Rationale and Architecture Principles for Medical Application Platforms

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

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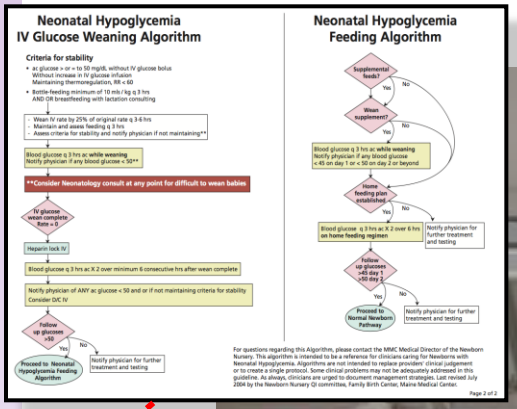
Health Care Involves A Variety of System Components



Clinical Protocols

Sensor Data Displays

Safety

Clinicians

Actuators

Security

Information Systems

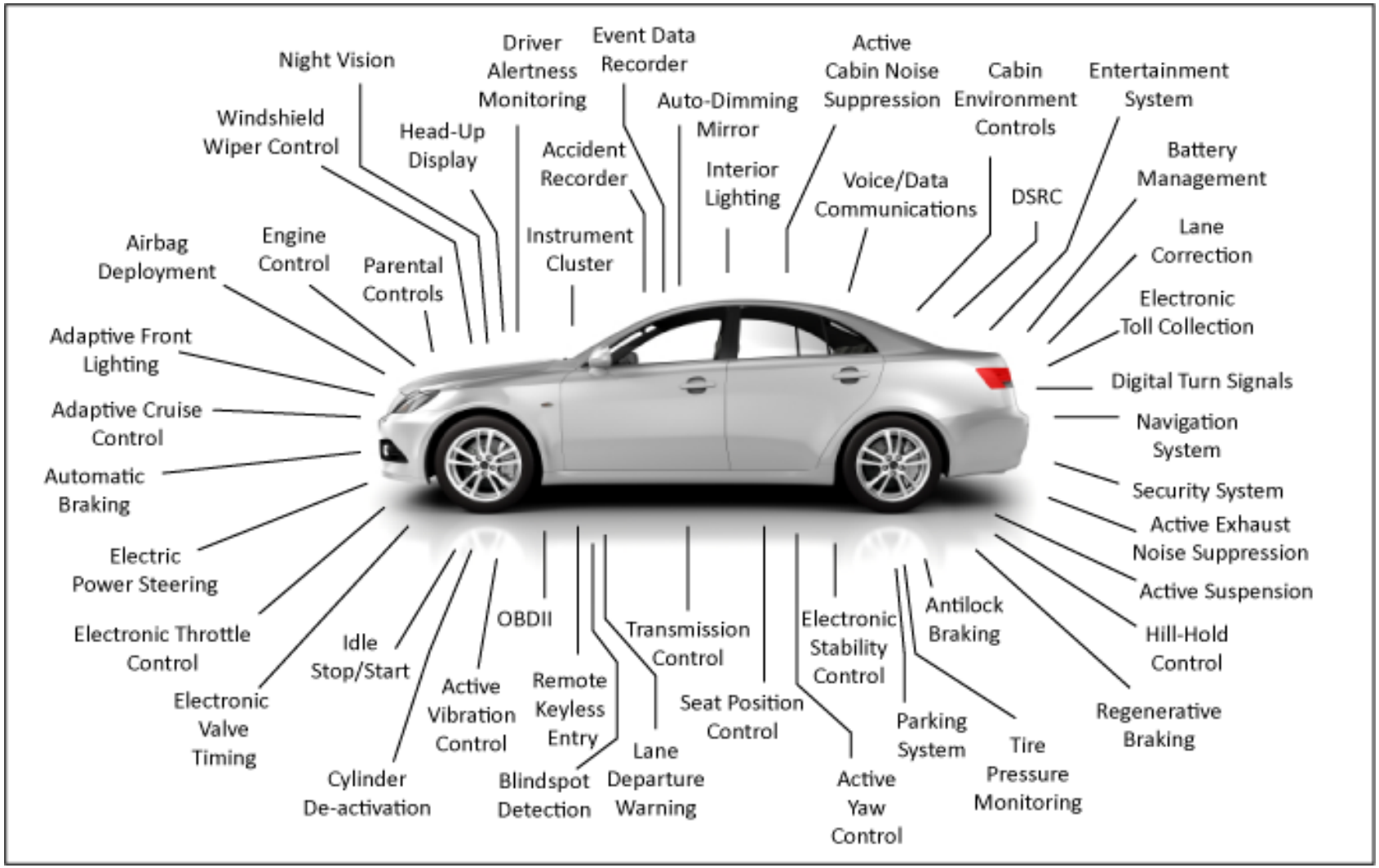
Patient !

Sensors

Together these elements form the precursor of a Cyber-Physical System of Systems. Unfortunately, these elements are largely un-integrated, and so appropriate automated systems solutions cannot be applied.

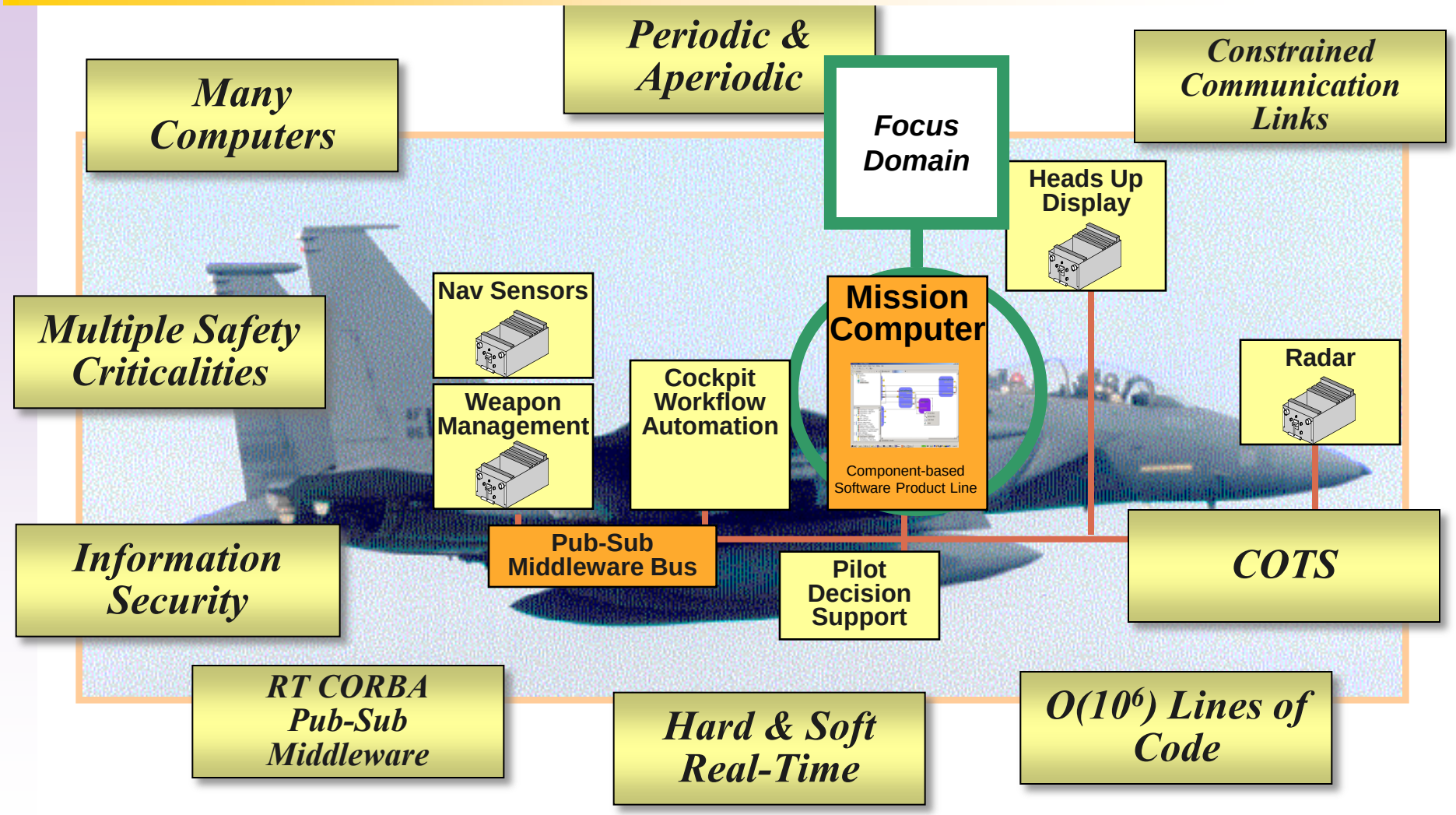
Systems of Systems

Automotive



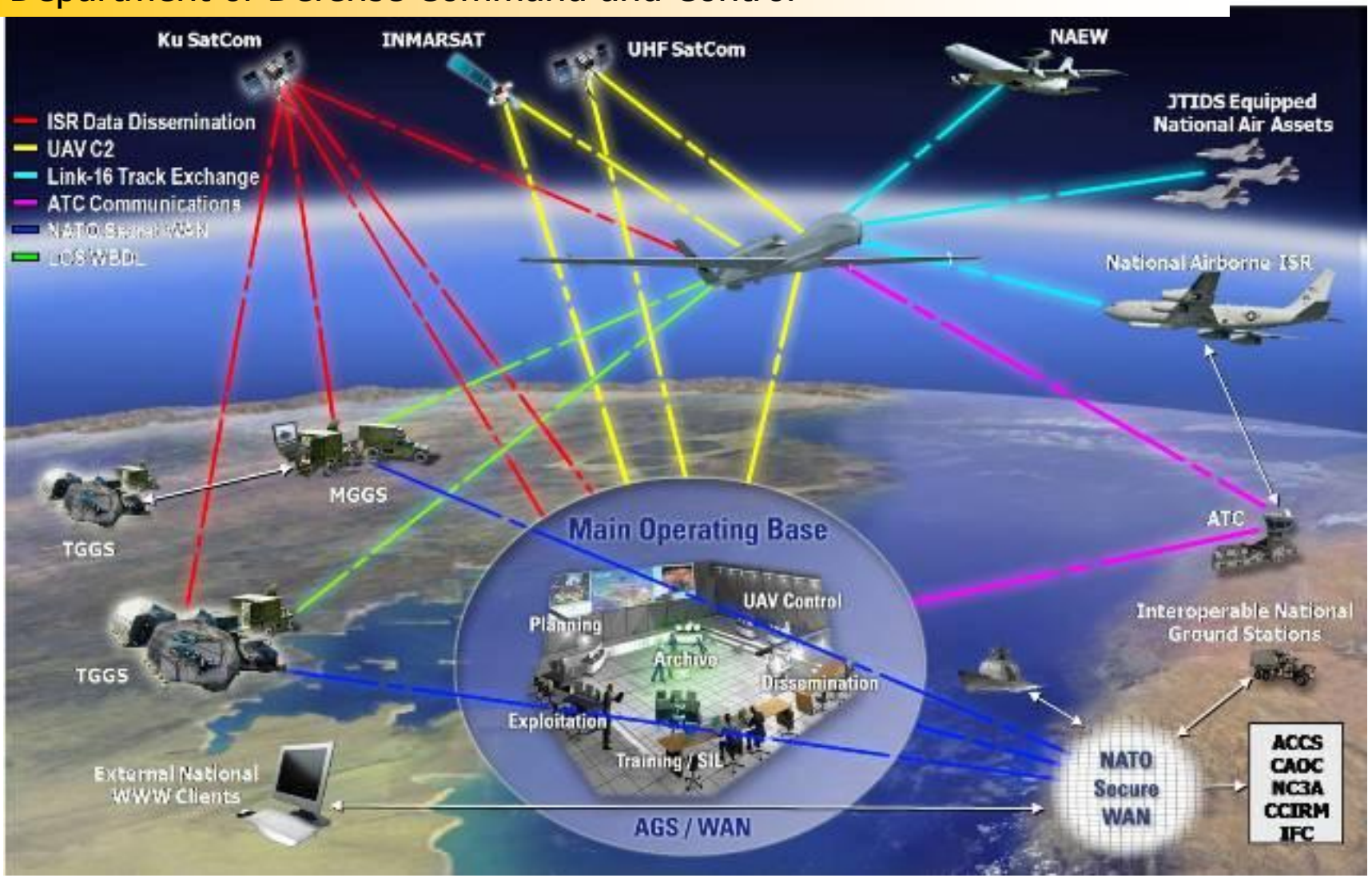
Systems of Systems

Boeing Bold Stroke Platform for F-18 Fighter



Systems of Systems

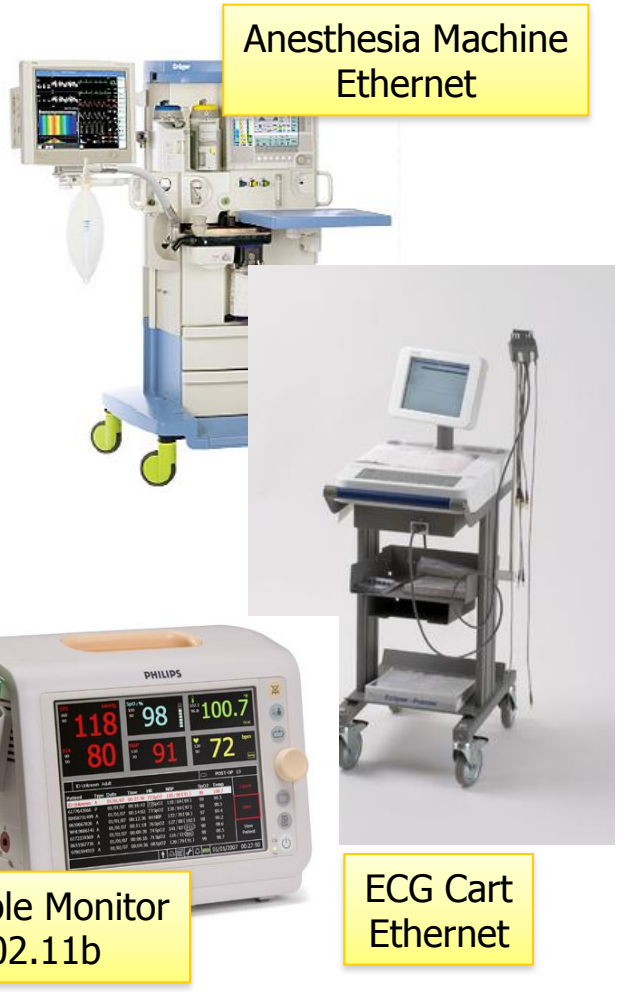
US Department of Defense Command and Control



Still Struggling with Connectivity

Many modern medical devices have some form of connectivity, but do not implement standardized protocols for device discovery and communication...

