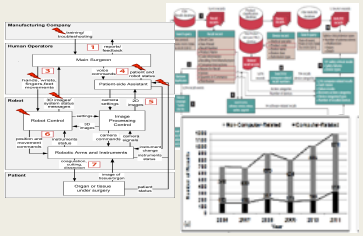

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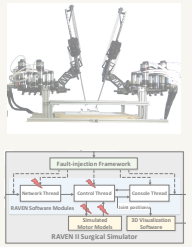

Resilient Medical Cyber-Physical Systems

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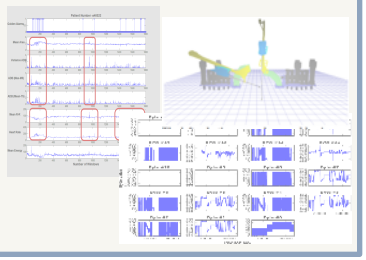
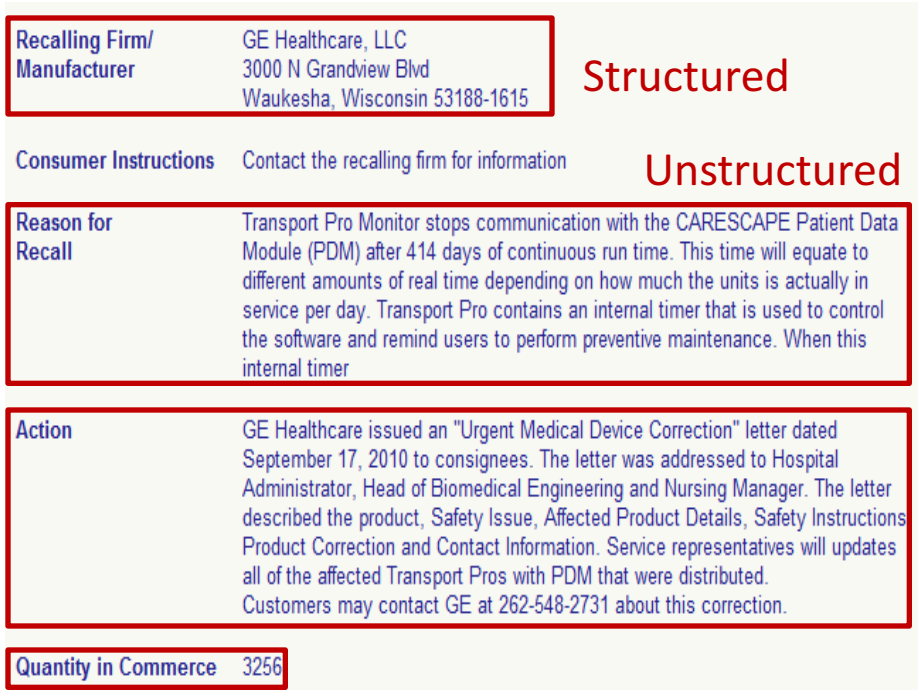


Medical Device Incidents

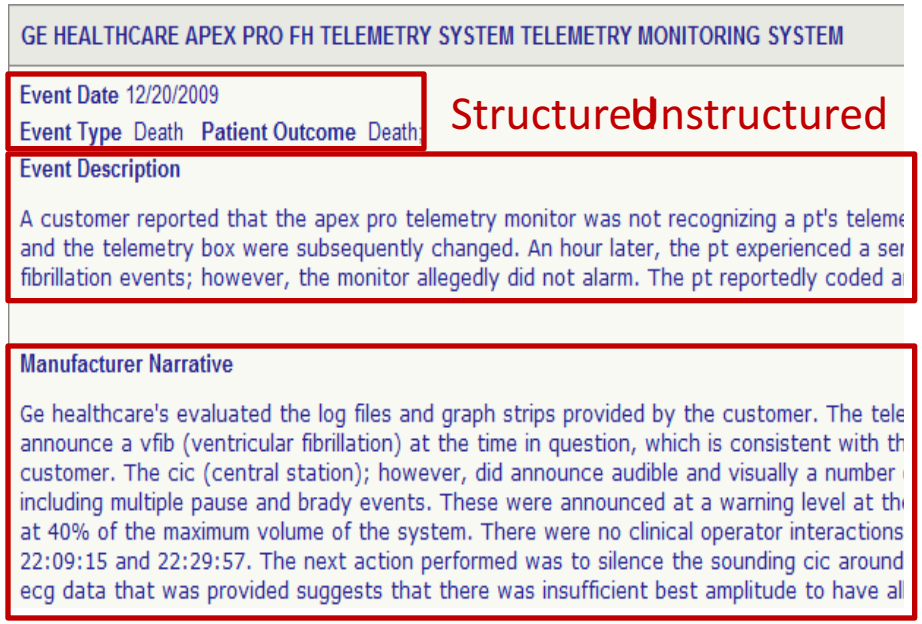
U.S. Food and Drug Administration (FDA)

Recalls: actions to correct/remove defective devices



Recalling Firm/ Manufacturer	GE Healthcare, LLC 3000 N Grandview Blvd Waukesha, Wisconsin 53188-1615
Consumer Instructions	Contact the recalling firm for information
Reason for Recall	Transport Pro Monitor stops communication with the CARESCAPE Patient Data Module (PDM) after 414 days of continuous run time. This time will equate to different amounts of real time depending on how much the units is actually in service per day. Transport Pro contains an internal timer that is used to control the software and remind users to perform preventive maintenance. When this internal timer
Action	GE Healthcare issued an "Urgent Medical Device Correction" letter dated September 17, 2010 to consignees. The letter was addressed to Hospital Administrator, Head of Biomedical Engineering and Nursing Manager. The letter described the product, Safety Issue, Affected Product Details, Safety Instructions Product Correction and Contact Information. Service representatives will updates all of the affected Transport Pros with PDM that were distributed. Customers may contact GE at 262-548-2731 about this correction.
Quantity in Commerce	3256

Adverse Events: deaths, serious injuries, and malfunction reports



GE HEALTHCARE APEX PRO FH TELEMETRY SYSTEM TELEMETRY MONITORING SYSTEM

Event Date 12/20/2009
Event Type Death Patient Outcome Death

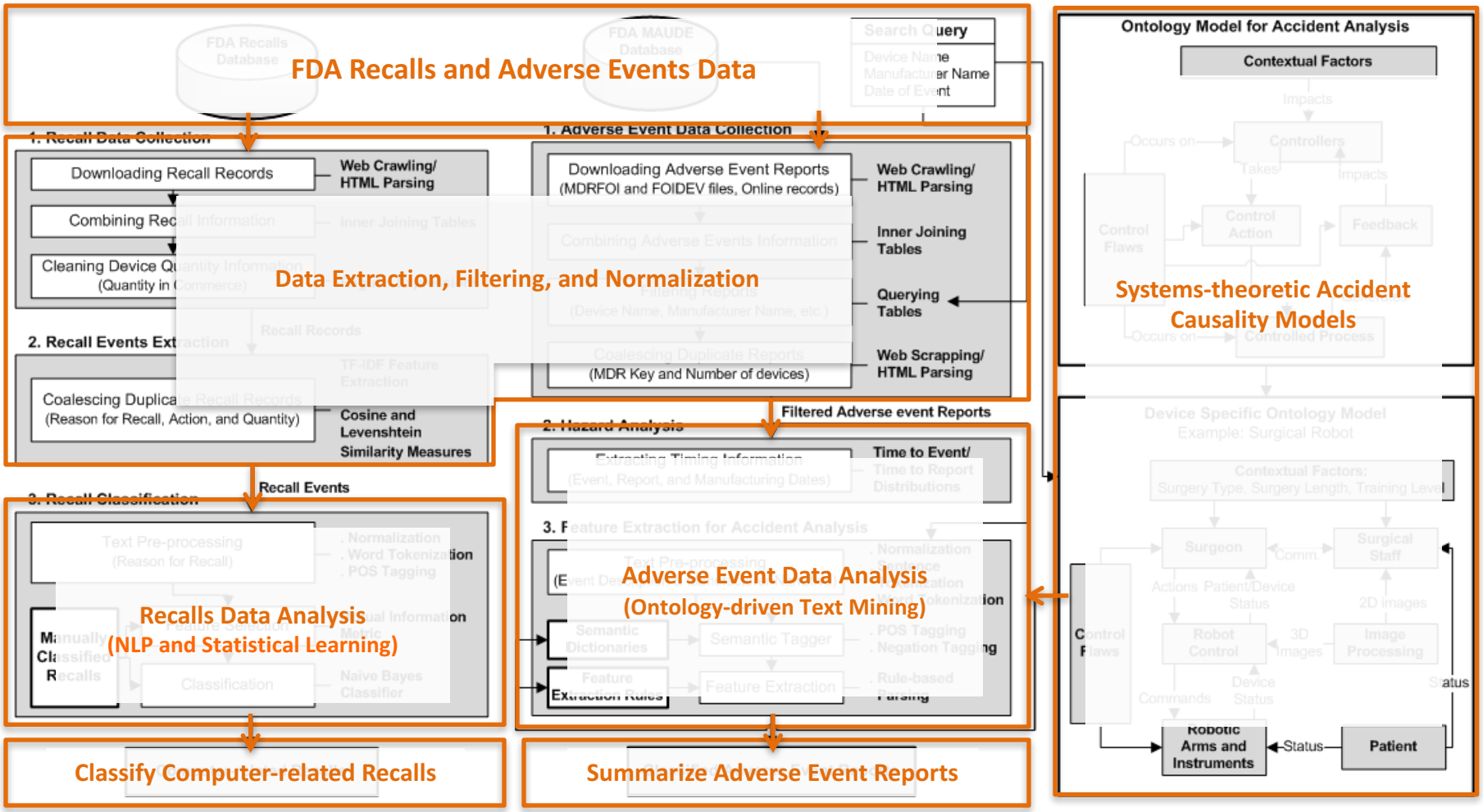
Event Description

A customer reported that the apex pro telemetry monitor was not recognizing a pt's teleme and the telemetry box were subsequently changed. An hour later, the pt experienced a ser fibrillation events; however, the monitor allegedly did not alarm. The pt reportedly coded a