- The most extensive medical connectivity standard 11073 POC is so complicated that almost no one implements it
- A simpler version (11073 PHD) for personal health devices only supports a very limited set of consumer devices
- 11073 is missing many features necessary for integrated systems
  - Authentication, safety modes, real-time constraints on device response, etc., etc.
- Entire branches of companies exist to develop custom interfaces to existing devices



This Talk

High-level presentation of issues related to architecture/regulation – not specific solutions

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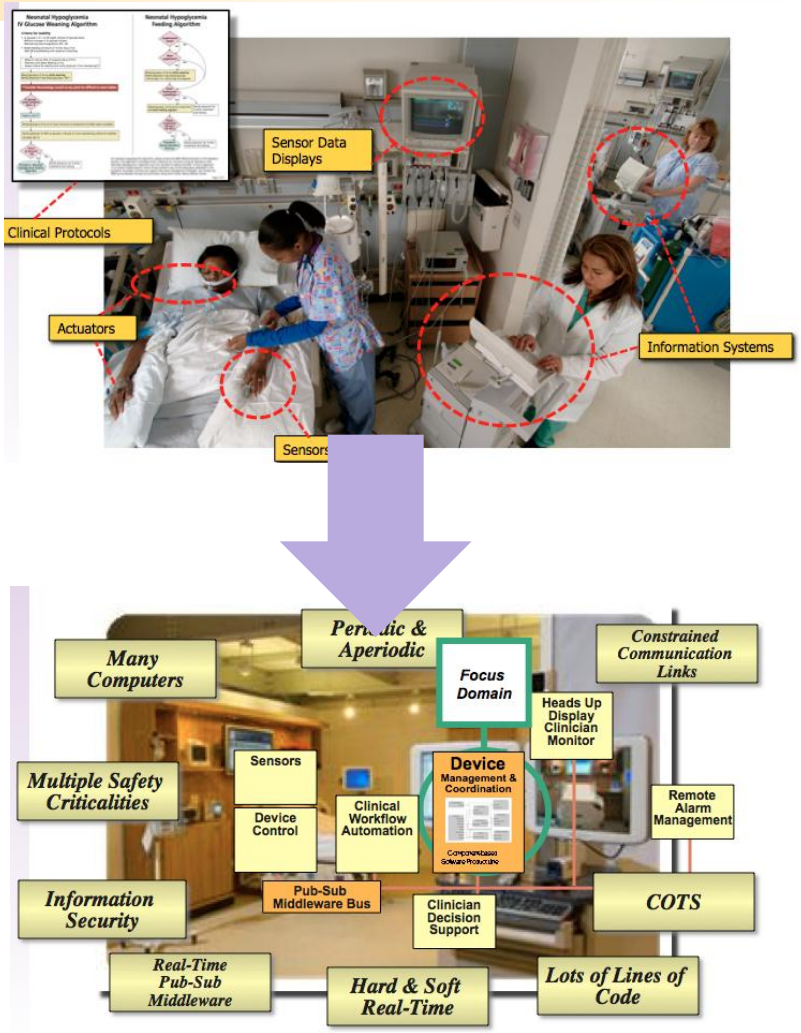
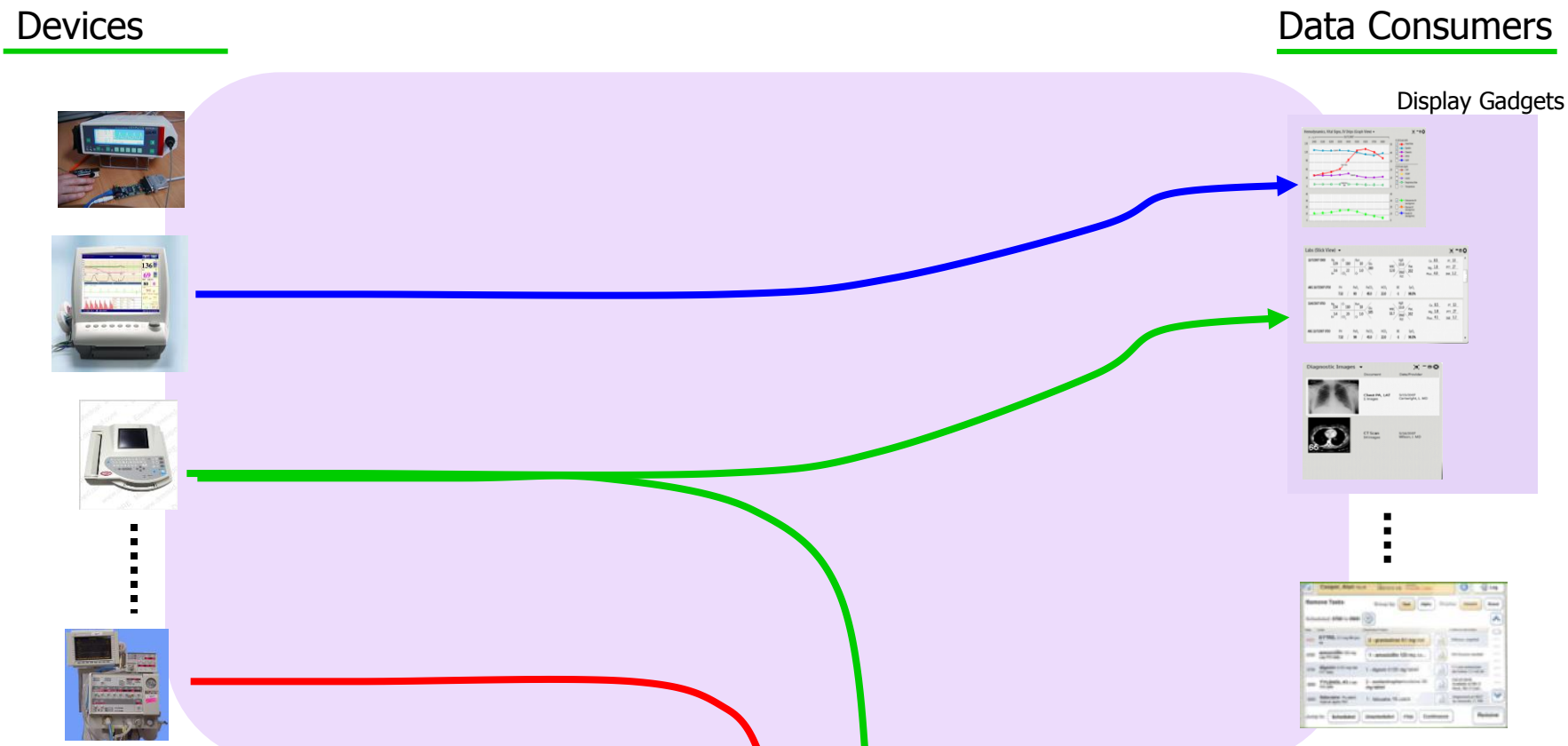


Recent Commercial Systems

Medical Device Data Systems (MDDS) -- Data only flows from producers to consumers; data must be faithfully re-presented



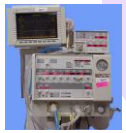
Current FDA regulations for MDDS do not allow any automated control of devices/settings or significant reformatting of data.

Integrating Data Streams

Fully leverage device data streams

Devices

***Moving forward**: aggregating data streams to create "smart alarms" that reduce nuisance alarms by triggering alarms only when multiple physiological parameters are in agreement, e.g., agreement in trends on ET CO2 as well as pulse ox SpO2*



Data Stream 1

Data Stream 2

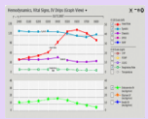
Smart Alarm Logic

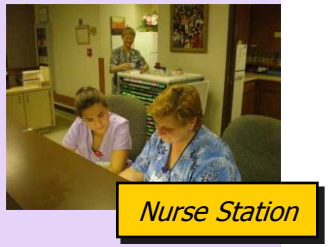
Alarm Info

"Medical Device Integration Platform application (app)"

Data Consumers

iAware Gadgets





Nurse Station

Sensor fusion

From Wikipedia, the free encyclopedia

Sensor fusion is the combining of sensory data or data derived from sensory data from disparate sources such that the resulting information is in some sense *better* than would be possible when these sources were used individually. The

Why is it so hard to do this in the health care space?

Safety Interlocks

Fully leverage device data streams and the ability to *control* devices

Devices

***Moving forward**: aggregating data streams to solve **systems problems** by making devices context aware.*

Data Consumers

Display Gadgets

O_2 Conc. Data

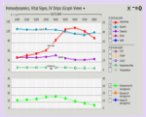
Laser Activation Data

Laser Disable Command

Disable laser if inspired O_2 is > 25%.

Safety Interlock Logic

Alarm Info



Surgical Team

Tracheal tube fire hazard -- caused by failure to reduce O_2 concentration during tracheal laser surgery

Just enforcing a system invariant!

Proposed and published by Sem Lampotang, PhD, Univ. of Florida -- not commercially available. Device coordination systems can provide a solution.

From Dr. Julian Goldman -- MDPnP.

Closed Loop Safety Interlock

Example Use-Case: PCA Monitoring

- Patients are commonly given patient-controlled analgesics after surgery
- Crucial to care, but numerous issues related to safety

A 49-year old woman underwent an uneventful operation (total abdominal hysterectomy and bilateral salpingo-oophorectomy). Postoperatively, the patient complained of severe pain and received intravenous morphine sulfate in small increments. She began receiving a continuous infusion of morphine via a patient controlled analgesia (PCA) pump. A few hours after leaving the PACU [post anethesia care unit] and arriving on the flow, she was found pale with shallow breathing, a faint pulse, and pinpoint pupils. The nursing staff called a "code", and the patient was resuscitated and transferred to the intensive care unit on a respirator. Based on family wishes, life support was withdrawn and the patient died. Review of the case implicated a PCA overdose. Delayed detection of respiratory compromise in patients undergoing PCA therapy is not uncommon because monitoring of respiratory status has been confounded by excessive nuisance alarms.

Simple Closed Loop Control

Motivating Clinical Problem: PCA Overdose

apsf
www.apsf.org

NEWSLETTER

The Official Journal of the Anesthesia Patient Safety Foundation

Volume 21, No. 4, 61-88 Circulation 80,350 Winter 2006-2007

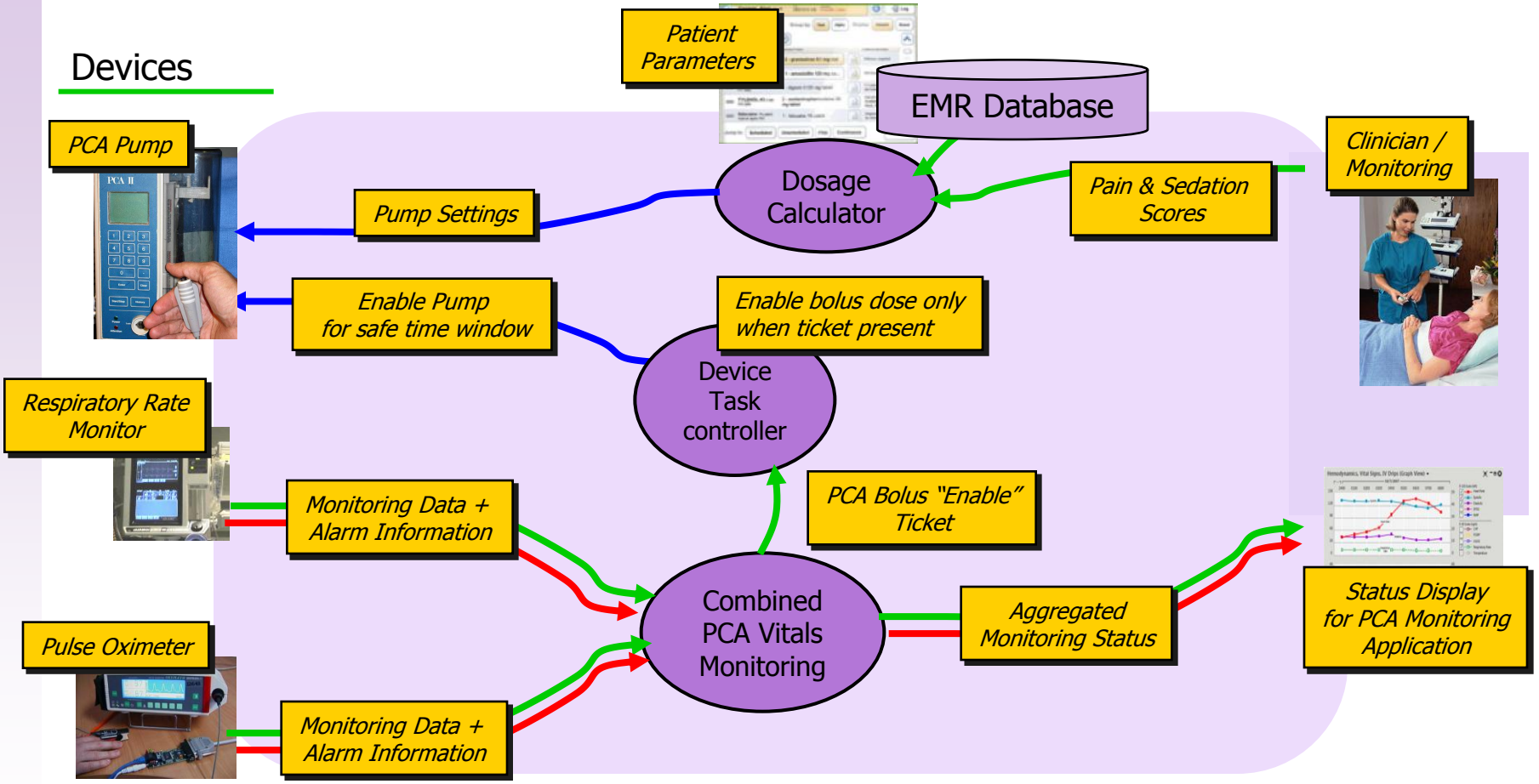
Dangers of Postoperative Opioids

APSF Workshop and White Paper Address Prevention of Postoperative Respiratory Complications

- "A particularly attractive feature may be the ability to automatically terminate or reduce PCA (or PCEA) infusions when monitoring technology suggests the presence of opioid-induced respiratory depression. To facilitate such capabilities, we strongly endorse the efforts to develop international standards for device interoperability and device-device communication.
- It is critical that any monitoring system be linked to a reliable process to summon a competent health care professional to the patient's bedside in a timely manner. "

Closed Loop Safety Interlock

Fully leverage device data streams and the ability to *control* devices



See the paper for a number of other examples, many drawn from the ASTM Integrated Clinical Environment standard.

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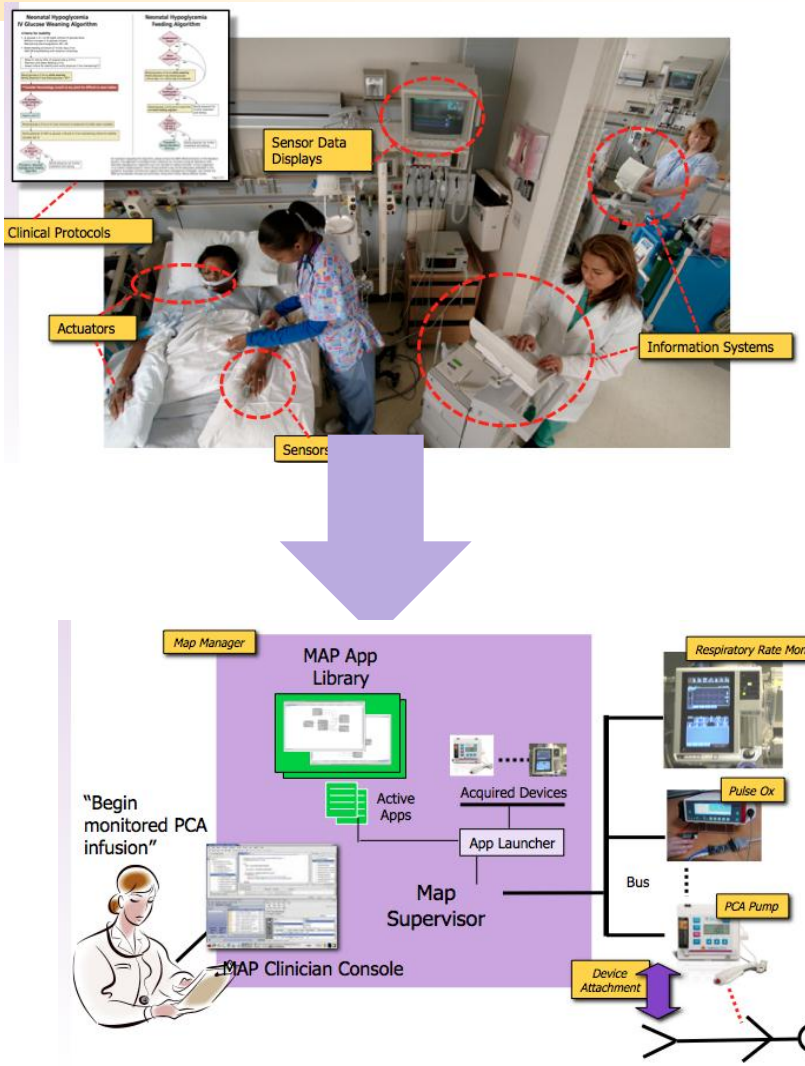
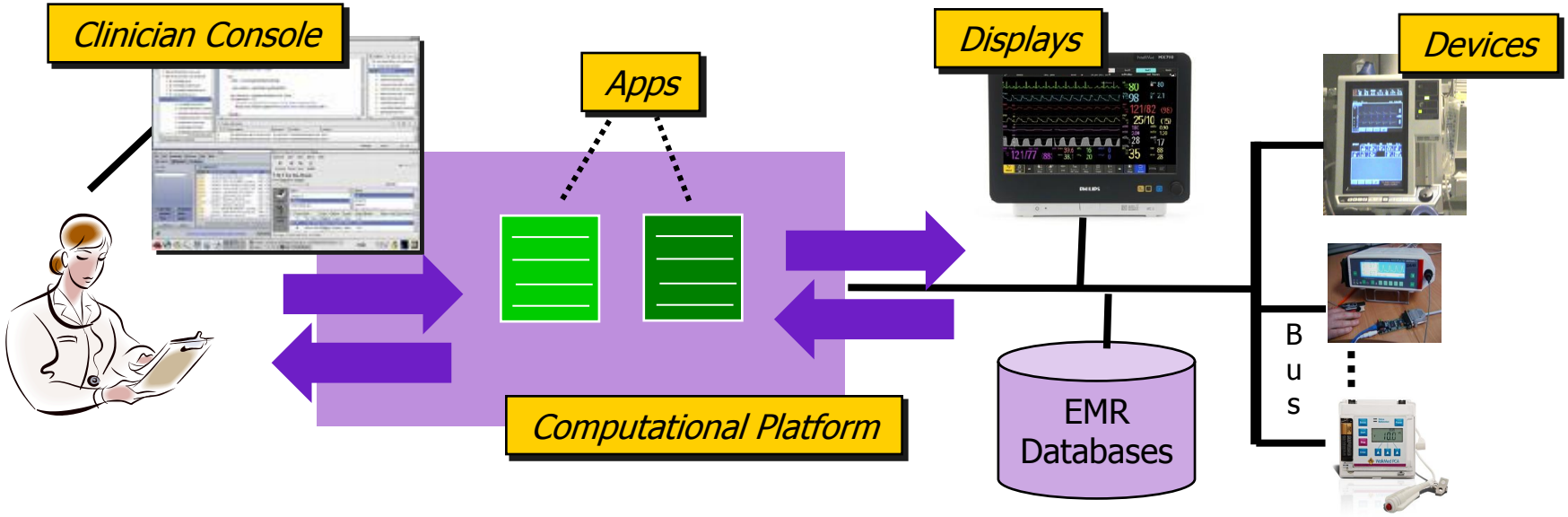