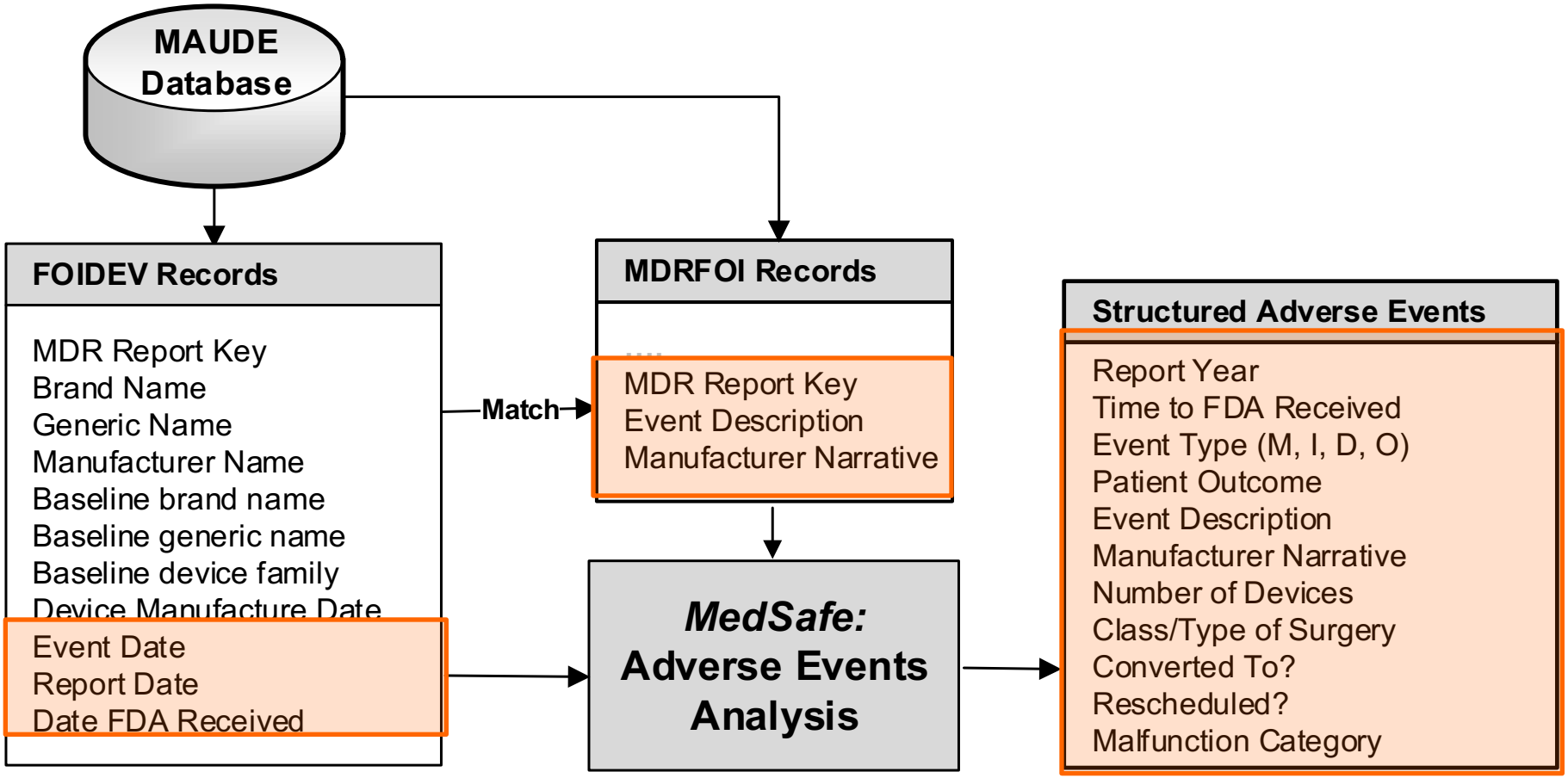
Manufacturer Narrative

Ge healthcare's evaluated the log files and graph strips provided by the customer. The tele announce a vfib (ventricular fibrillation) at the time in question, which is consistent with th customer. The cic (central station); however, did announce audible and visually a number including multiple pause and brady events. These were announced at a warning level at th at 40% of the maximum volume of the system. There were no clinical operator interactions 22:09:15 and 22:29:57. The next action performed was to silence the sounding cic around ecg data that was provided suggests that there was insufficient best amplitude to have al

MedSafe


FDA Recalls and Adverse Events Data
Data Extraction, Filtering, and Normalization
Recalls Data Analysis
(NLP and Statistical Learning)
Adverse Event Data Analysis
(Ontology-driven Text Mining)
Systems-theoretic Accident Causality Models
Classify Computer-related Recalls
Summarize Adverse Event Reports
Ontology Model for Accident Analysis
Contextual Factors
Controllers
Control Action
Feedback
Control Flaws
Controlled Process
Device Specific Ontology Model
Example: Surgical Robot
Surgeon
Surgical Staff
Robot Control
Image Processing
Robotic Arms and Instruments
Patient
Status
1. Recall Data Collection
Downloading Recall Records
Web Crawling/ HTML Parsing
Combining Recall Information
Inner Joining Tables
Cleaning Device Quantity Information
(Quantity in Commerce)
Recall Records
2. Recall Events Extraction
TF-IDF Feature Extraction
Coalescing Duplicate Recall Records
(Reason for Recall, Action, and Quantity)
Cosine and Levenshtein Similarity Measures
Recall Events
3. Recall Classification
Text Pre-processing
(Reason for Recall)
. Normalization
. Word Tokenization
. POS Tagging
Manually Classified Recalls
Classification
Naïve Bayes Classifier
1. Adverse Event Data Collection
Downloading Adverse Event Reports
(MDRFOI and FOIDEV files, Online records)
Web Crawling/ HTML Parsing
Combining Adverse Events Information
Inner Joining Tables
Filtering Reports
(Device Name, Manufacturer Name, etc.)
Querying Tables
Coalescing Duplicate Reports
(MDR Key and Number of devices)
Web Scrapping/ HTML Parsing
Filtered Adverse event Reports
2. Hazard Analysis
Extracting Timing Information
(Event, Report, and Manufacturing Dates)
Time to Event/ Time to Report Distributions
3. Feature Extraction for Accident Analysis
Text Pre-processing
. Normalization
. POS Tagging
. Negation Tagging
Semantic Dictionaries
Semantic Tagger
Feature Extraction Rules
Feature Extraction
. Rule-based Parsing

Adverse Event Data Analysis



Adverse Event Data Analysis

Event Description:

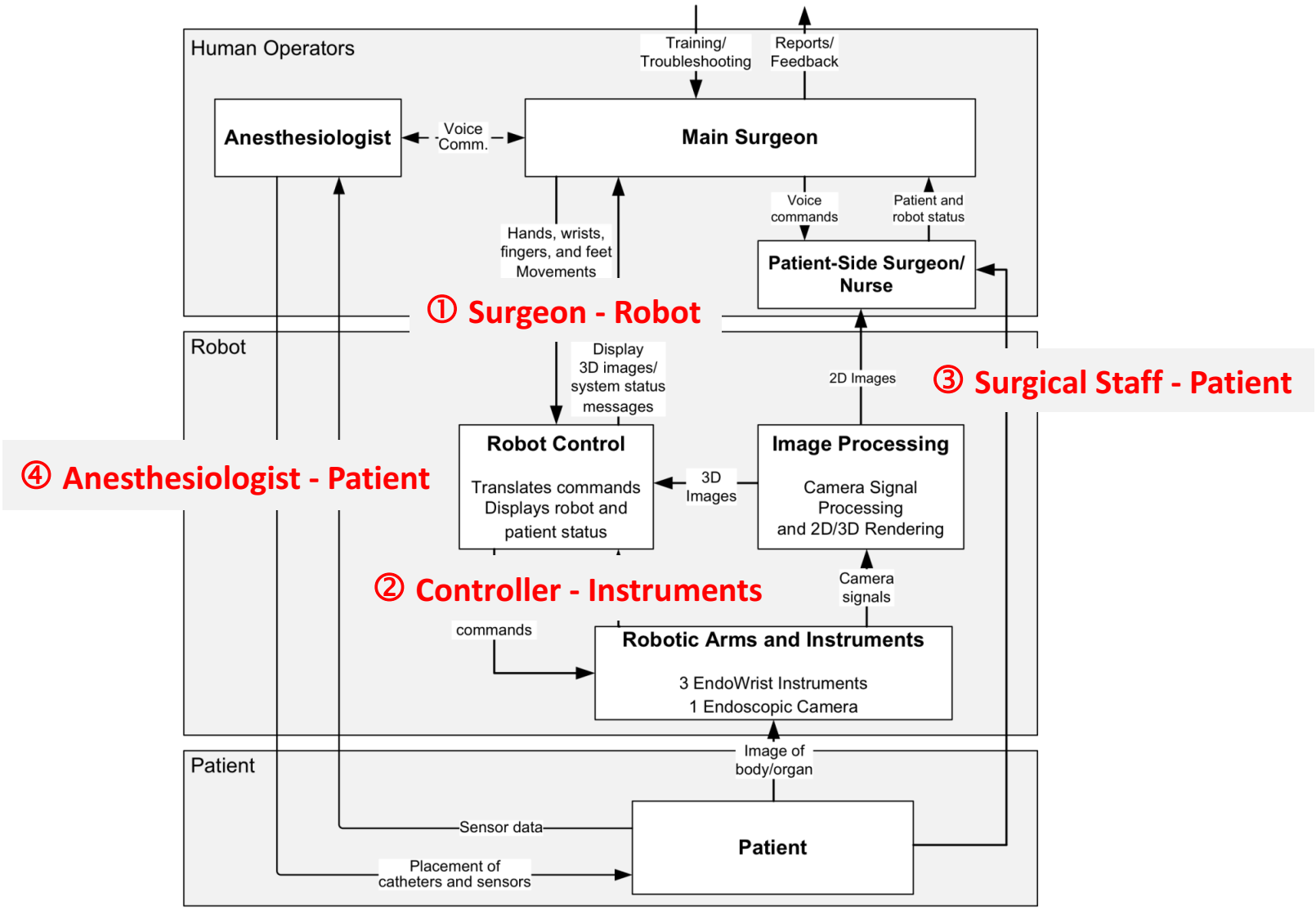
- Surgical robot produced a system error code during a procedure.
- Error reoccurred even after **restating** the system.
- **Surgeon decided** to continue using **manual camera manipulation** for 5-6 hours.
- A loss of carbon dioxide insufflation occurred
- Heart pushed up into the endoscope, **causing lacerations to patient's** right ventricle.
- Procedure lasted for **14 hours**.

Manufacturer Narrative:

Faulty electronics (printed circuit assembly, remote arm controller)
System Error indicating communication failure between modules

FDA MAUDE Report 2240665

Systems-Theoretic Causality Modeling



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FDA MAUDE Report 2240665

Flaws in the control loops

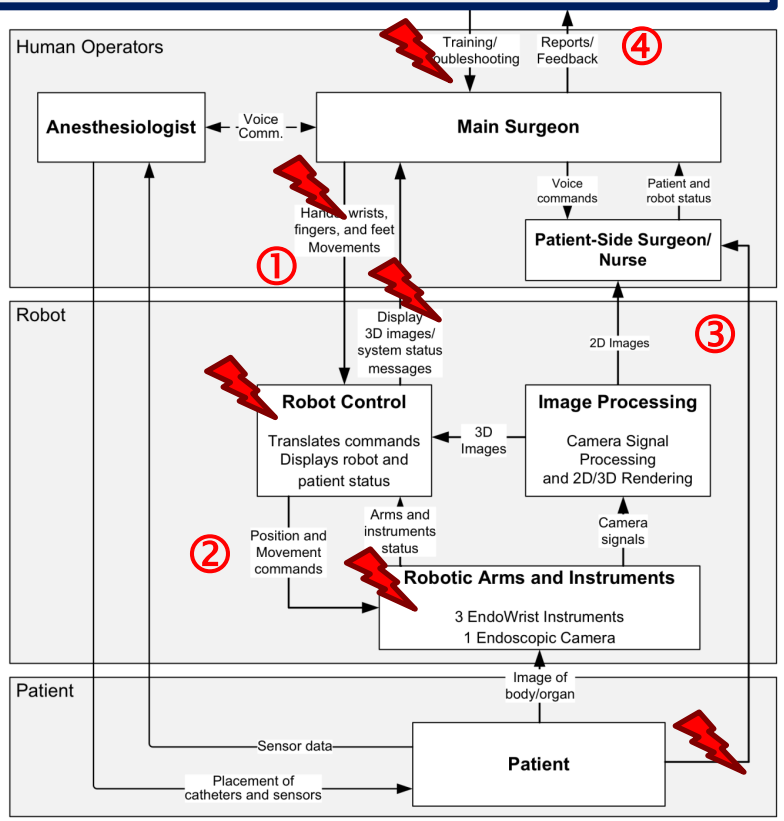
Inadequate feedback to surgeon

Unsafe actions by surgeon

Inadequate support from company

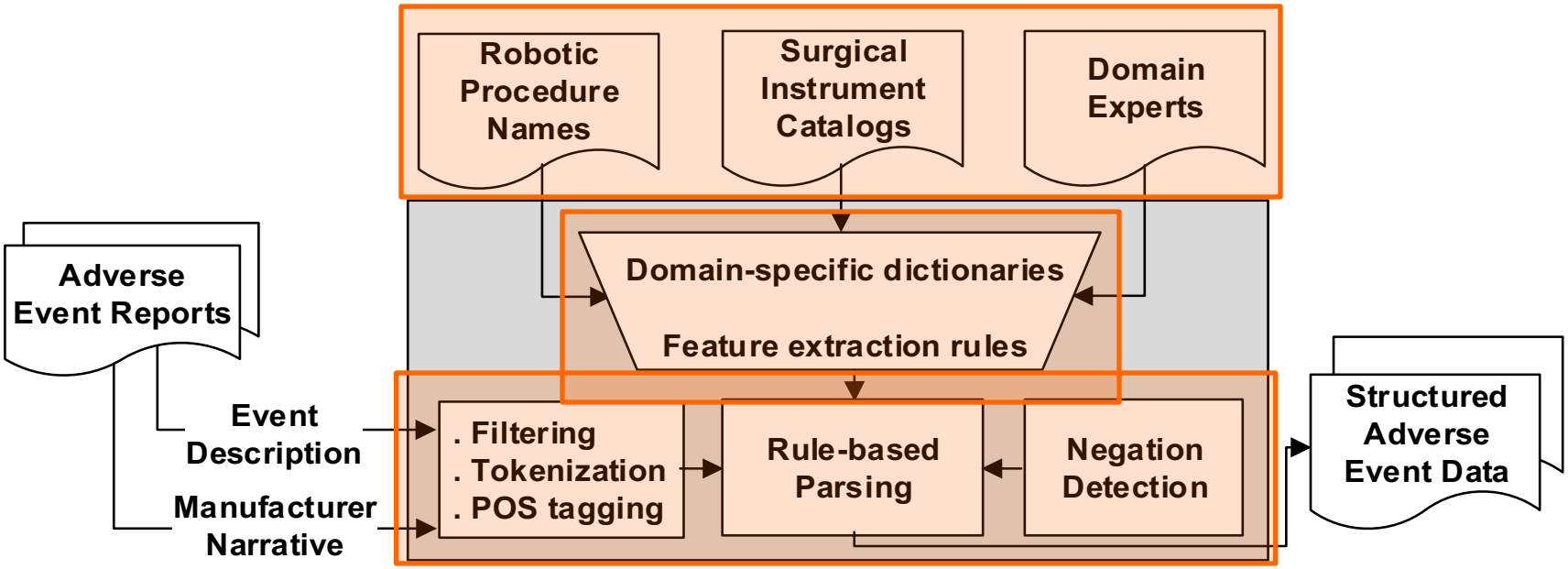
Inadequate feedback on patient status

Robot control and instruments **failures**



Extraction of Safety Features

- **Domain-specific dictionaries:**
  - Surgery types, injury types, instrument names
- **Feature extraction rules:**
  - Patterns of parts-of-speech tags
  - Surgery classes, device malfunctions, operator actions, etc.



Semantic Tagging

- Annotating safety-related roles and relations in the narratives
- Rule-based mapping of annotations to control structure

Feedback (Loop 3)

Faulty Image Processing

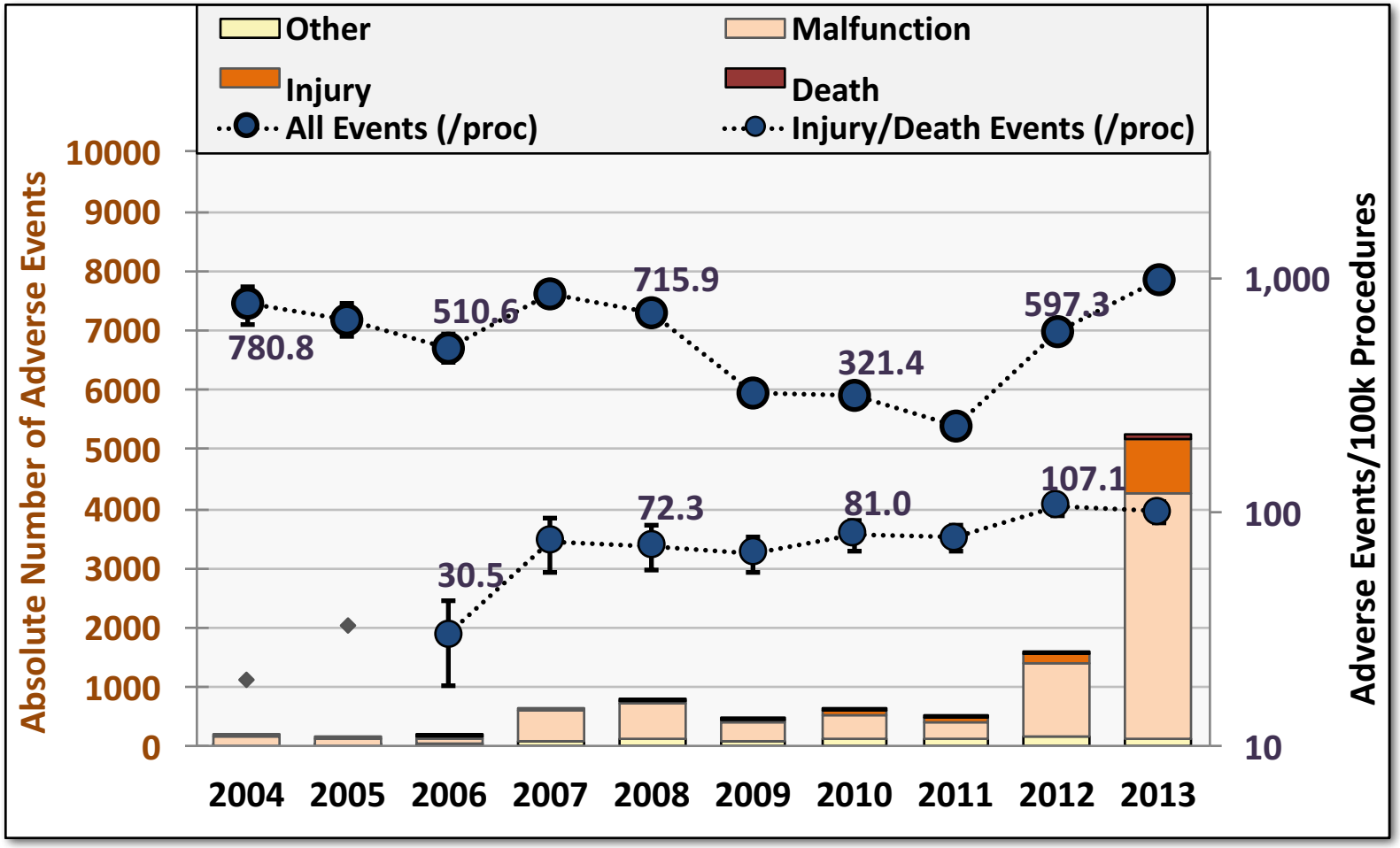
It was reported that approximately **30 minutes into**\Temporal_Information a partial **nephrectomy**\SurgeryType procedure, the right eye **image**\VIDEO in the high resolution stereo viewer went **black**\COND.

Unable to resolve the issue, the **surgeon**\STAFF decided to **convert**\ControlAction to traditional open surgical techniques to complete the planned procedure. **No**\NEGATION **patient**\PT **harm**\INJ was reported.

Control Action (Loop 3)

Not a Patient Injury

Safety Incidents in Robotic Surgery



Featured in Wall Street Journal, MIT Technology Review, BBC, NBC News, Gizmodo, among others.

Device Malfunctions and Patient Impacts

Burnt/Broken pieces of instruments (14.7%):
- Falling into the patient's body, burning, and injury
- Interruption of procedure

Electrical arcing of instruments (10.5%):
- Burning of the tissues/organs under surgery

System errors, Video/imaging problems (7.6%)
- Interruption of procedure

Unintended instrument operation (8.6%)
- Puncture/cut of organ under surgery

Featured in Wall Street Journal, MIT Technology Review, BBC, NBC News, Gizmodo, among others.

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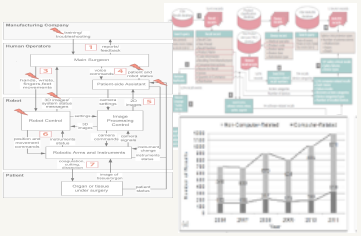
Given an adverse event, ~24% chance of negative patient impact:

- **Injuries and deaths (14.4%)**
- **System resets to troubleshoot technical problems (3.1%)**
- **Conversion to non-robotic techniques (7.3%)**
- **Rescheduling the procedure (2.5%)**

[STS 2014, PLOS ONE 2016]

Analyzing Data on Past Safety Incidents

- **Automated analysis** of incident reports
- Systems-theoretic **causality modeling**



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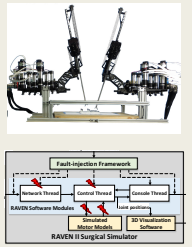

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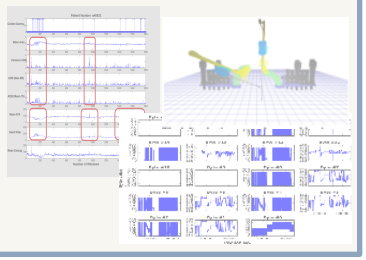
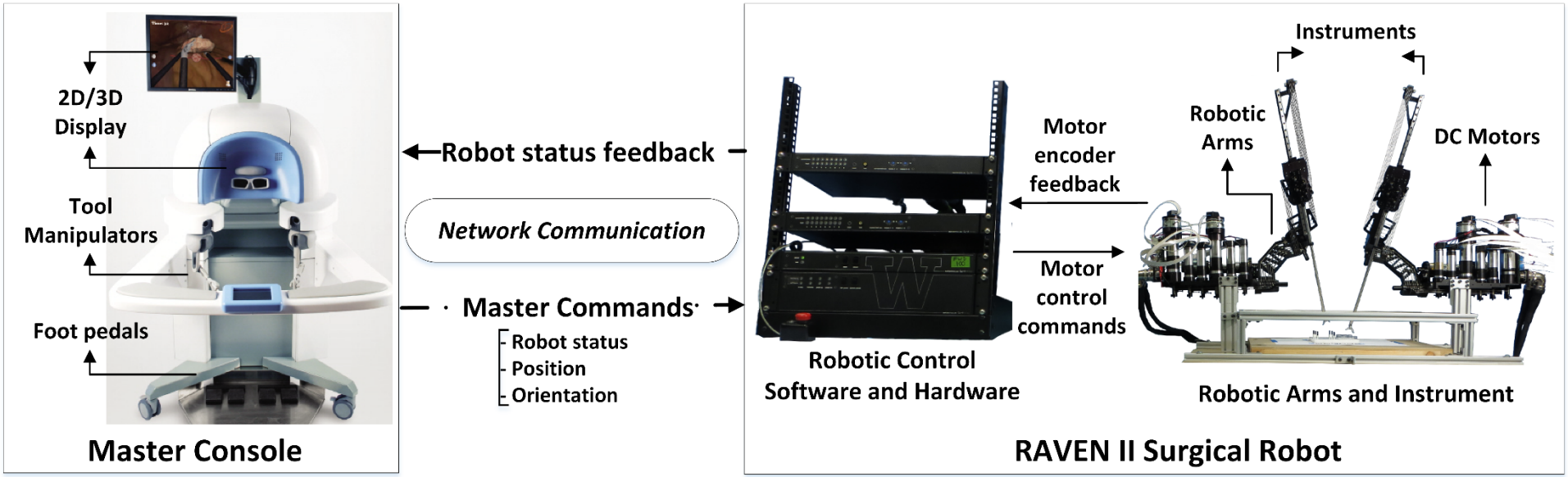
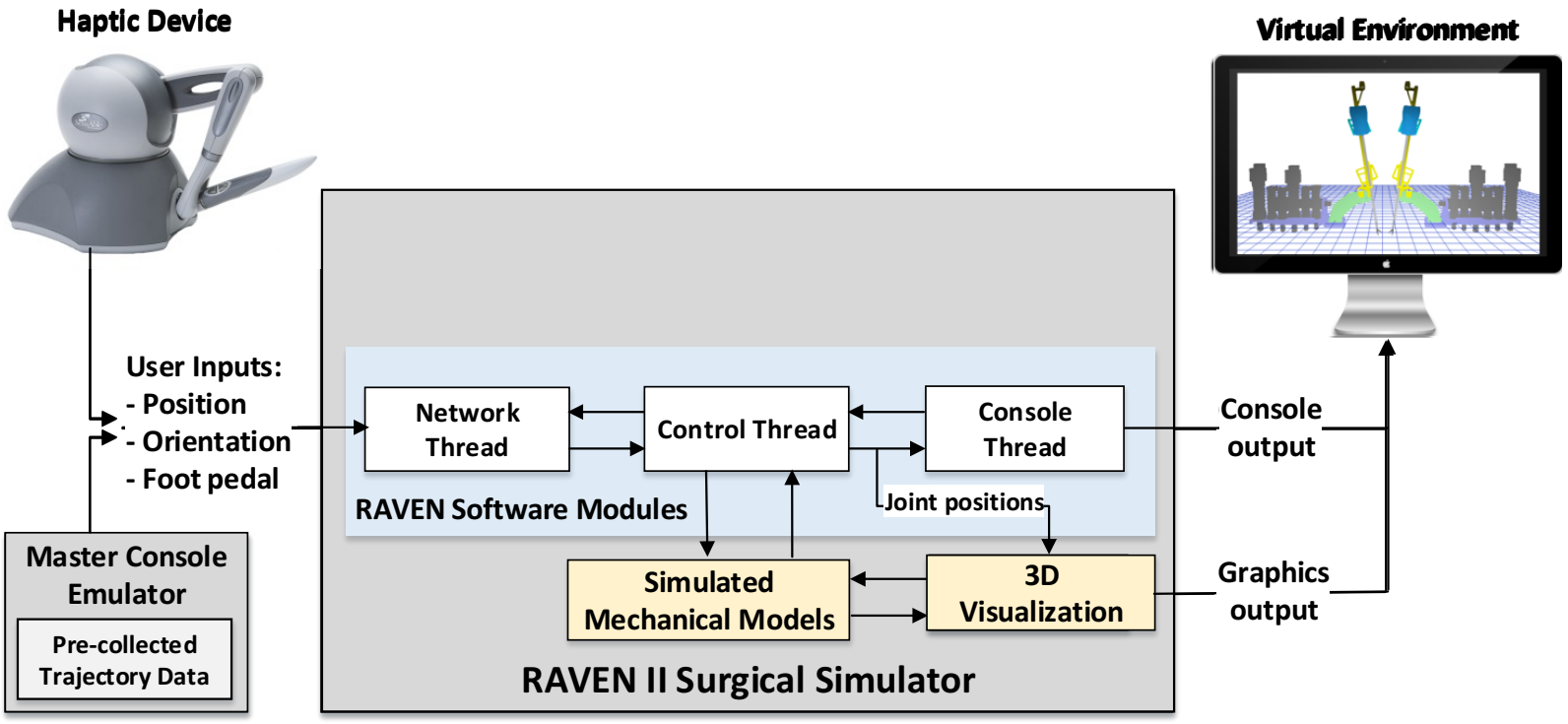