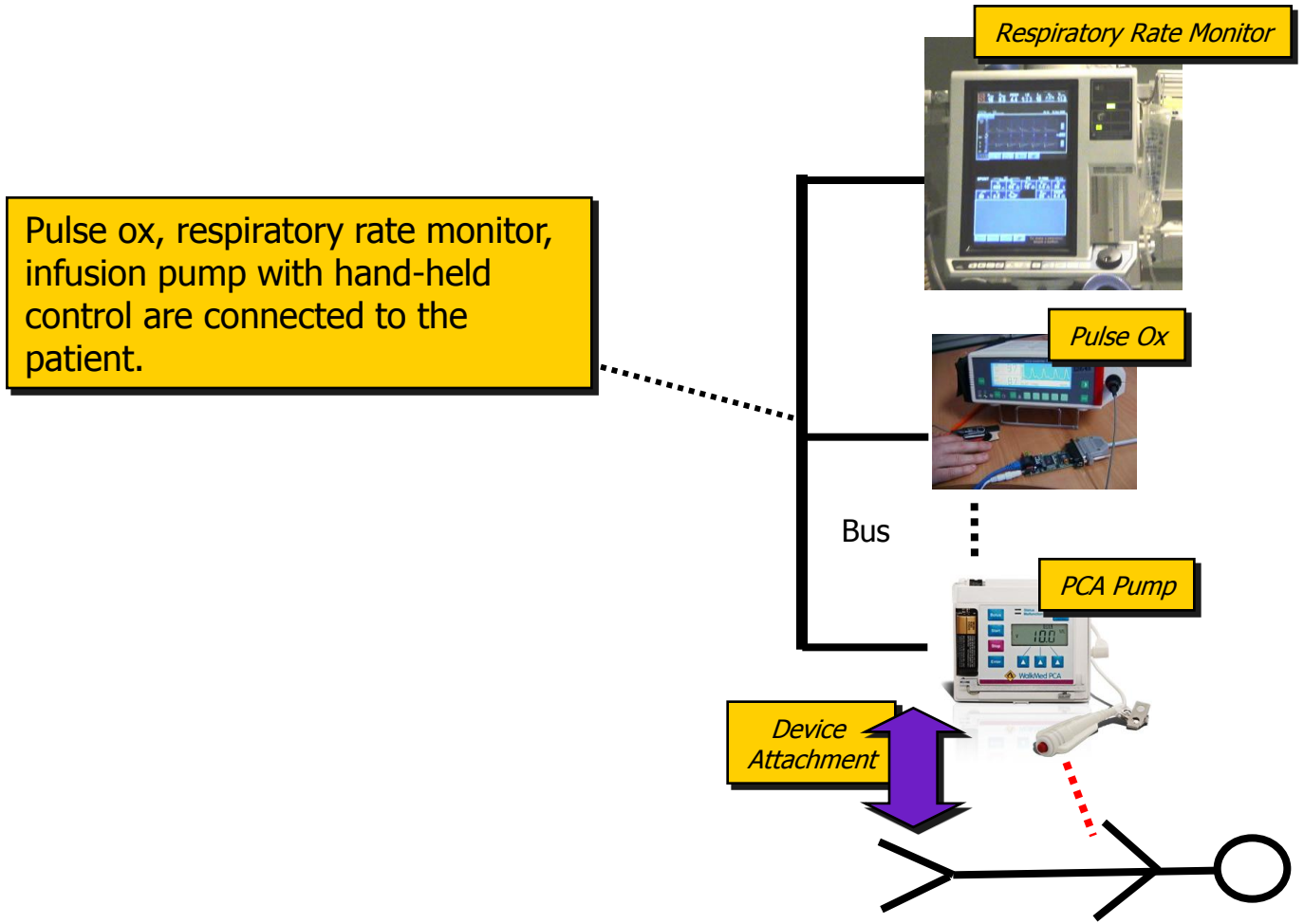
Medical Application Platforms



- A *Medical Application Platform* is a safety- and security-critical real-time computing platform for…
  - Integrating heterogeneous devices, medical IT systems, and information displays via communications infrastructure, and
  - Hosting applications ("apps") that provide medical utility via the ability to acquire information from and update/control integrated devices, IT systems, and displays

MAP Functional View

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



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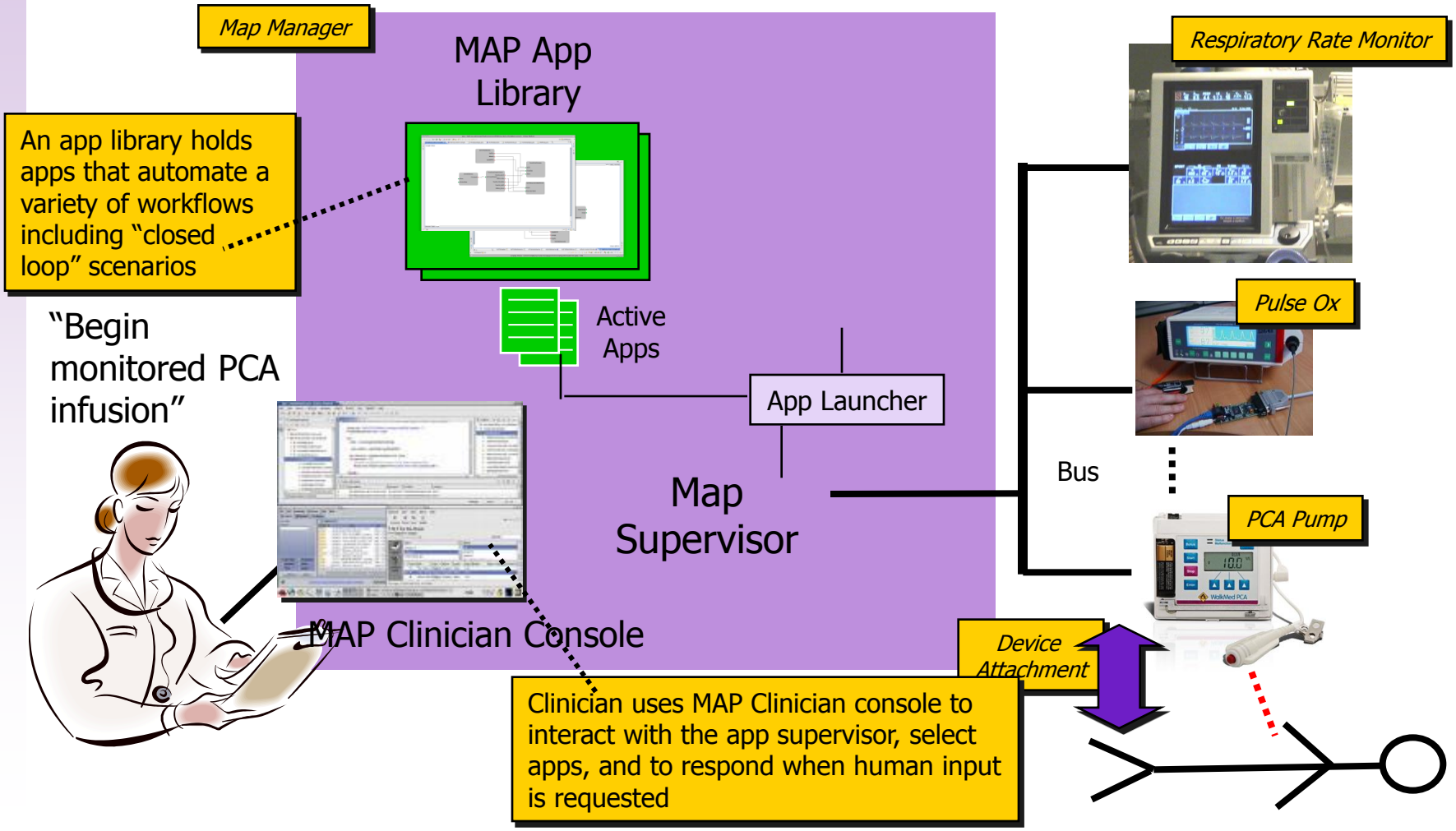

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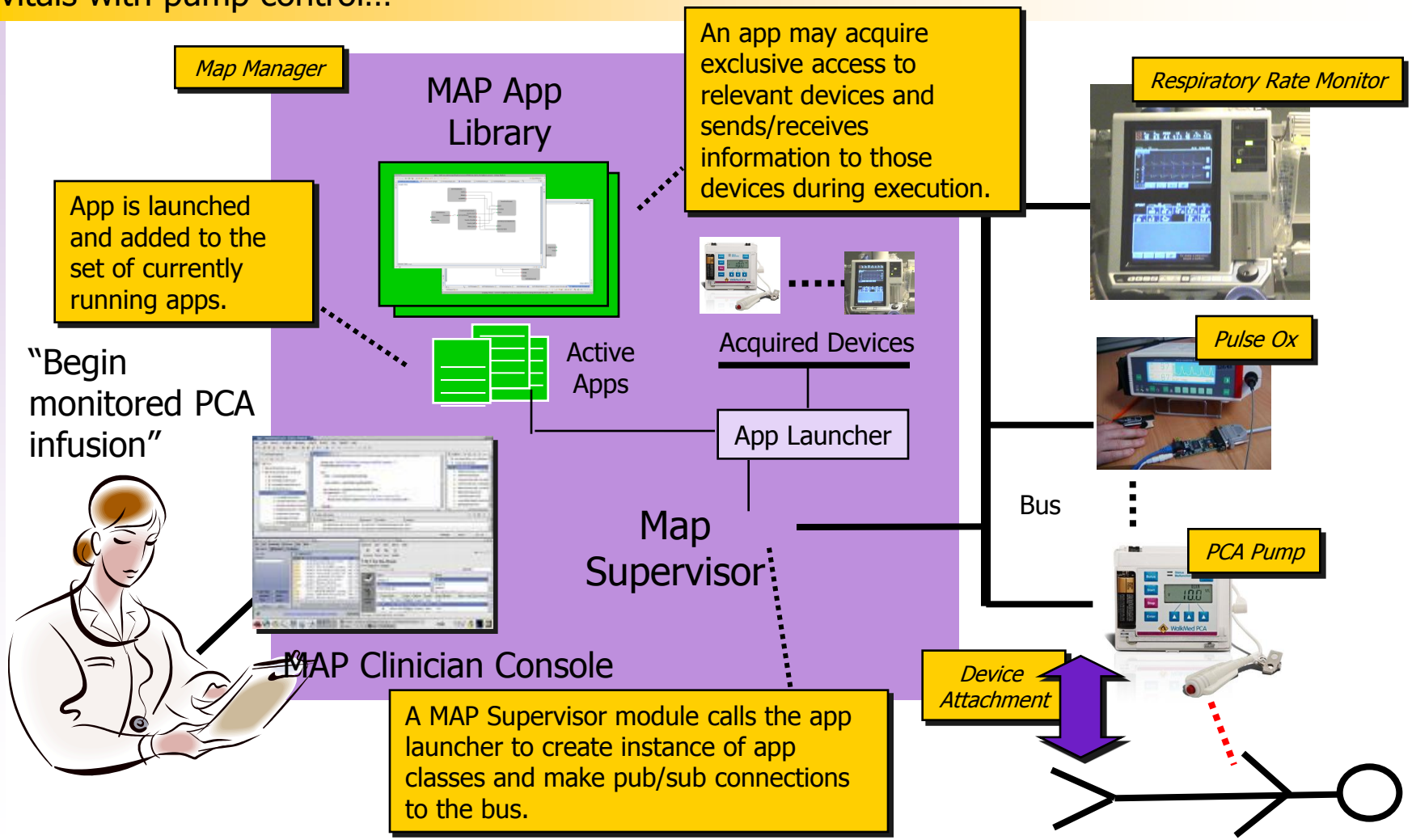

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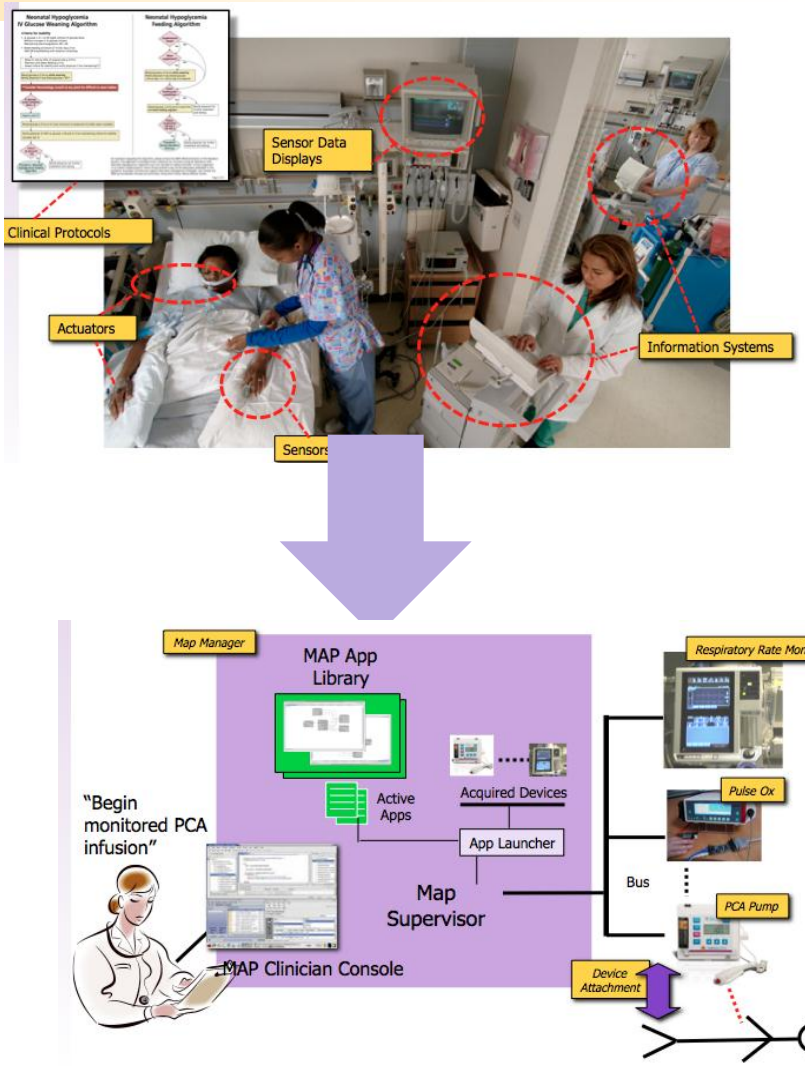
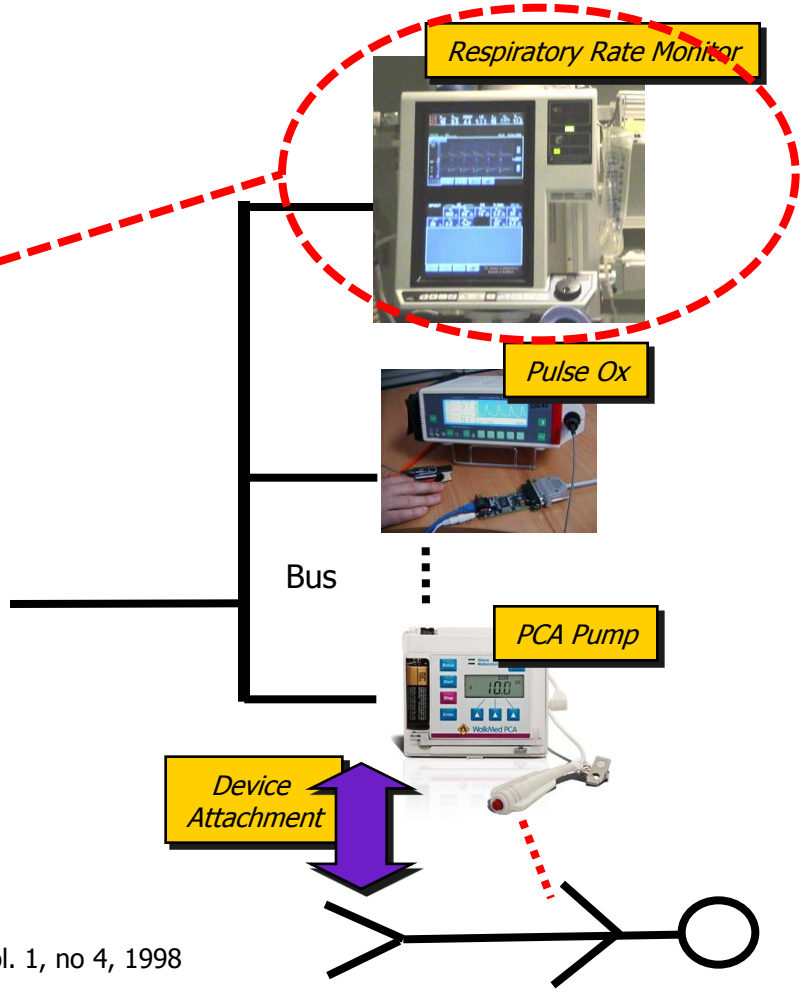