Safety Hazard Simulation



RAVEN II Robot, Applied Dexterity and Biorobotics Lab, University of Washington

Safety Hazard Simulation



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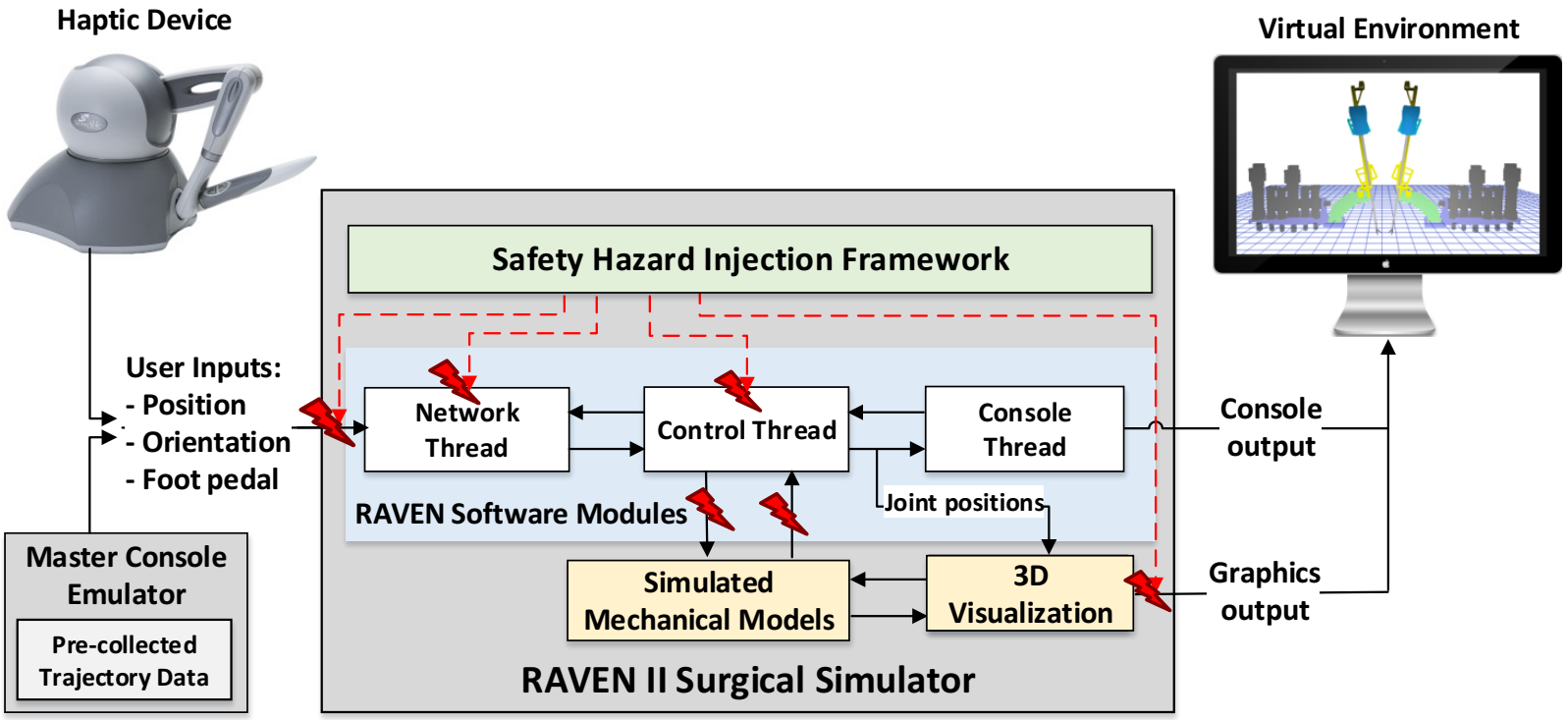
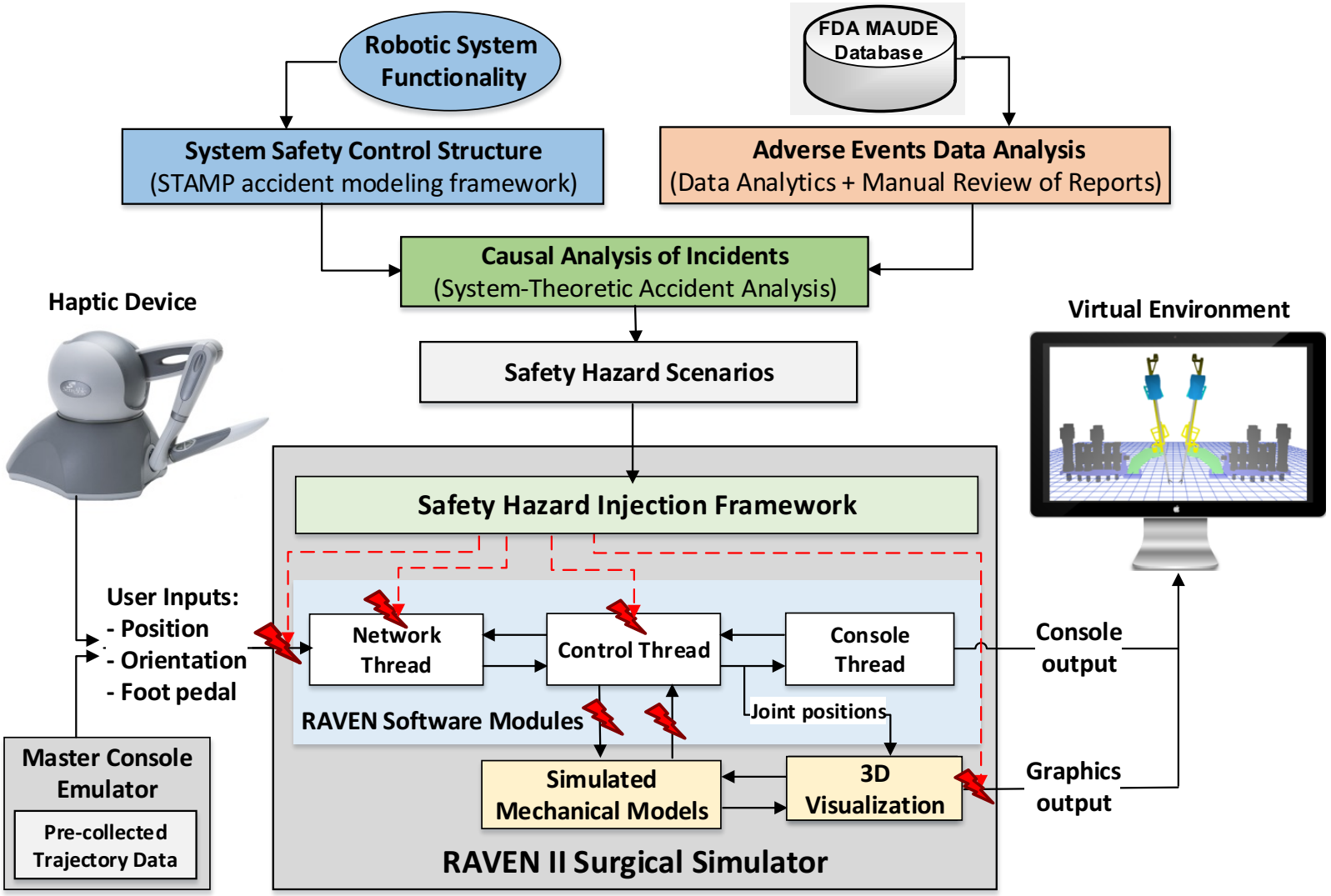


Available at: https://github.com/homa-alem/raven2_sim

Safety Hazard Simulation



Safety Hazard Simulation

Example Unsafe Scenario

Potential hazard: Robot arms will move with an unintended velocity

Unsafe control action: A motor command is ***provided*** by control software, when desired position is at large distance of current position

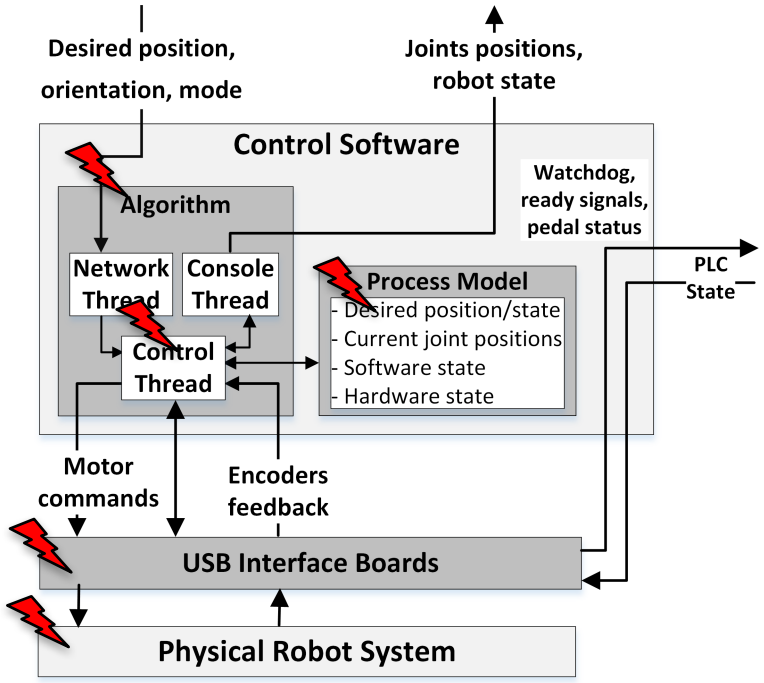
Targeted Fault Injection:

Faulty USB communication

Function: *putUSBPacket*

Variables: *Joints current commands*
[Stuck At Random Value]

Triggers: *robot_state = Homing*
robot_state = Pedal Up

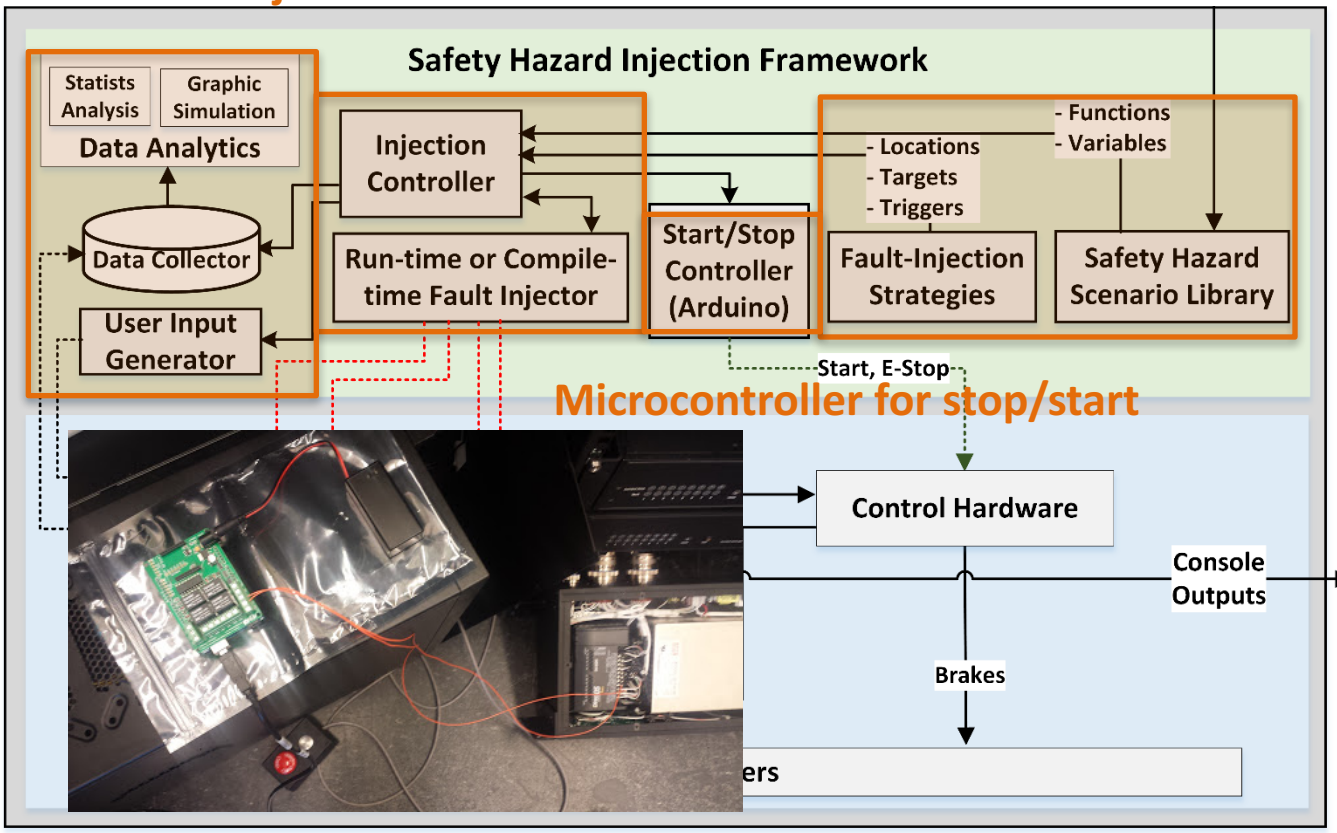


[SafeComp 2015]

Safety Hazard Injection Framework

Fault injectors

Trajectory generator and results analysis



Injection targets

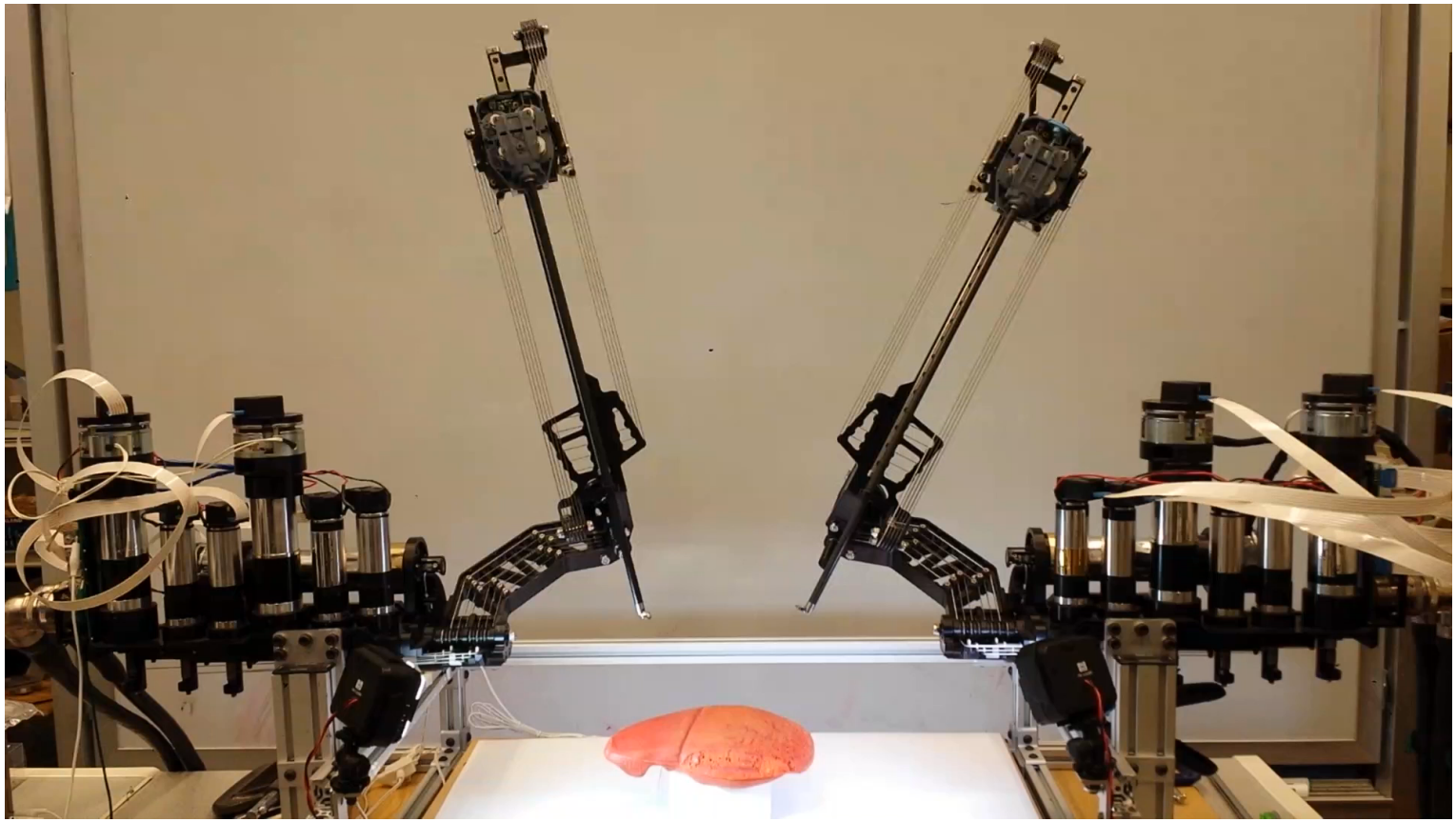
Targeted Fault-Injection

Injected Software Fault *Target Function*: **Variables** **[Fault Type, Values]**	**No.**	**Observed System Behavior**	**Hazard**
network_process: Position and Orientations [Stuck At Out of Range]	20	During Homing: No impact After Homing in Pedal Down: IK-failure, small jumps, no movements with no E-STOP, E-STOP	H1 H3
network_process: Foot Pedal Status [Stuck At 0, Stuck At 1]	20	During Homing: No impact After Homing: Does not start movement if Stuck At 0, No impact if Stuck at 1.	

- Emulated 45 safety scenarios by injecting faults to RAVEN II control software
- Injected single functional faults within 13 software functions
- A total of 368 targeted fault-injections
- Each scenario repeated > 10 times to validate the observed behavior