MAP System Characteristics

MAPs allow one to construct complex medical cyber-physical *systems of systems*

- Following Maier's characterization of "systems of systems"
  - Constituents are autonomous
  - Capacity for independent operation
  - Independent evolution responding to new technology and mission needs at its own pace and direction



M. Maier, "Architecting principles for systems of systems", *Systems Engineering*, vol. 1, no 4, 1998

Current Products

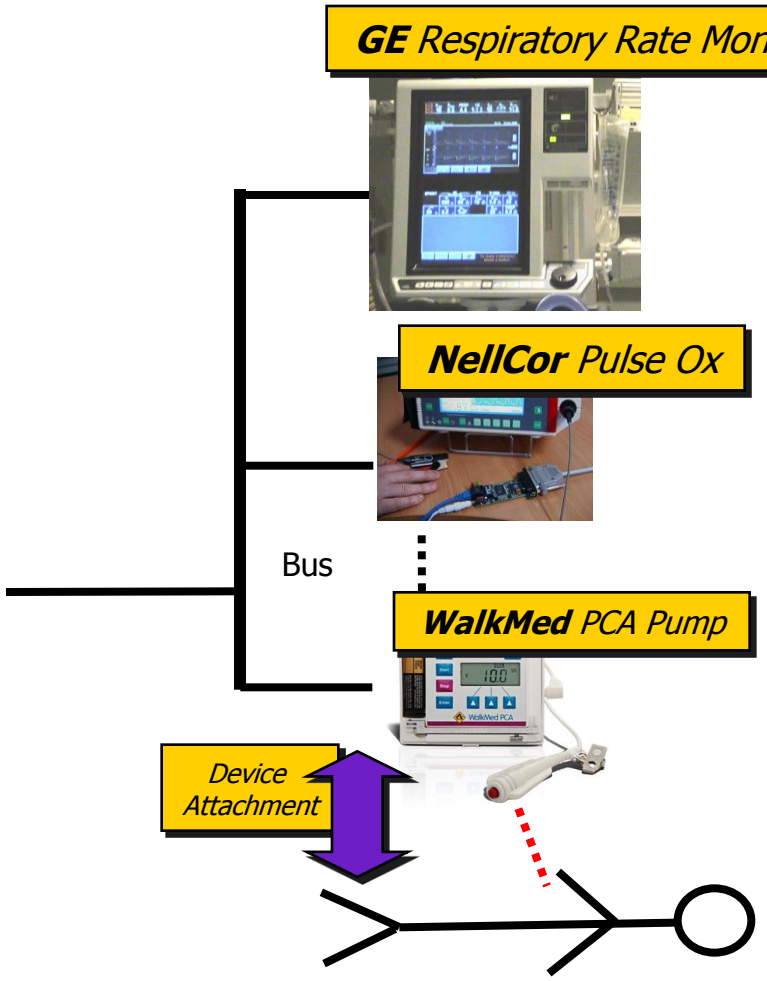
Current connectivity products *use proprietary interfacing* and many *limit components* to those from a signal vendor or limited collection of vendors

For example, Philips MP90 networked monitoring solution integrates *with other Philips* products in the IntelliVue line, or pulse oximeters from Masimo and Nellcor. *Note:* IntelliVue is not a MAP; it does not support app-based behavioral configuration.

MAP System Characteristics

MAPs should support *interoperability* with *heterogeneous components*

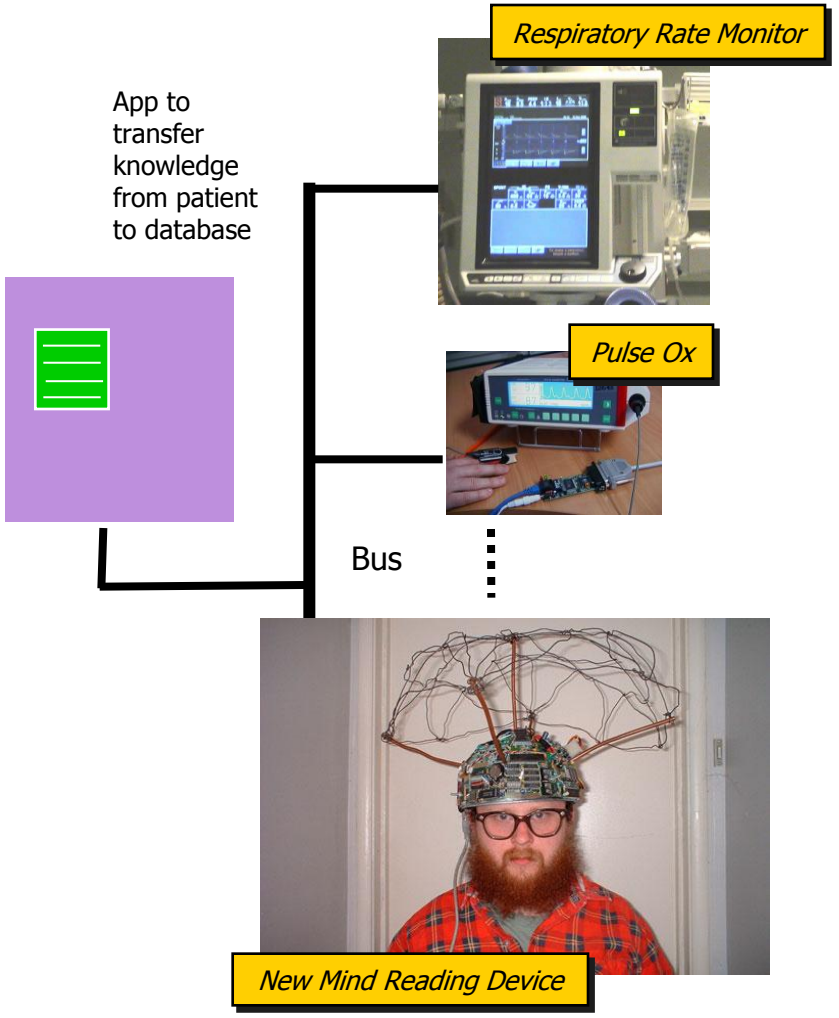
- MAP should support components produced by different vendors
- Success of the MAP approach depends on individual vendors being willing to…
  - Pursue interoperability as a business strategy
    - Sometimes a "forcing function" is need, e.g. MD-FIRE
  - Conform to (envisioned) open interfacing & safety standards



MAP System Characteristics

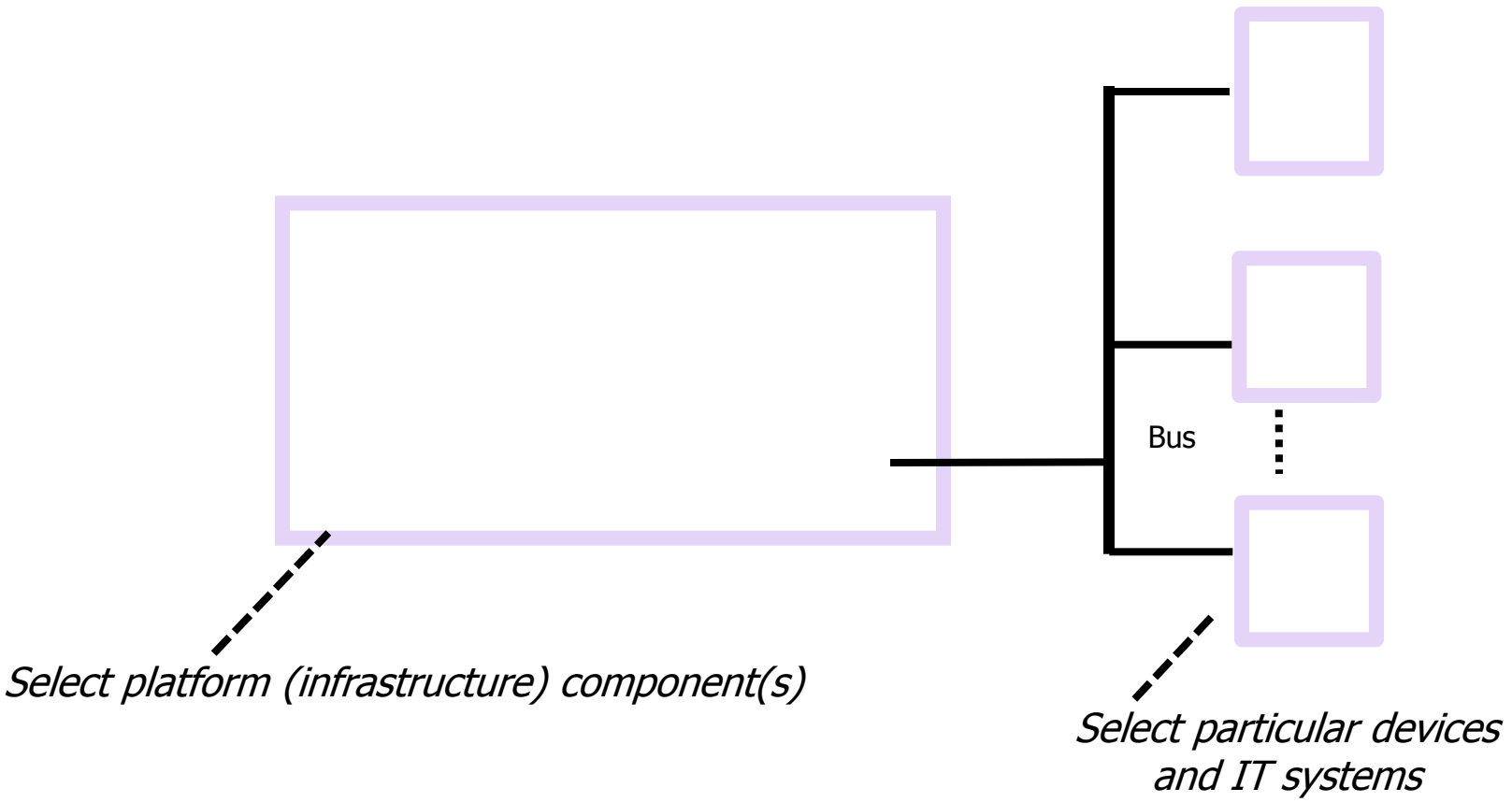
MAPs are *open and extensible* – new devices and apps that were unknown when the platform was developed/approved can be incorporated

- When most conventional critical systems are deployed, the set of possible constituents is known in advance.
- MAP infrastructure is developed and deployed…
  - …subsequently used to support new devices, new device types, and apps that were not anticipated at the time of development, V & V, and regulatory approval
- Relies on the fact that the MAP provides…
  - …an interface definition language (IDL) that devices uses to describe their capabilities
  - …an app language that developers use to write apps
- Because the MAP is verified to support the IDL and app language, it can work with any device/app whose capabilities/function can be described in those languages.



MAP Instance

A *MAP instance* is an instantiation of the MAP architecture – i.e., a selection of specific MAP hardware components that conform to specific architectural and interfaces specified (standardized!) by the MAP framework.



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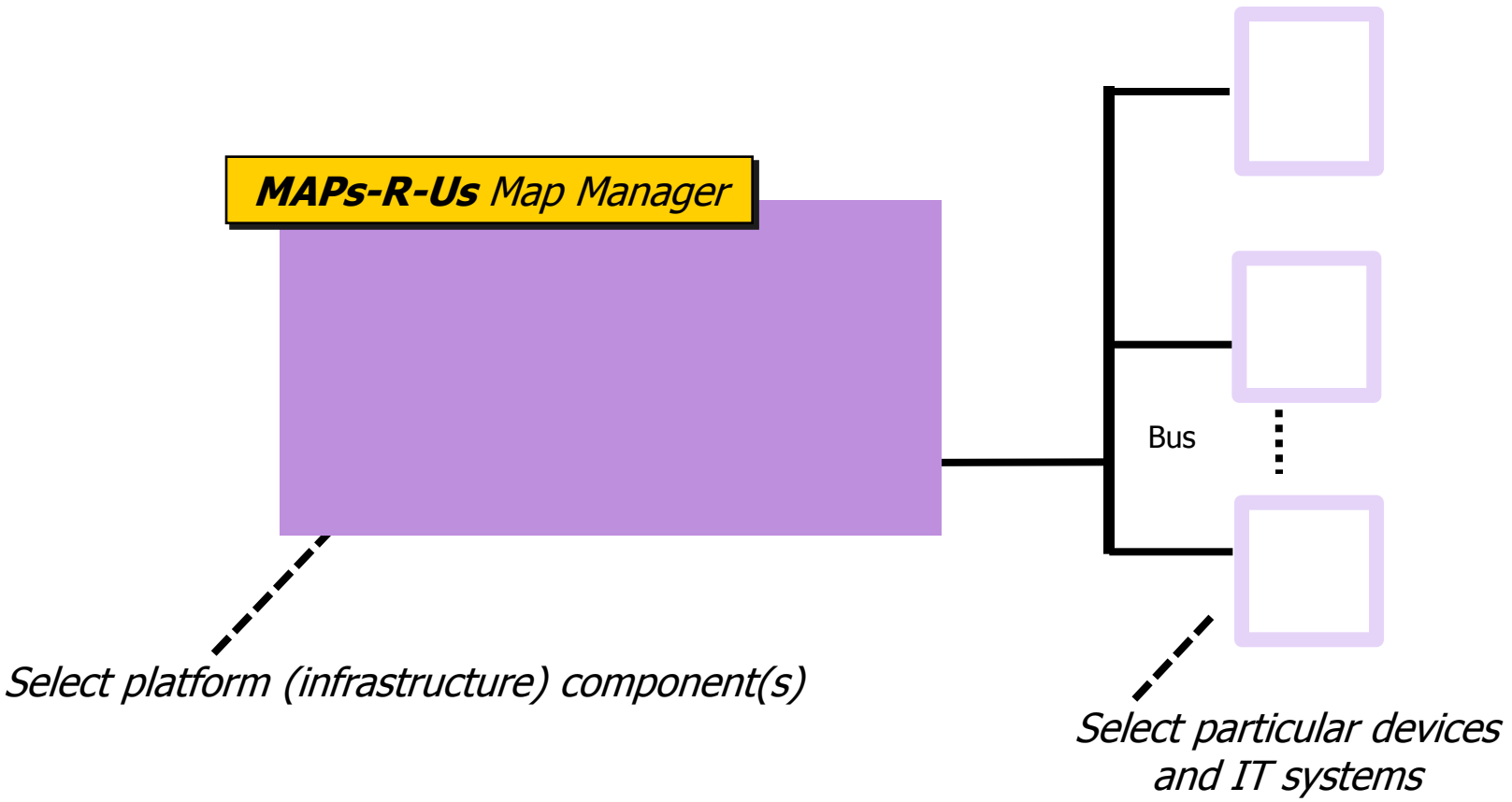

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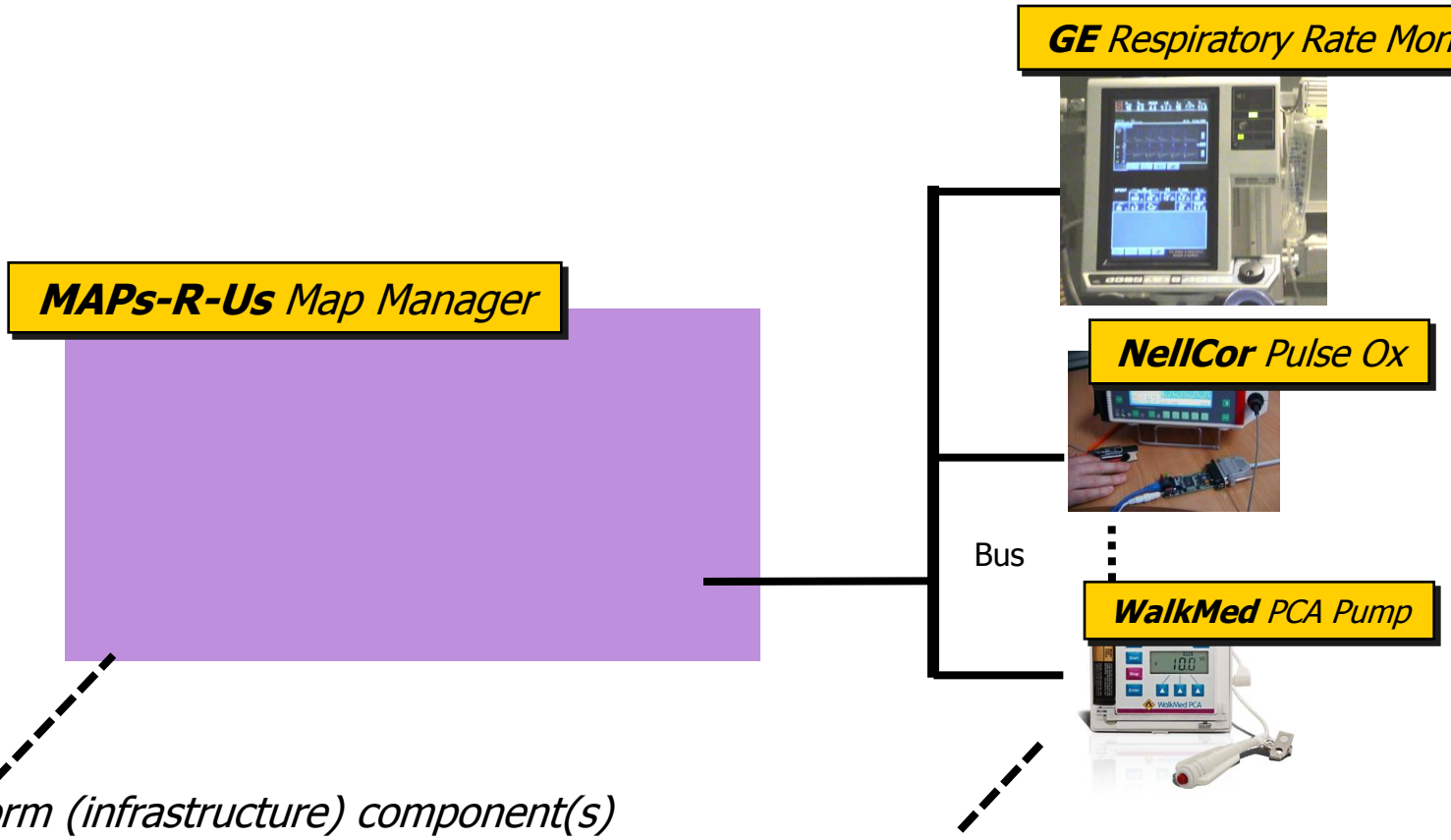
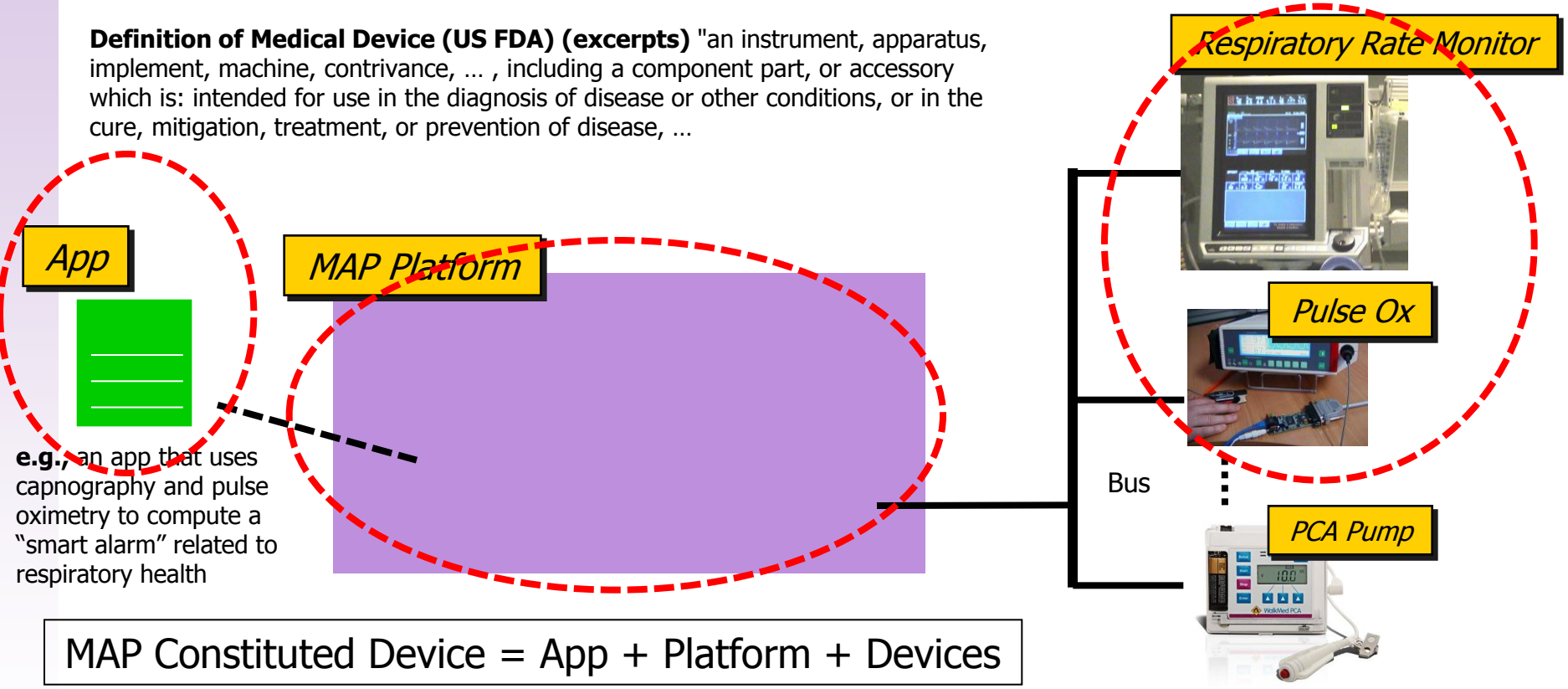


What are we regulating / verifying? The architecture? An instance? All possible instances? What exactly constitutes the *medical device* whose safety and effectiveness we are interested in?

MAP Constituted Device

A *MAP constituted device* is the (composite, virtual) device/system behavior obtained by running an app on a particular MAP instance. The device is conceptual until the app is launched.

Definition of Medical Device (US FDA) (excerpts) "an instrument, apparatus, implement, machine, contrivance, … , including a component part, or accessory which is: intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, …



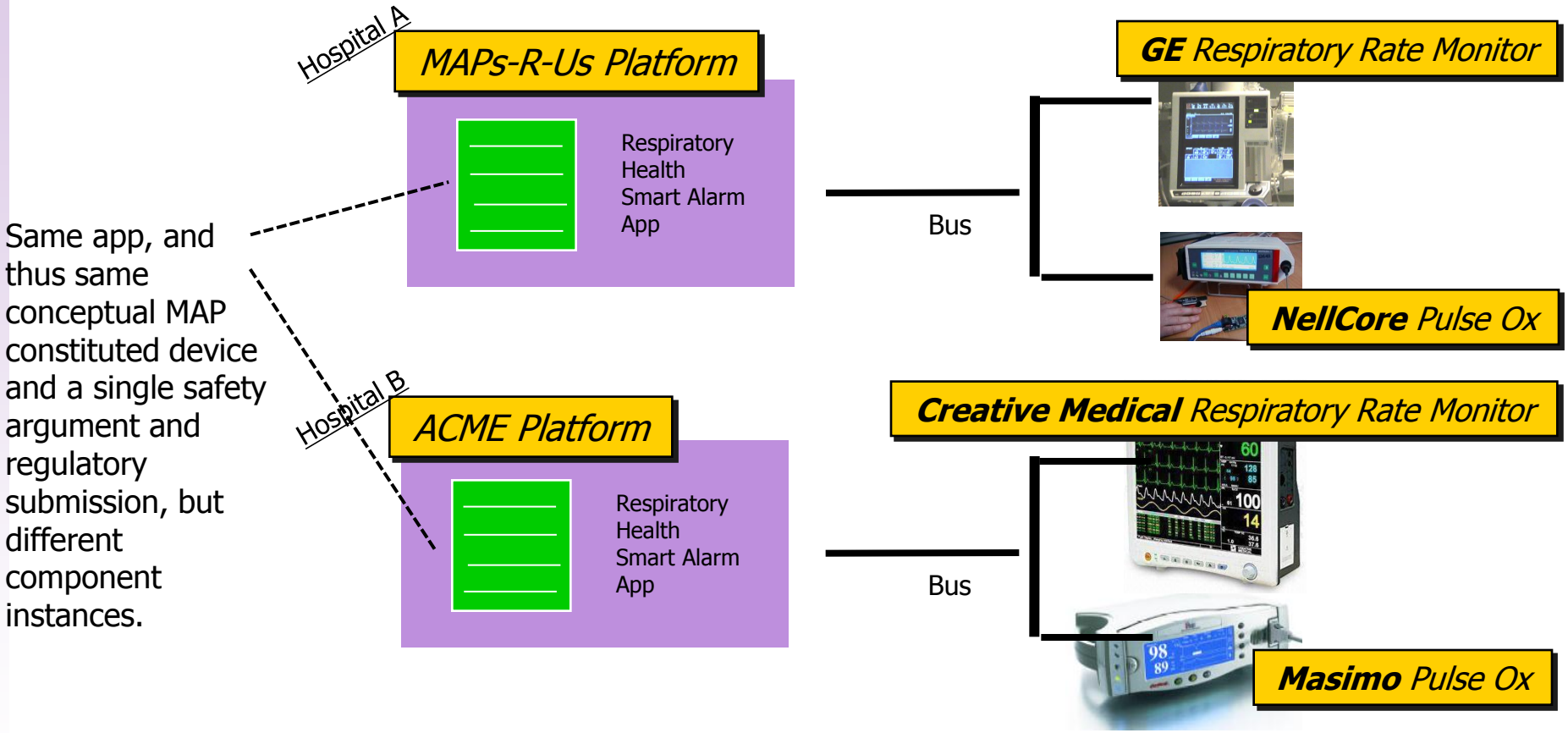
e.g., an app that uses capnography and pulse oximetry to compute a "smart alarm" related to respiratory health

MAP Constituted Device = App + Platform + Devices

No one of these entities defines the behavior of the system alone – they each contribute behavior to the composite system. The app plays a special role – it *specifies* the composite behavior and thus defines the *clinical intended use* (regulatory term) of the MAP constituted device that results from running the app.

MAP Characteristics

MAP constituted device instances are variable – the constituents that form the MAP constituted device may different on different invocations of the device.



Implications: Possible variances/ranges in the behavior must be taken into account by the device interfacing strategy, by the app and its associated safety arguments. Some devices may not meet the apps requirements and should be rejected by platform services.

System Integration

In other safety critical domains, there is a typically a prime contractor that is responsible for integration and system-level verification and validation.

- Integration is performed *before* deployment with full knowledge and behavior of components being integrated
- Integrator has expert-level technical knowledge of components & system behavior
- Responsible for overall system
  - Verification & Validation
  - Safety arguments
  - Certification

787 Final Assembly Integrator - The Boeing Company

As Prime Contractor/Integrator for the final assembly of the composite 787 Dreamliner in Everett, WA,

Boeing is the prime contractor and weapon system integrator for the EA-18G Growler and leads the industry team, which includes Northrop Grumman as principal subcontractor and airborne electronic attack subsystem integrator.

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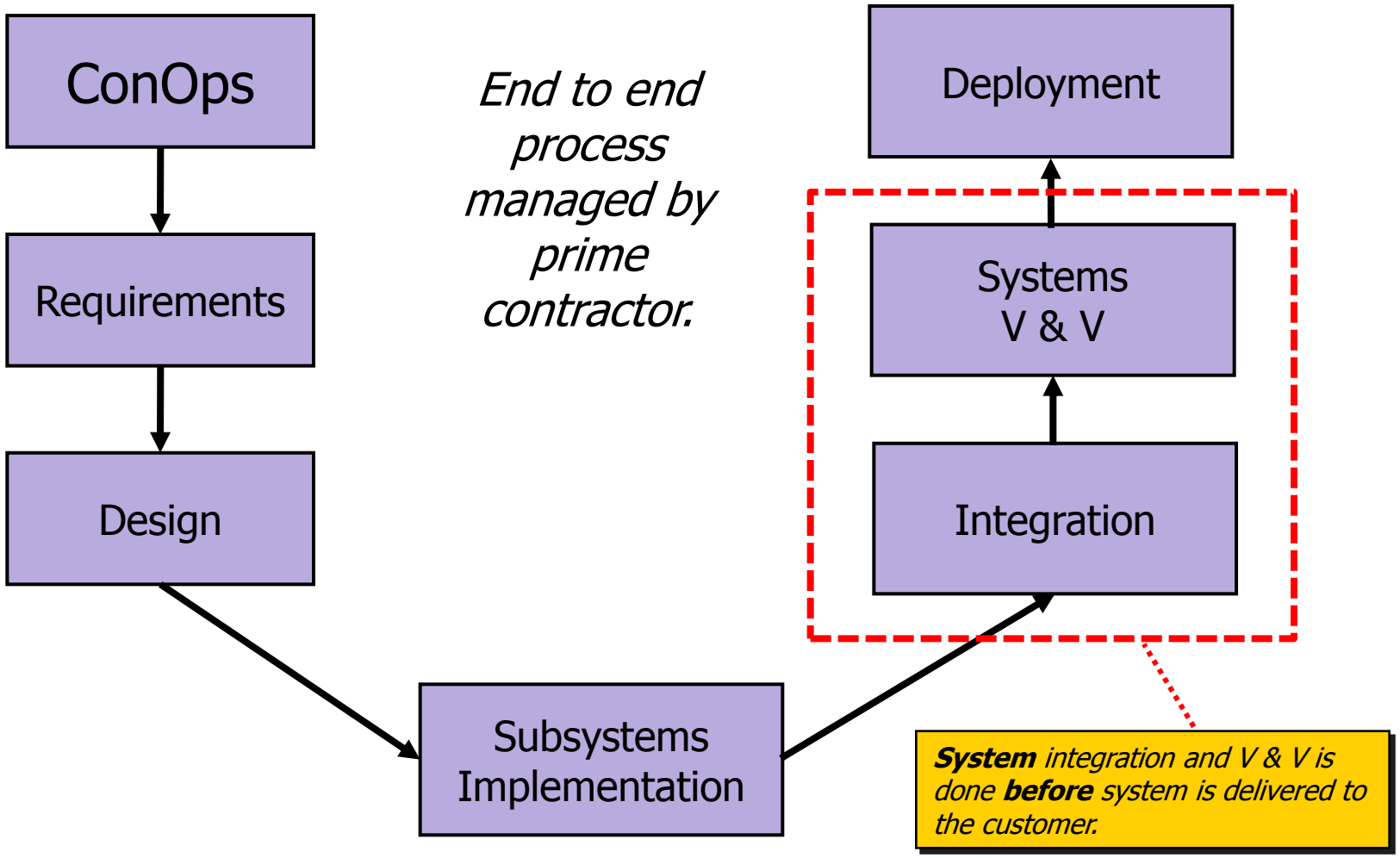
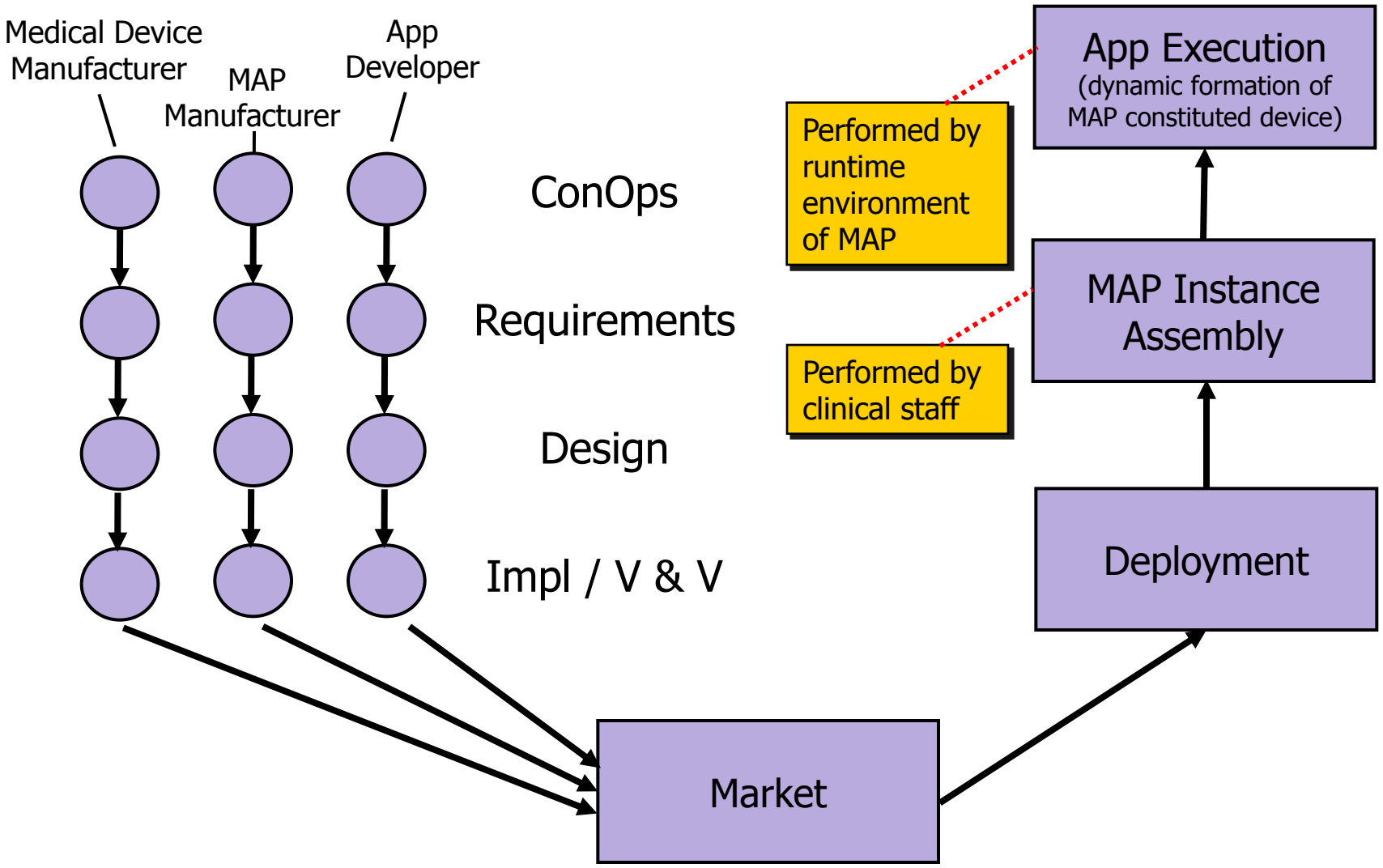