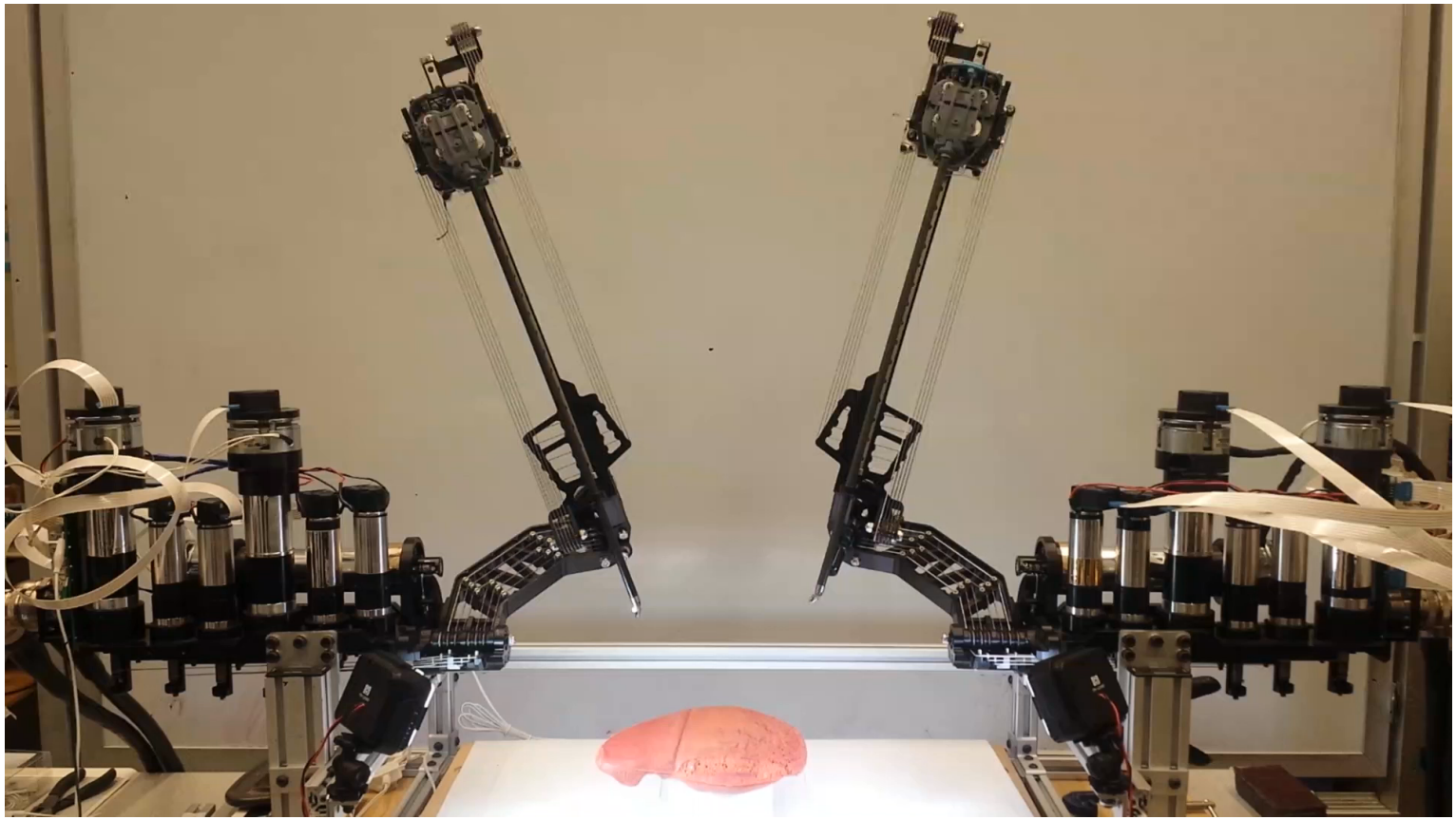
Safety Hazard Simulation

Abrupt Jump



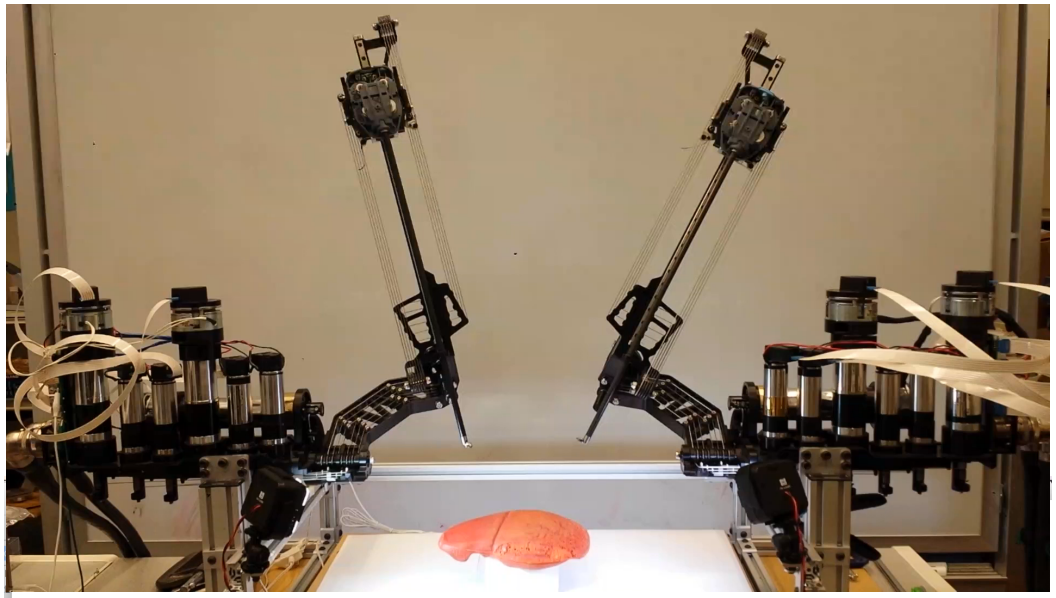
Safety Hazard Simulation

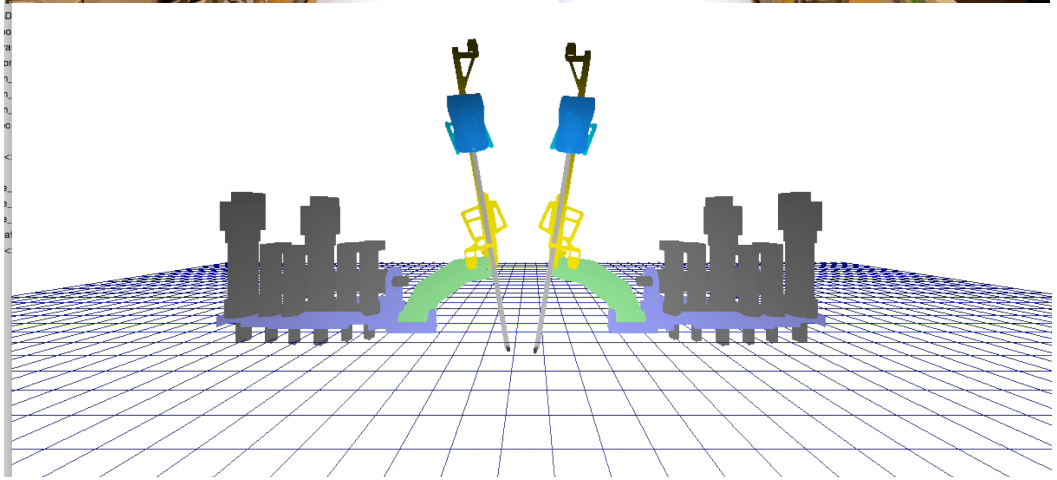
Homing Failure



Safety Hazard Simulation

Safety Validation



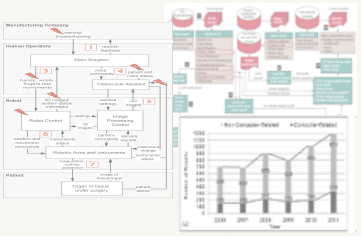


Safety Training

[MedicalCPS 2015, IROS 2016]

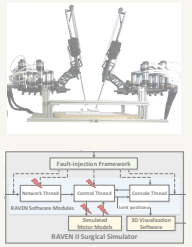
Analyzing Data on Past Safety Incidents

- **Large-scale analysis** of incident reports
- Systems-theoretic **causality modeling**



Assessing Resilience to Safety Hazards

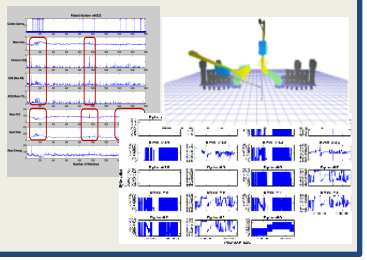
- Hazard analysis to identify causes for **unsafe scenarios**
- Software fault-injection to **create realistic hazards**



Resilient Medical Cyber-Physical Systems

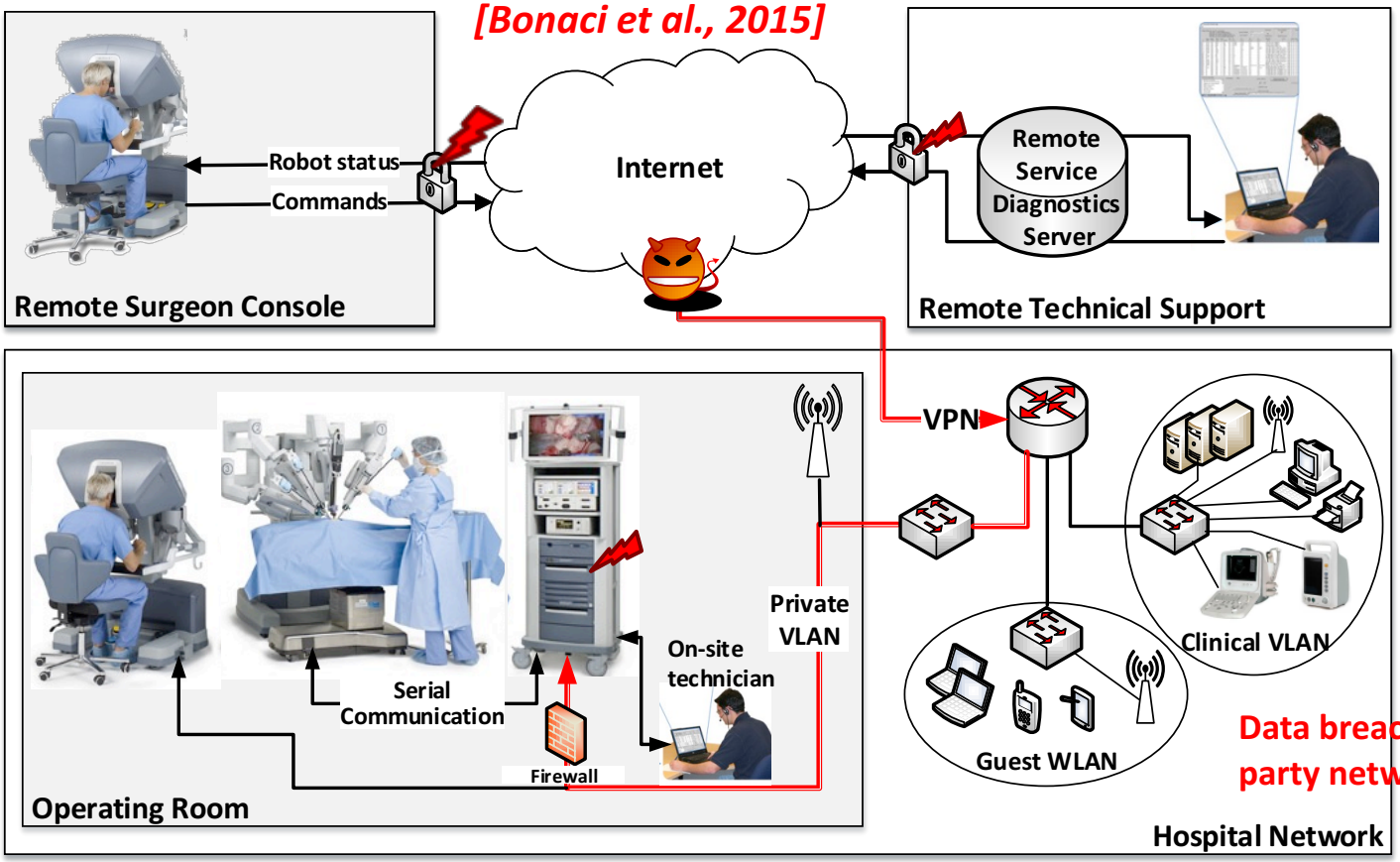
Designing Resilient Systems

- **Real-time detection** and **mitigation** of safety hazards
- **Safety validation** in presence of **accidental failures** or **malicious attacks**



Attacks on Surgical Robots

DOS and MITM Attacks
[Bonaci et al., 2015]



Email phishing attacks, 2014

Passwords of office devices, 2014

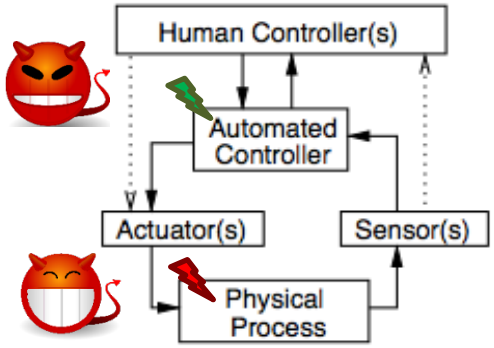
Medical devices, 2015

Data breach through 3rd party networks, 2015

Attacks on robot control system *[DSN 2016]*

Safety-Critical Cyber-Physical Attacks

- **Initiated in cyber domain, launched in physical layer**
  - Installs a self-triggered malware
  - Exploits vulnerabilities in OS or control software
  - Analyzes system activity to infer a *critical time*
  - Injects maliciously-crafted commands

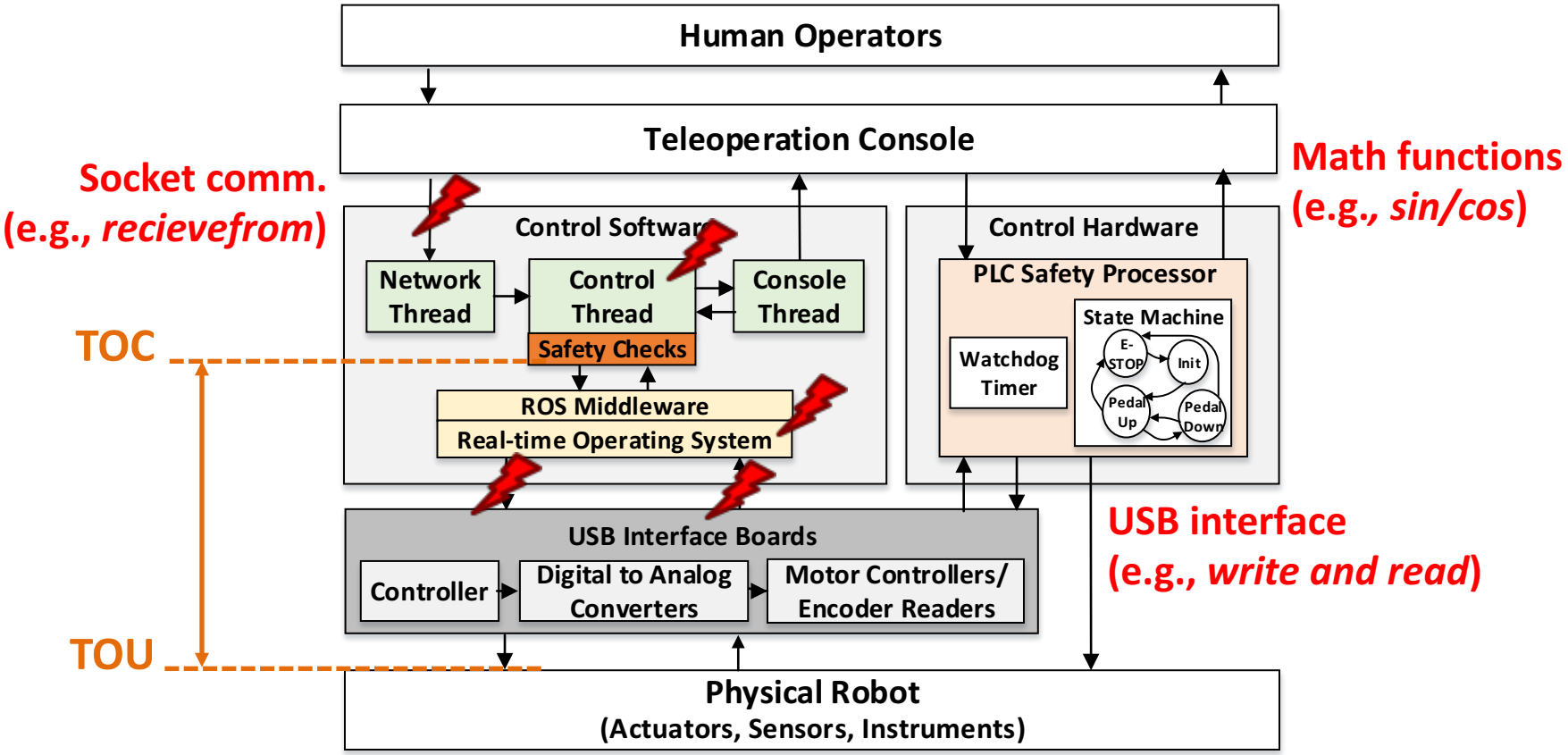


- **Directly result in violation of safety constraints and catastrophic impact in physical domain:**
  - Damage the physical system or harm the patient