MAP Development & Assembly



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- Integration is performed *before* deployment with full knowledge and behavior of components being integrated
- Integrator has expert-level technical knowledge of components & system behavior
- Responsible for overall system
  - Verification & Validation
  - Safety arguments
  - Certification

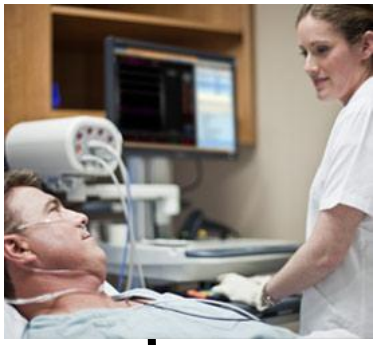
With MAPs, there is **no** prime contractor that is responsible for integration and system-level verification and validation.

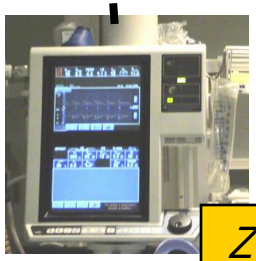
- Assembly is performed *after* deployment
- Assembler (hospital staff) **does not have** expert-level technical knowledge of components & system behavior
- **App developer** is responsible for overall
  - System safety arguments
- Platform services (compatibility checks) assist in determining **at app launch time** if platform and attached devices satisfy requirements of app
- The app's directions for assembly of the platform constituted device are stated **only in terms of properties/capabilities that are exposed on the interfaces** of the platform and devices.

Needed: New Regulatory Approach

Current regulation of integrated systems (e.g., central station monitors) requires **"pair-wise" clearance**: whenever a new type of device is added to the monitoring platform, the entire infrastructure must be re-cleared.

Regulatory Clearance





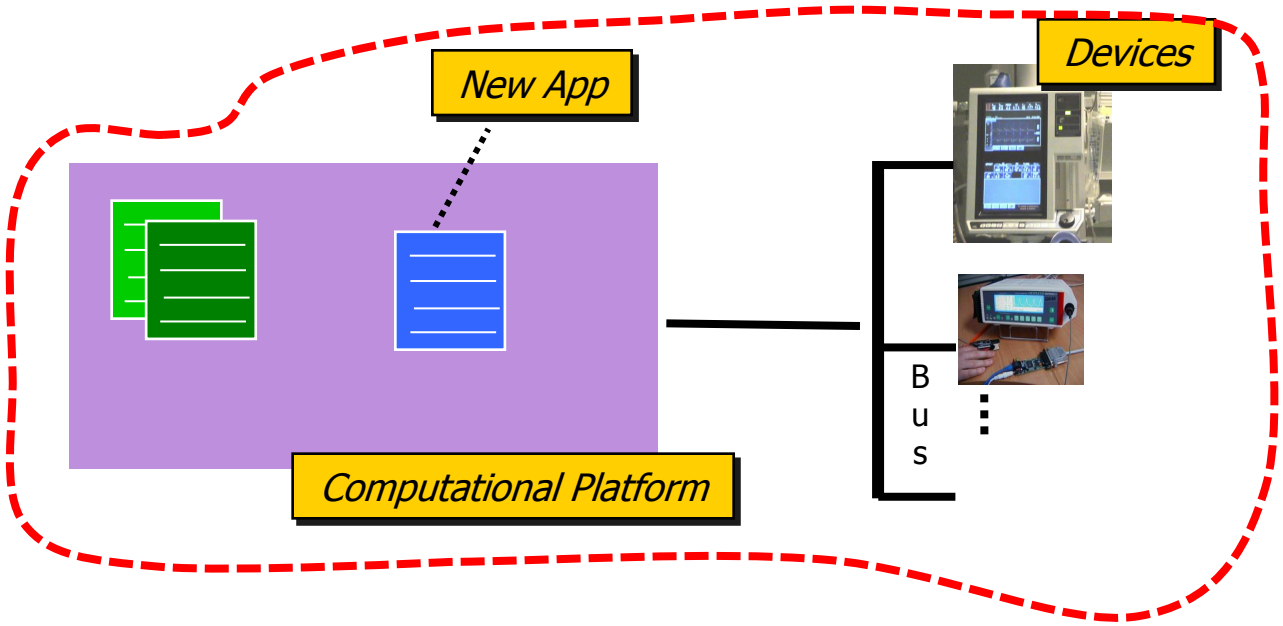
+

Z X Y

Assume monitoring system was originally developed, verified, and received regulatory clearance for devices of type X & Y.

In current regulatory approach, adding a new type of device (e.g., Z) typically causes the entire system to be re-submitted for regulatory clearance.

Needed: New Regulatory Approach



Scope of regulation in a pair-wise approach

- In the current "pair-wise" regulatory approach, when adding a new app…
  - …the scope of regulation would be the entire system
  - …i.e., set of all MAP instances and app would need to be submitted for regulatory approval

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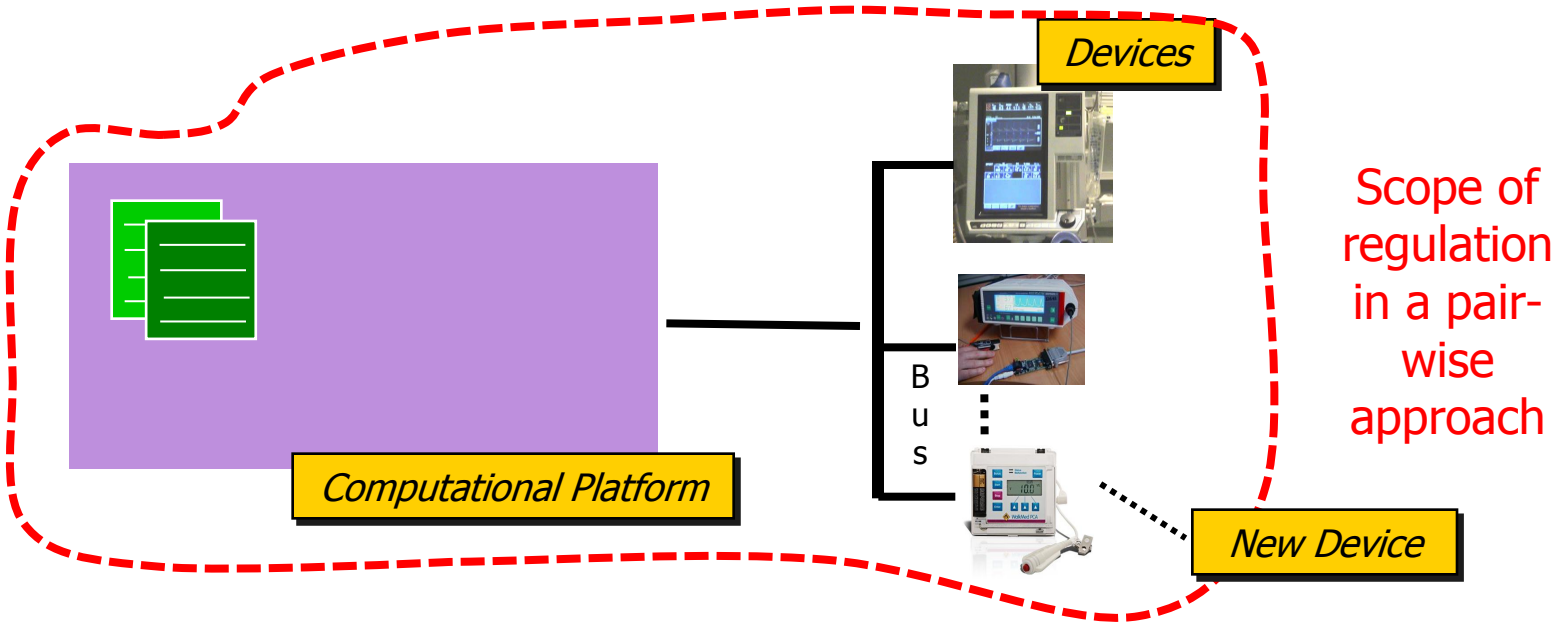

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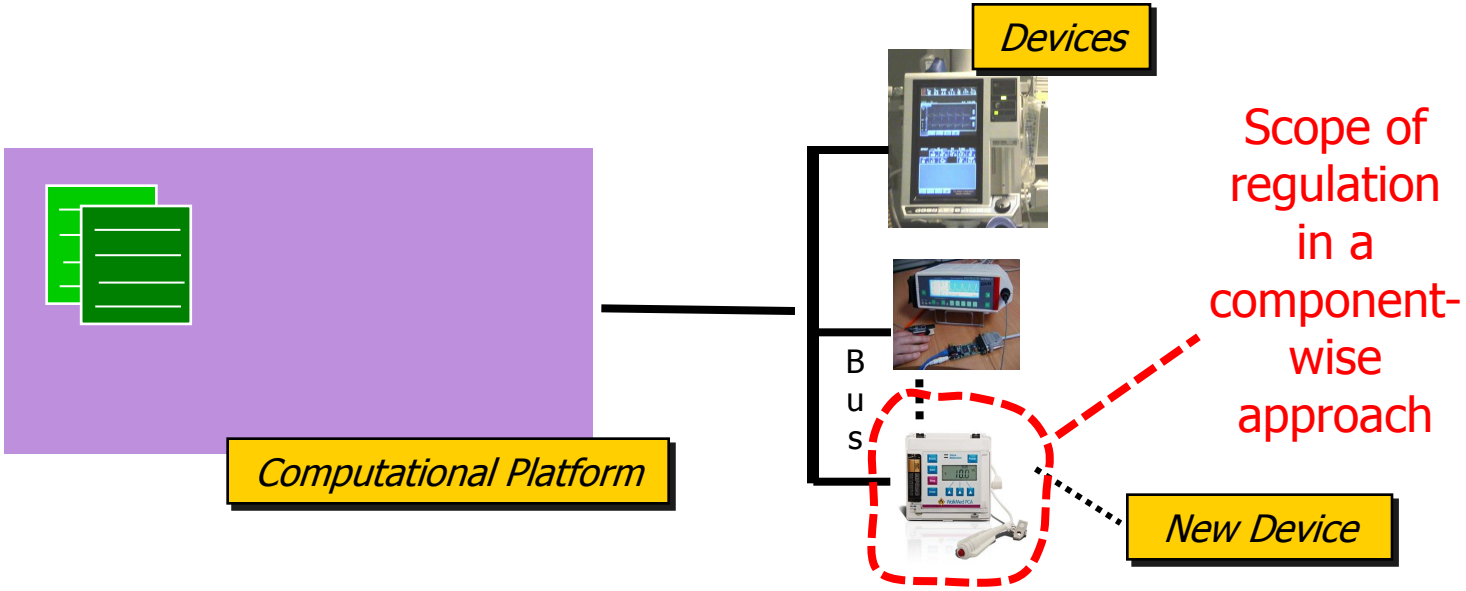
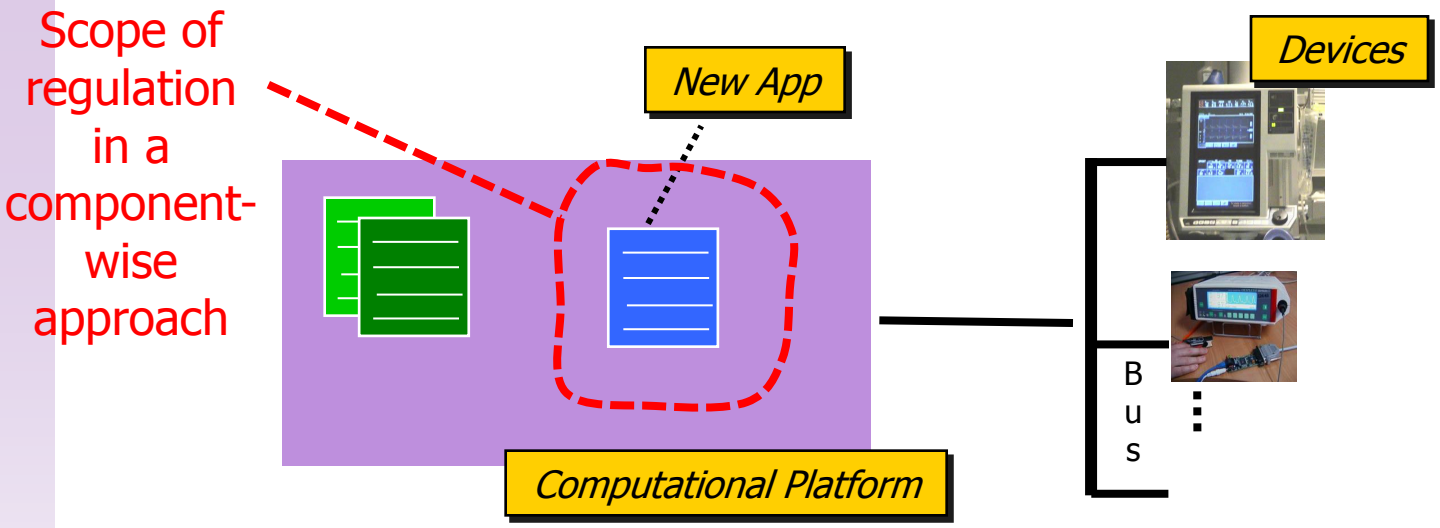
Envisioned Compositional Approach



- In an envisioned "component-wise" regulatory approach, when adding a new device…
  - …the scope of regulation would be the device and its MAP interface
    - Does it appropriately declare its capabilities, hazards, safety-states?
    - Does it appropriately implement the MAP networking protocols?