- **Hard to distinguish from accidental failures and human errors**

Vulnerabilities in Control System

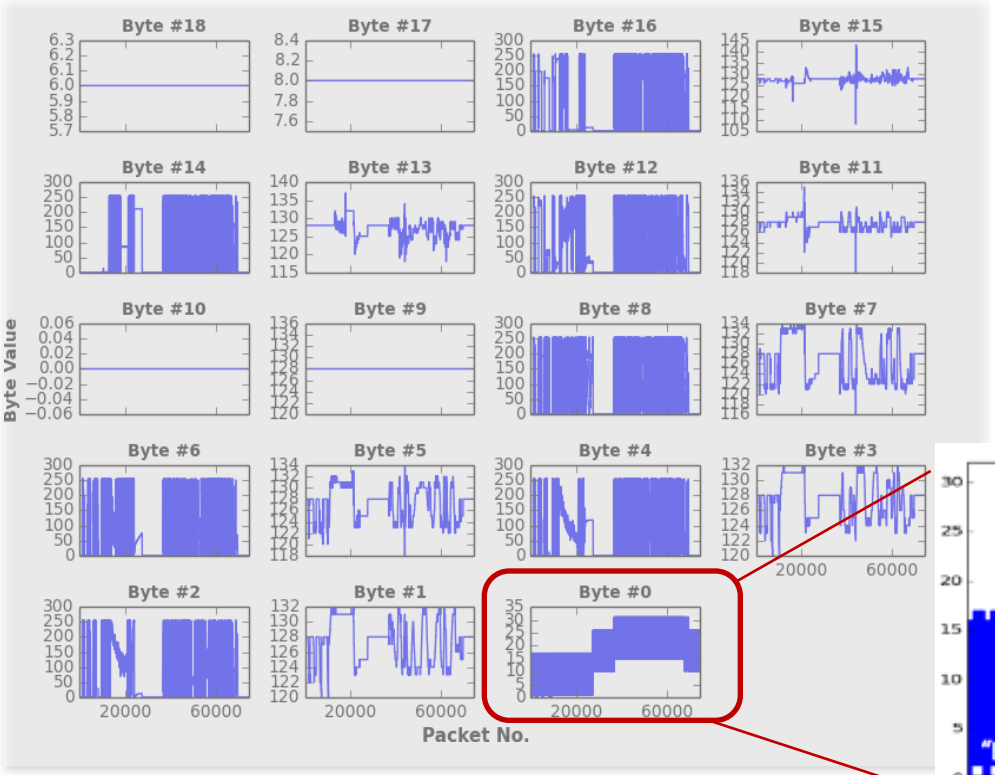
- Time of Check To Time of Use (TOCTTOU) gap
- Dynamic loading of system libraries