Envisioned Compositional Approach

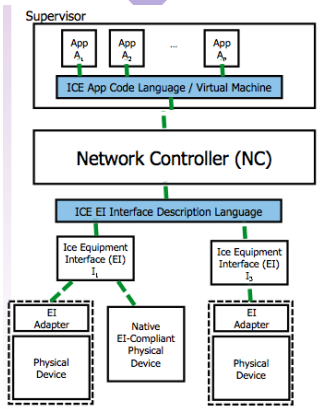


- In an envisioned "component-wise" regulatory approach, when adding a new app…
  - …the scope of regulation would be the just the app
  - …the app specifies its requirements for devices and platform capabilities (which would be checked by the platform at launch time)
  - …the app regulatory submission provides an overall argument for safety of the constituted device

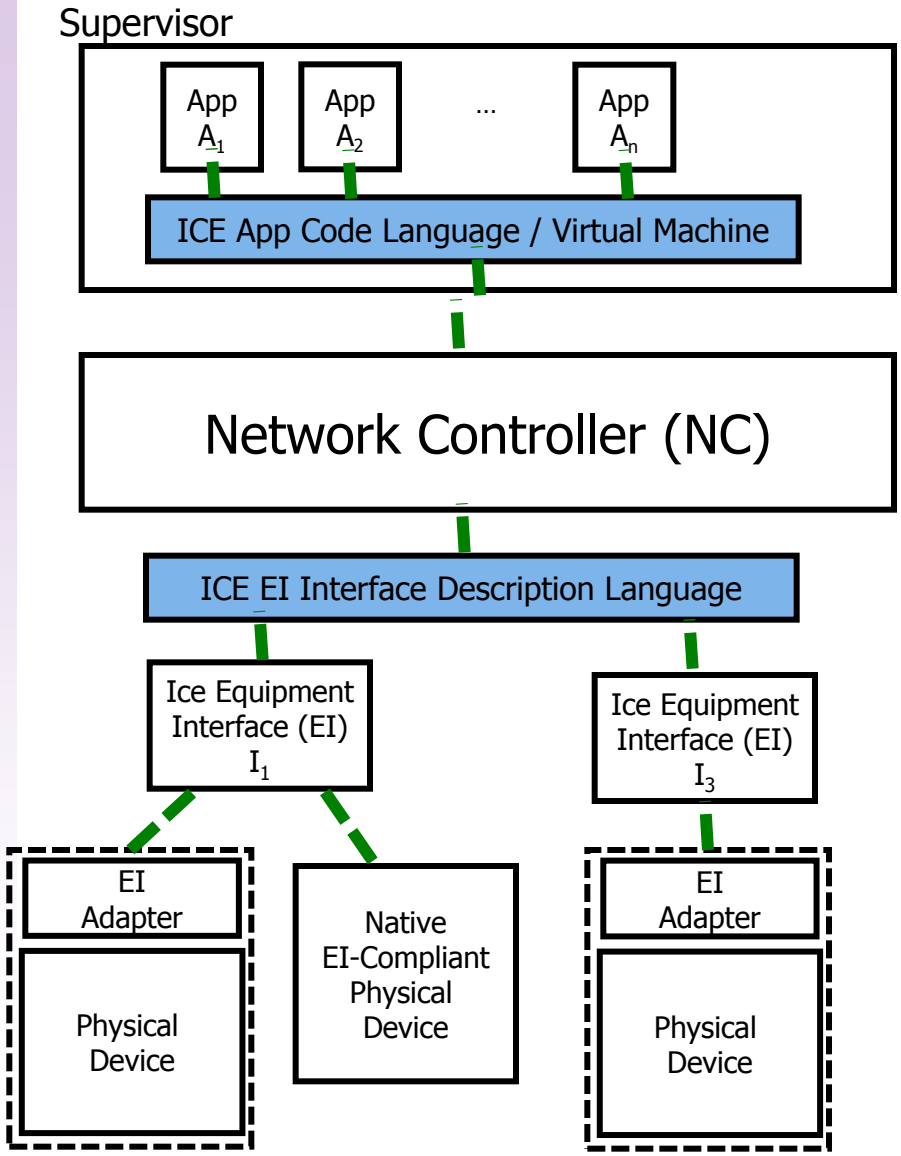
This Talk

High-level presentation of issues related to architecture – not specific solutions

- Clinical motivation for cyber-physical systems of systems
- Concept of a Medical Application Platform (MAP)
- Distinguishing characteristics of MAPs
- Integrated Clinical Environment – an architectural standard for MAPs
- Medical Device Coordination Framework (MDCF) – an open source framework for prototyping MAP concepts

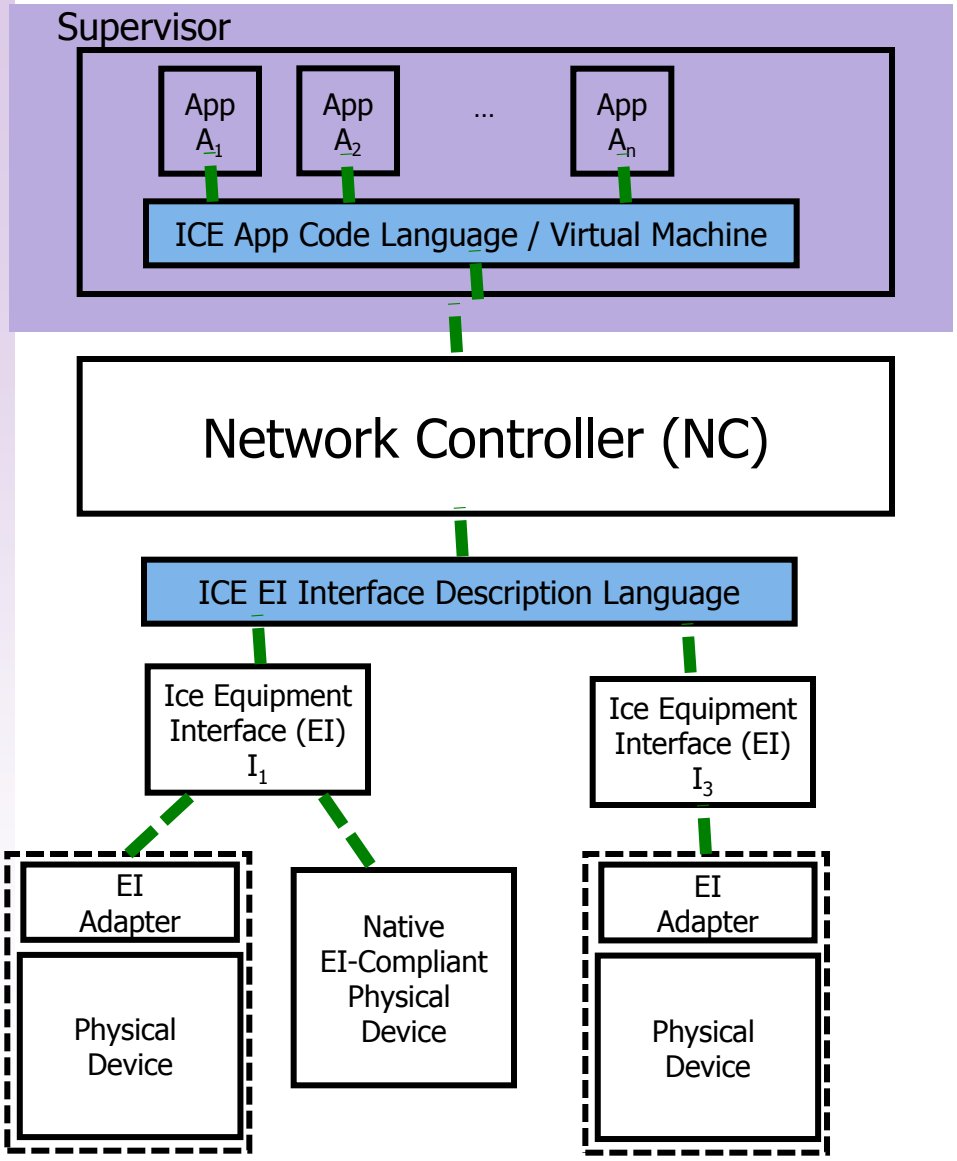


Integrated Clinical Environment



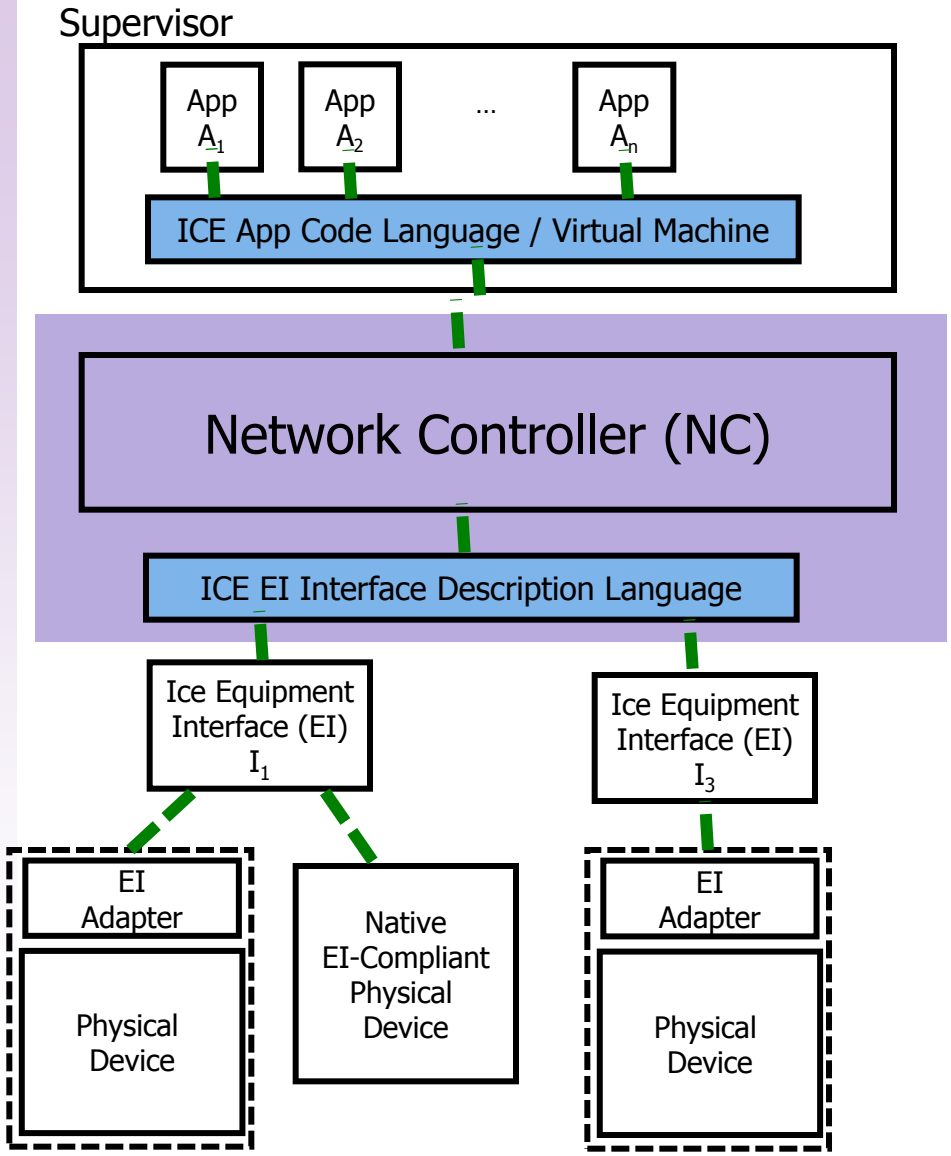
- ASTM Standard F2761-2009 for ICE defines a high-level architecture and functional concept
- Subsequent standards are intended to provide specific functional and interfacing requirements for components
- The ICE architecture standard is the focal point for FDA's evaluation of MAP concepts in future medical systems
  - A key element of this evaluation is moving from regulation of "systems as a whole" to component-wise regulation

Supervisor Concept/Goals



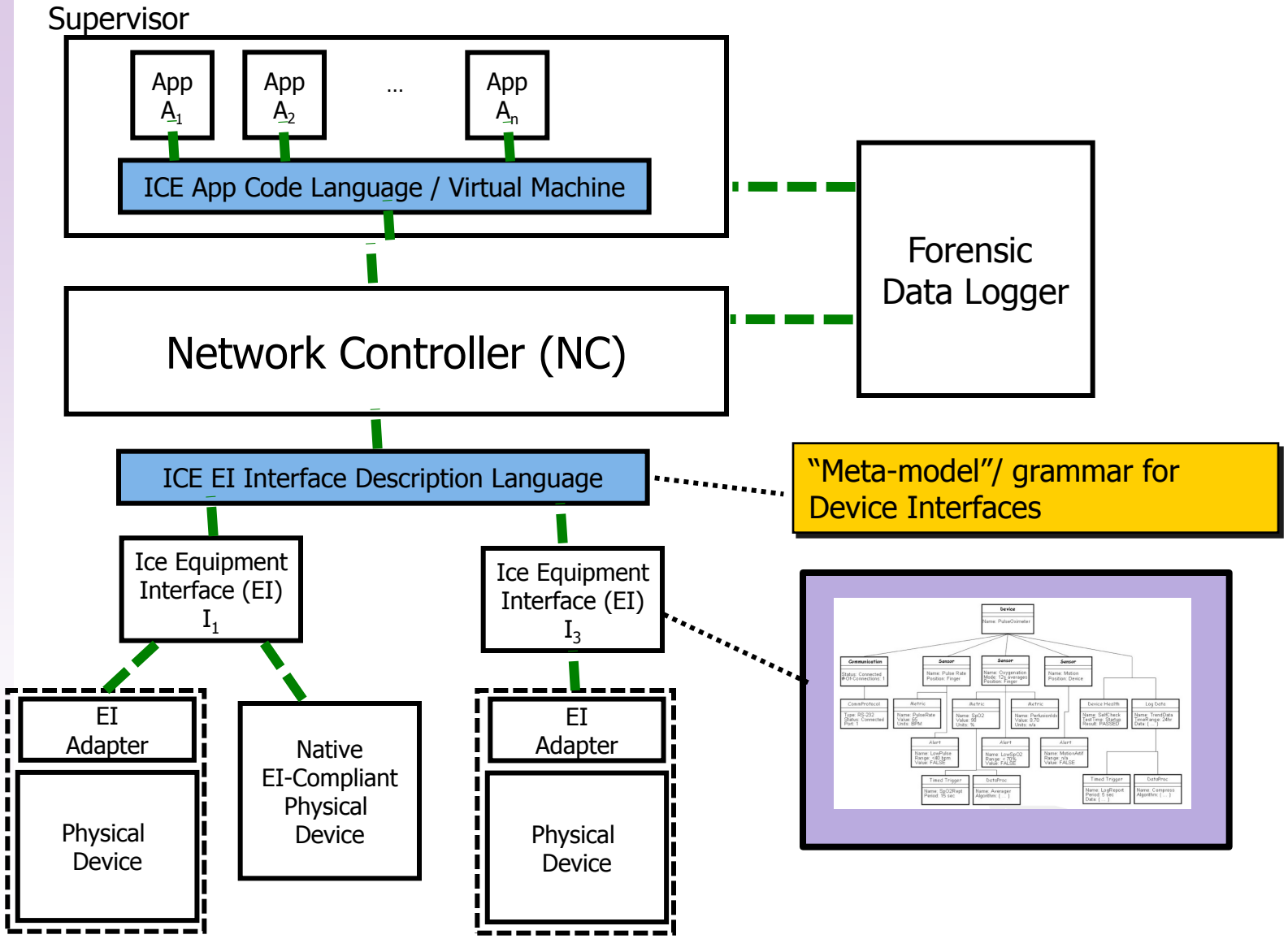
- Provides virtual machine (separation kernel) functionality to host apps
  - Data partitioning
  - Time partitioning
- [Vision] Dynamic scheduleability analysis determines if the Supervisor and Network Controller have the resources to support real-time execution requirements of app and real-time communication requirements via Network Controller to devices
- During app execution, interprets app requests for device info to appropriate transactions on the network controller
- Propagates important device (+connection) state changes to app exception handlers
- Supports device/patient binding