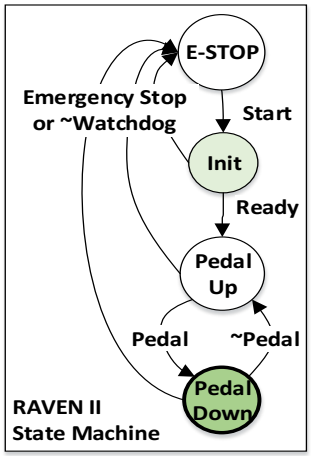
Vulnerabilities in Control System

- Leaking of state information from the communication links

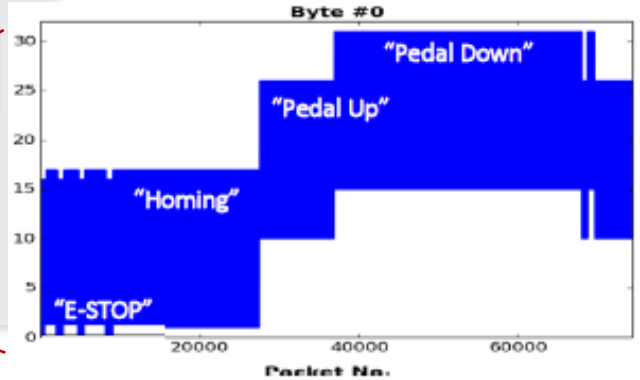
Real-time data



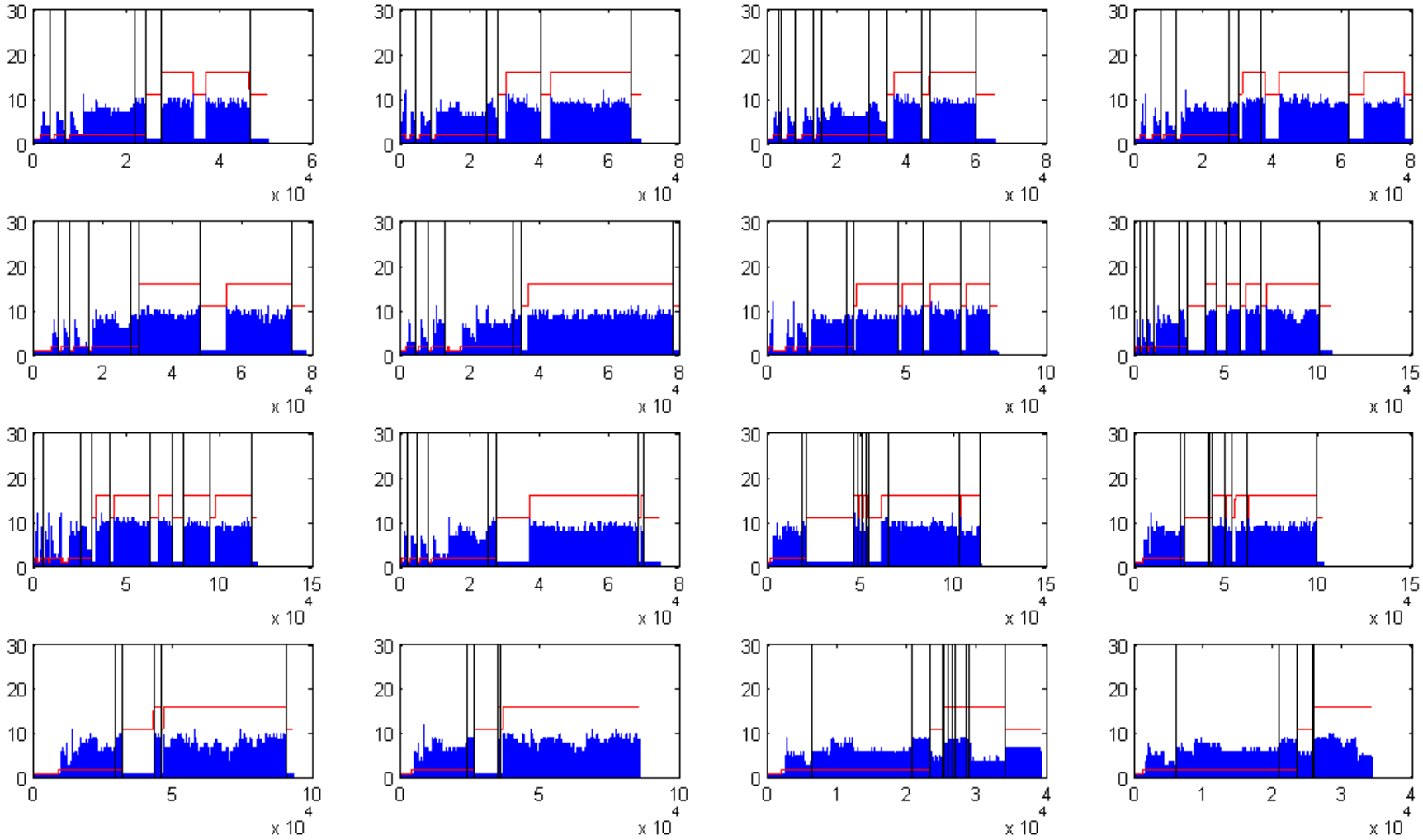
Public documents



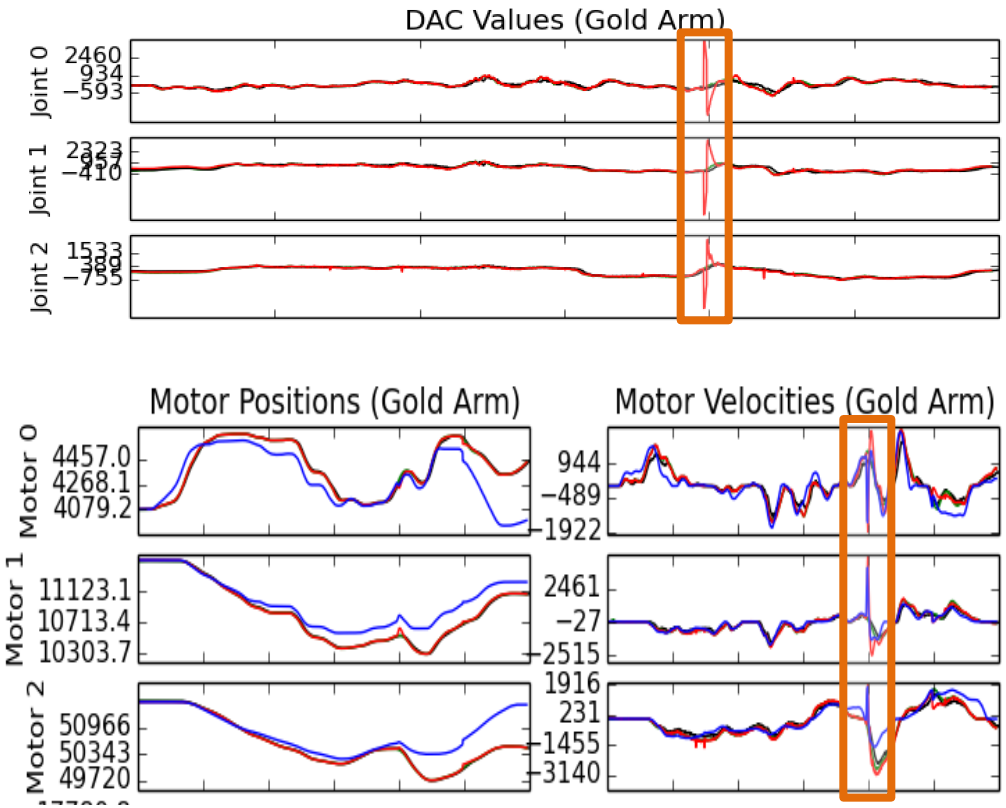
Infer robot state



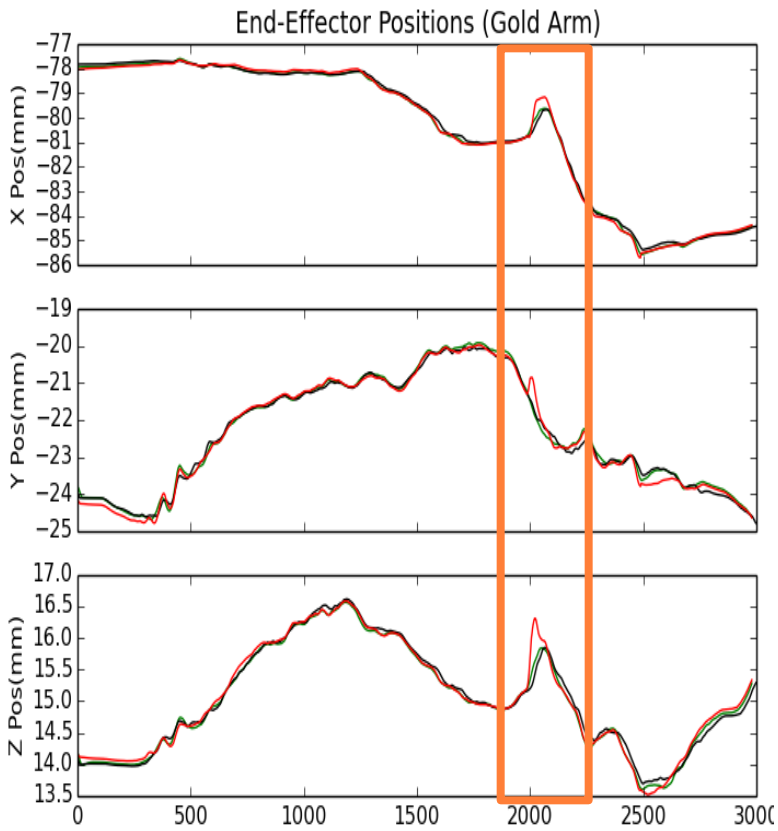
Autonomous Inference of Critical State



Simulated Safety Hazards



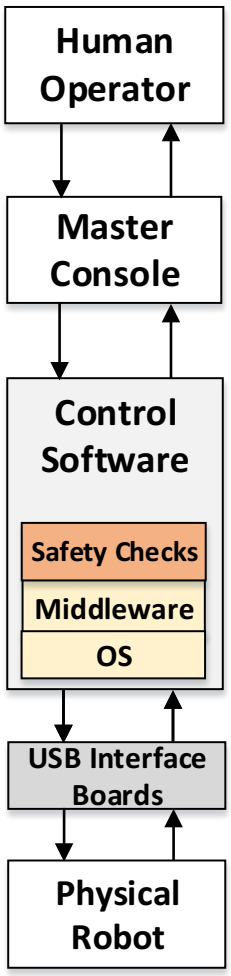
Inject error to control commands issued from control software to robot



Abrupt jump of end-effector

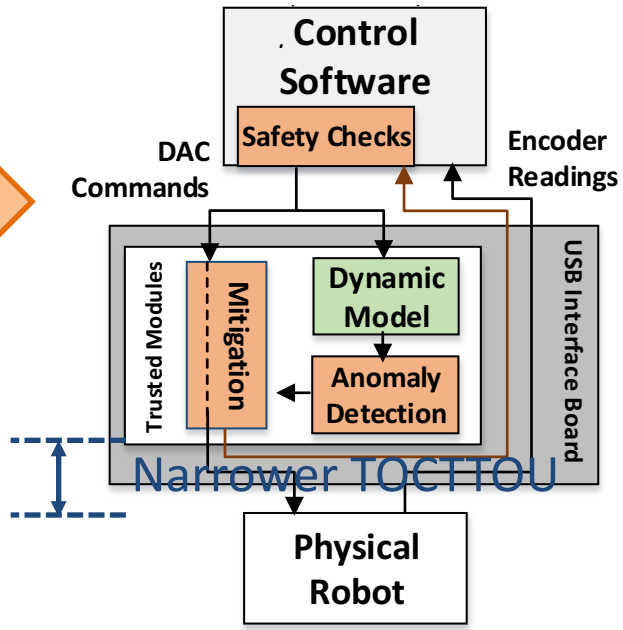
> 1mm change in arm position in one control cycle

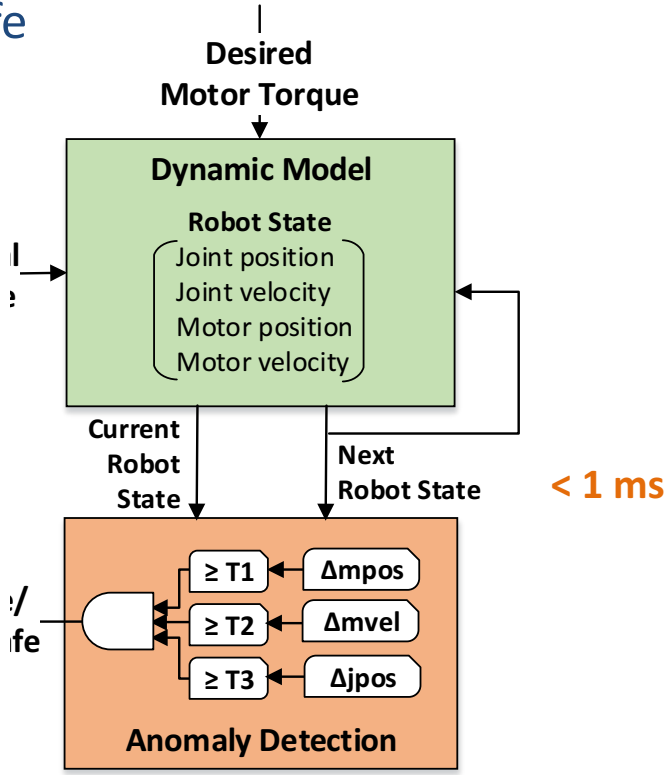
Dynamic Model Based Detection



Preemptive detection of safety hazards

- Real-time computation of joint/motor dynamics
- Estimation of next robot state
- Detect if distance is unsafe

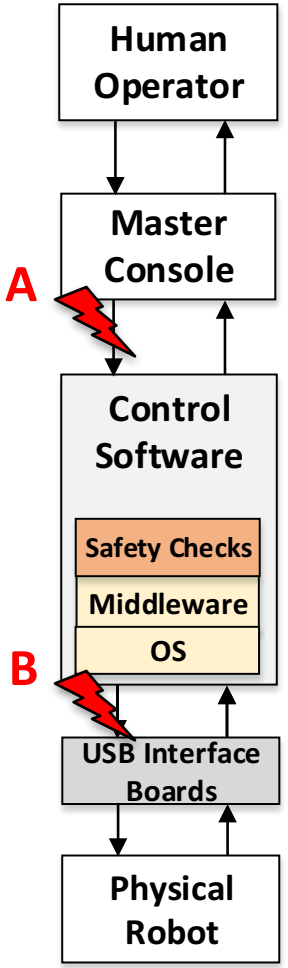




< 1 ms

Safety Hazard Detection Performance

Attack Scenario	Technique	ACC (%)	TPR (%)	FPR (%)	F1 (%)
A (User inputs)	DM	88.0	89.8	12.4	74.8
	RAVEN	84.6	53.3	7.7	57.8
B (Torque commands)	DM	92.0	99.8	11.8	89.1
	RAVEN	90.7	81.0	4.6	85.1



- DM detected **before** hazard manifested in physical layer
- RAVEN detected *at least* 1 cycle **after** safety hazard occurred

[DSN 2016]

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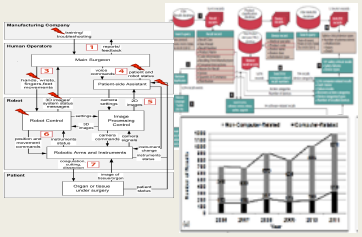

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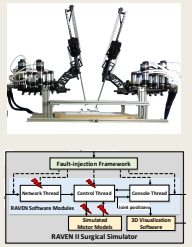

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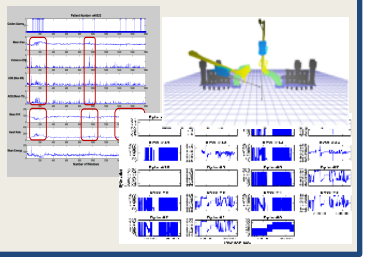

Publications

Analysis of Medical Device Recalls and Adverse Event Reports:

1. **"Automated Classification of Computer-based Medical Device Recalls,"**
   H. Alemzadeh, R. Hoagland, Z. Kalbarczyk, R. K. Iyer,
   In the *27th IEEE International Symposium on Computer-Based Medical Systems (CBMS'14).*

2. **"Safety Implications of Cardiothoracic Robotic Surgery: Analysis of Adverse Event Reports of da Vinci Surgical Systems,"**
   H. Alemzadeh, J. Raman, N. Leveson, R. K. Iyer,
   Presented as J. Maxwell Chamberlain Memorial Paper for the Adult Cardiac Surgery in the *50th Annual Meeting of the Society of Thoracic Surgeons (STS'14)*, Jan. 2014.
   Featured in Wall Street Journal, "Report Raises Concerns on Robotic Surgery Device", Nov. 8, 2013.

3. **"Safety Implications of Robotic Surgery: A Study of 14 Years FDA Data on da Vinci Surgical Systems,"**
   H. Alemzadeh, J. Raman, N. Leveson, Z. Kalbarczyk, R. K. Iyer,
   CSL Technical Report, UILU-ENG-13-2208, Nov. 2013, *PLoS ONE, vol. 11, no. 4: e0151470, 2016*
   Featured in the MIT Technology Review, BBC, NBC News, Daily Mail, Gizmodo, and others, July 2015.

4. **"Analysis of Safety-Critical Computer Failures in Medical Devices,"**
   H. Alemzadeh, R. K. Iyer, Z. Kalbarczyk, J. Raman,
   IEEE Security & Privacy (*IEEE S&P'13*), vol. 11, no. 4, pp. 14-26, July-Aug. 2013.

Safety and Security of Teleoperated Surgical Systems:

5. **"A Hardware-in-the-loop Simulator for Safety Training in Robotic Surgery"**
   X. Li, **H. Alemzadeh**, D. Chen, Z. Kalbarczyk, R. K. Iyer, T. Kesavadas
   In the IEEE/RSJ International Conference on Intelligent Robots and Systems (IROS), 2016.

6. **"Targeted Attacks on the Control Systems of Teleoperated Surgical Robots"**
   H. Alemzadeh, D. Chen, X. Li, T. Kesavadas, Z. T. Kalbarczyk, R. K. Iyer
   In the 46th IEEE/IFIP International Conference on Dependable Systems and Networks (DSN), 2016

7. **"Safety-critical Cyber-Physical Attacks: Analysis, Detection, and Mitigation"**
   H. Lin, **H. Alemzadeh**, D. Chen, Z. Kalbarczyk, R. K. Iyer
   In the Symposium and Bootcamp on the Science of Security (HOTSOS), 2016.

8. **"Systems-theoretic Safety Assessment of Telerobotic Surgical Systems"**
   H. Alemzadeh, D. Chen, A. Lewis, Z. Kalbarczyk, J. Raman, N. Leveson, R. K. Iyer
   In the 34th International Conference on Computer Safety, Reliability, and Security (SAFECOMP), Delft, Netherlands, September 2015.

9. **"A Software Framework for Simulation of Safety Hazards in Robotic Surgical Systems"**
   H. Alemzadeh, D. Chen, Z. Kalbarczyk, R. K. Iyer, X. Li, T. Kesavadas, J. Raman
   In the 6th Medical Cyber Physical Systems Workshop, Hosted at CPS Week, Seattle, WA, April 2015.

10. **"Simulation-based Training for Safety Incidents: Lessons from Analysis of Adverse Events in Robotic Surgical Systems" [Poster]**
    H. Alemzadeh, Z. Kalbarczyk, R. K. Iyer, T. Kesavadas, S. Small, J. Raman, In *the American College of Surgeons' 8th Annual Meeting of the Consortium of ACS-accredited Education Institutes*, March 2015.