Network Controller Concept/Goals



- High assurance communication medium that provides virtual "information channels" with guaranteed security and performance between devices and supervisor apps
  - Must support dynamic creation/reclaimation of channels as apps and devices run/connect and terminate/disconnect
- Exposes the ICE interfaces of attached devices to apps
  - Handles app requests to read/write to device interfaces with appropriate access/concurrency control
  - Tracks health of devices and device connections and notifies associated apps when problems occur
- Manages the discovery and connection protocol of devices that desire to connect to the ICE
  - *Authentication* ensures that only devices that have been previously certified as ICE compliant can connect/associate

Device Interfacing

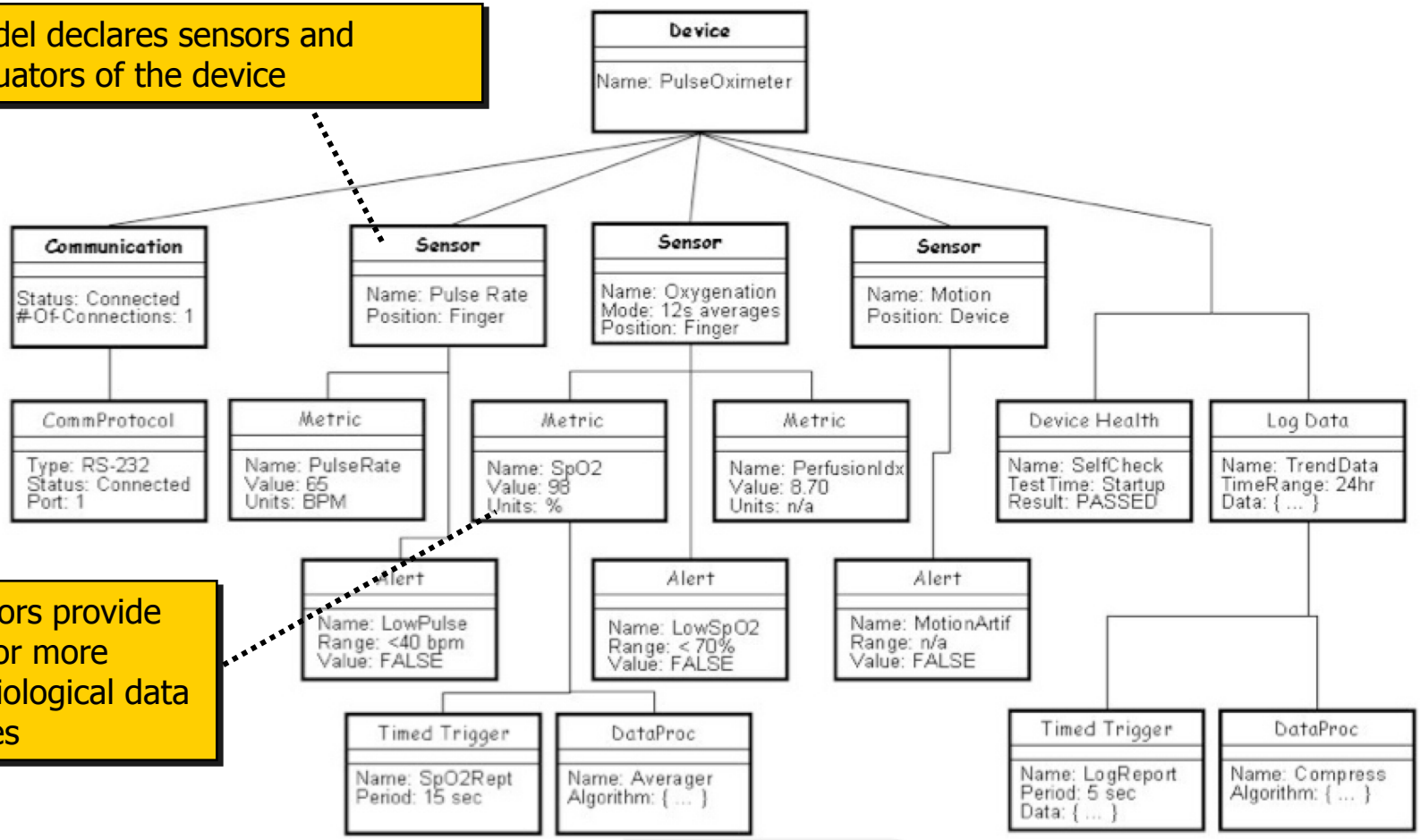


ICE Device Model Concepts

Device Model provides a declarative description of a devices capabilities that will be exposed to apps – one possible notion of *device model* is illustrated below.

Model declares sensors and actuators of the device

Sensors provide one or more physiological data values



ICE Device Model Concepts

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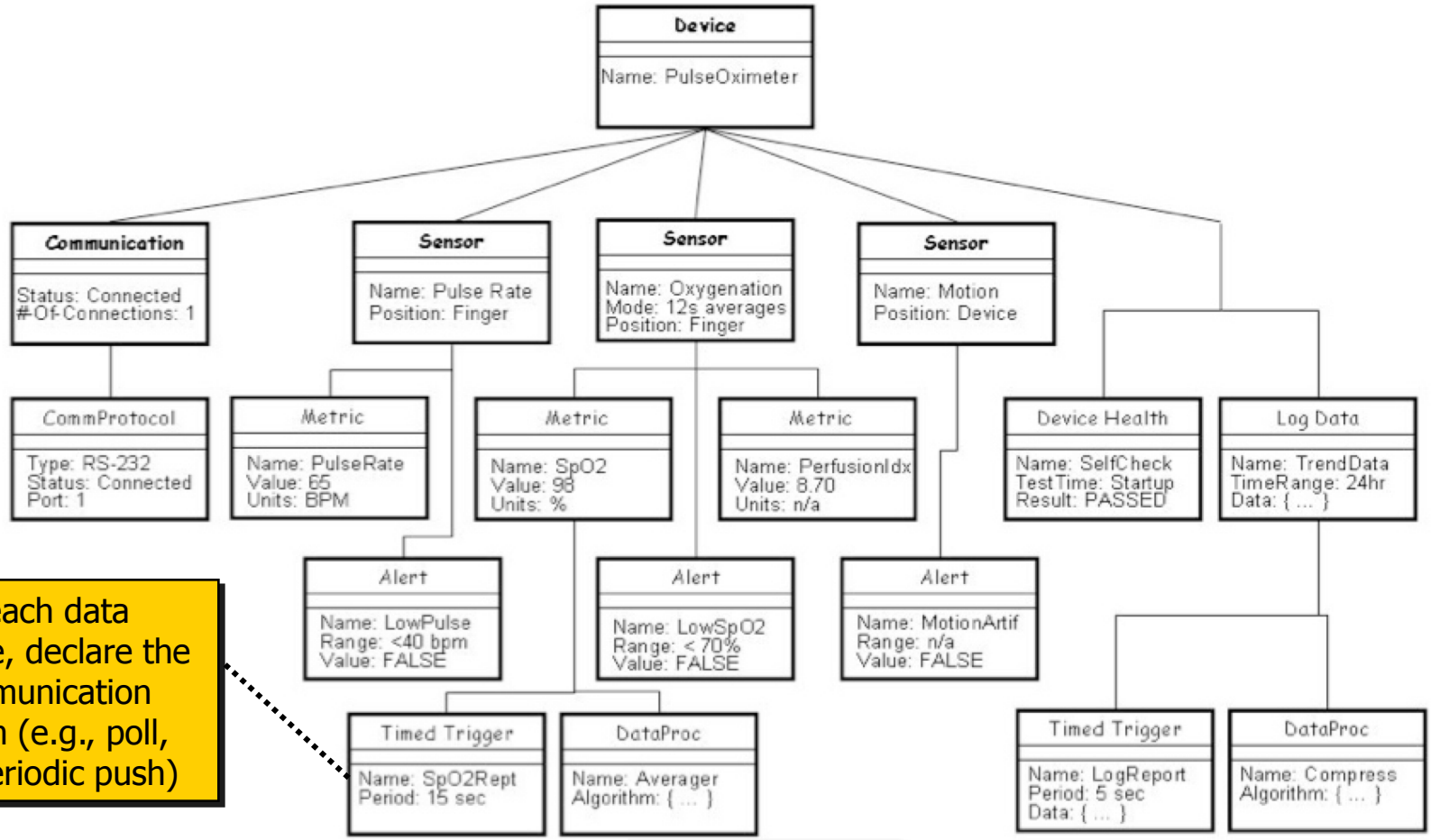

For each data value, declare the communication idiom (e.g., poll, or periodic push)

This Talk

High-level presentation of issues related to architecture – not specific solutions

- Clinical motivation for cyber-physical systems of systems
  - See also keynote talk of Dr. Julian Goldman
- Concept of a Medical Application Platform (MAP)
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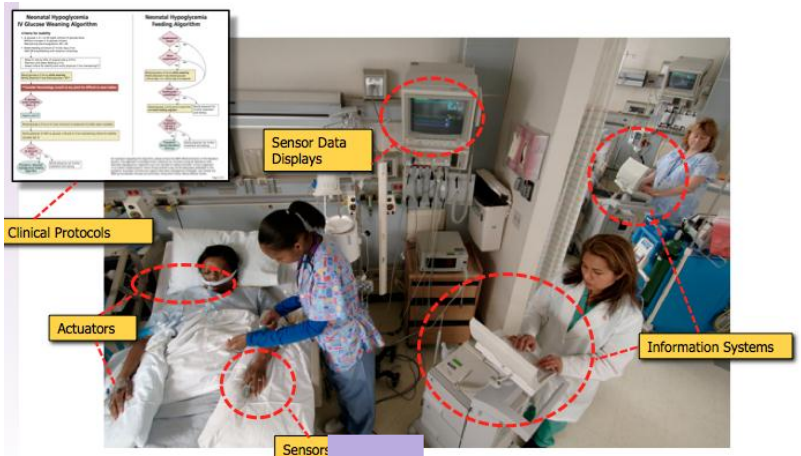
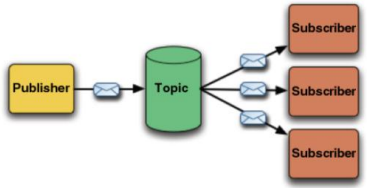
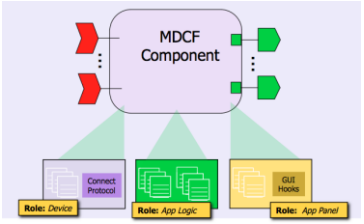
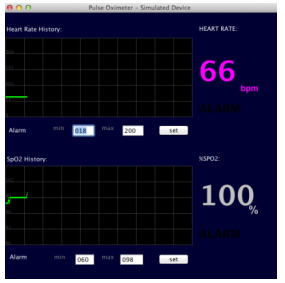








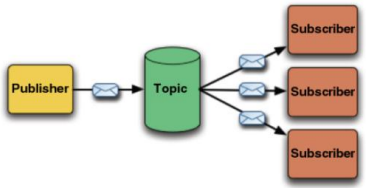
Medical Device Coordination Framework

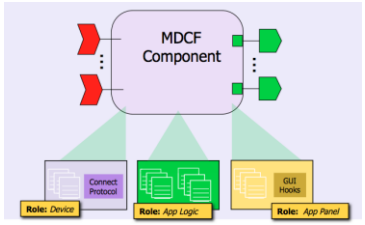
Open experimental ICE-compliant platform to bring together academic researchers, industry vendors, and government regulators

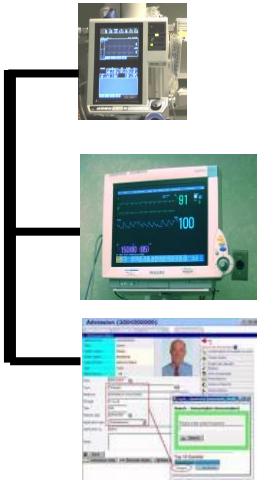
- Background
  - Developed by Kansas State University and U Penn
  - Funded by NSF CPS and NSF FDA Scholar-in-Residence programs
- Goals
  - Open source infrastructure
  - Meet performance requirements of realistic clinical scenarios
  - Provide middleware with reliability, real-time, security
  - Provide 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

MDCF Themes

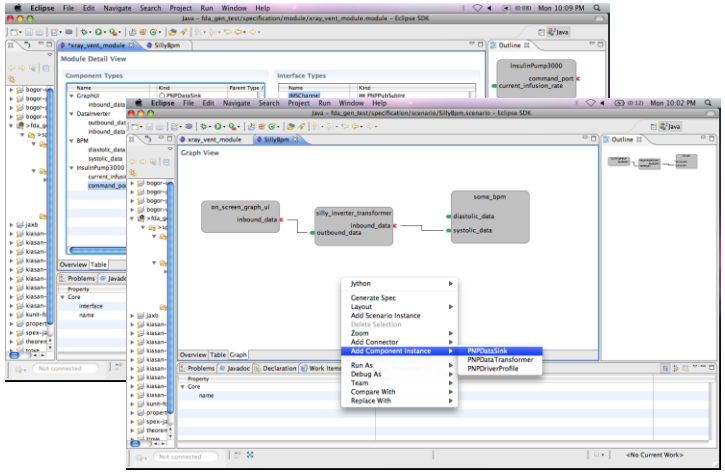
Communication Infrastructure



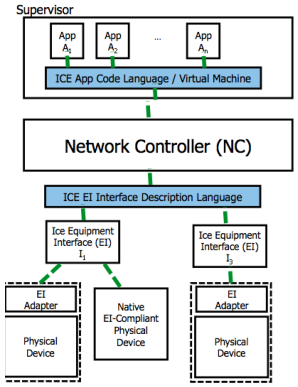




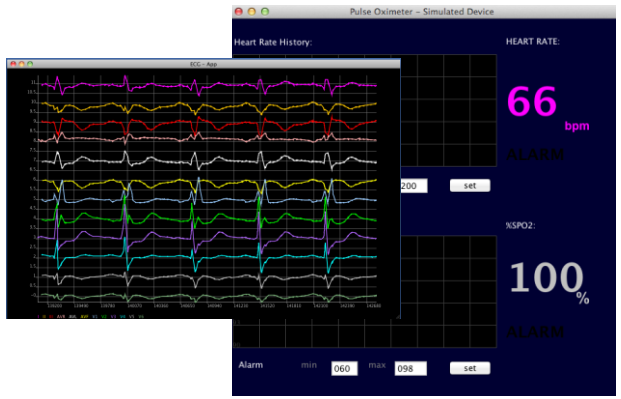
App Development Environment



Mapping to ICE Architecture



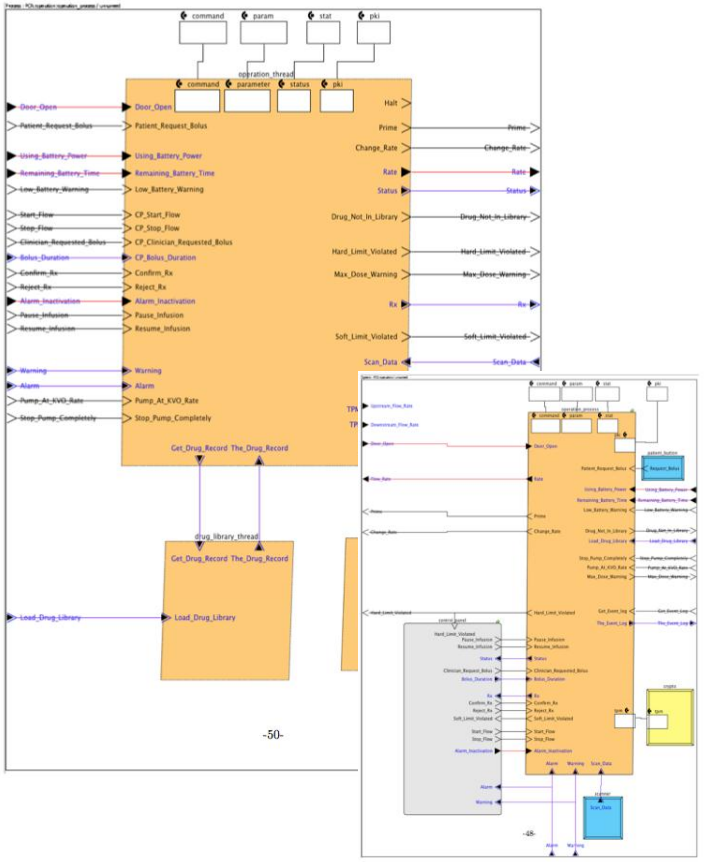
Mock Devices



PCA Pump Specification

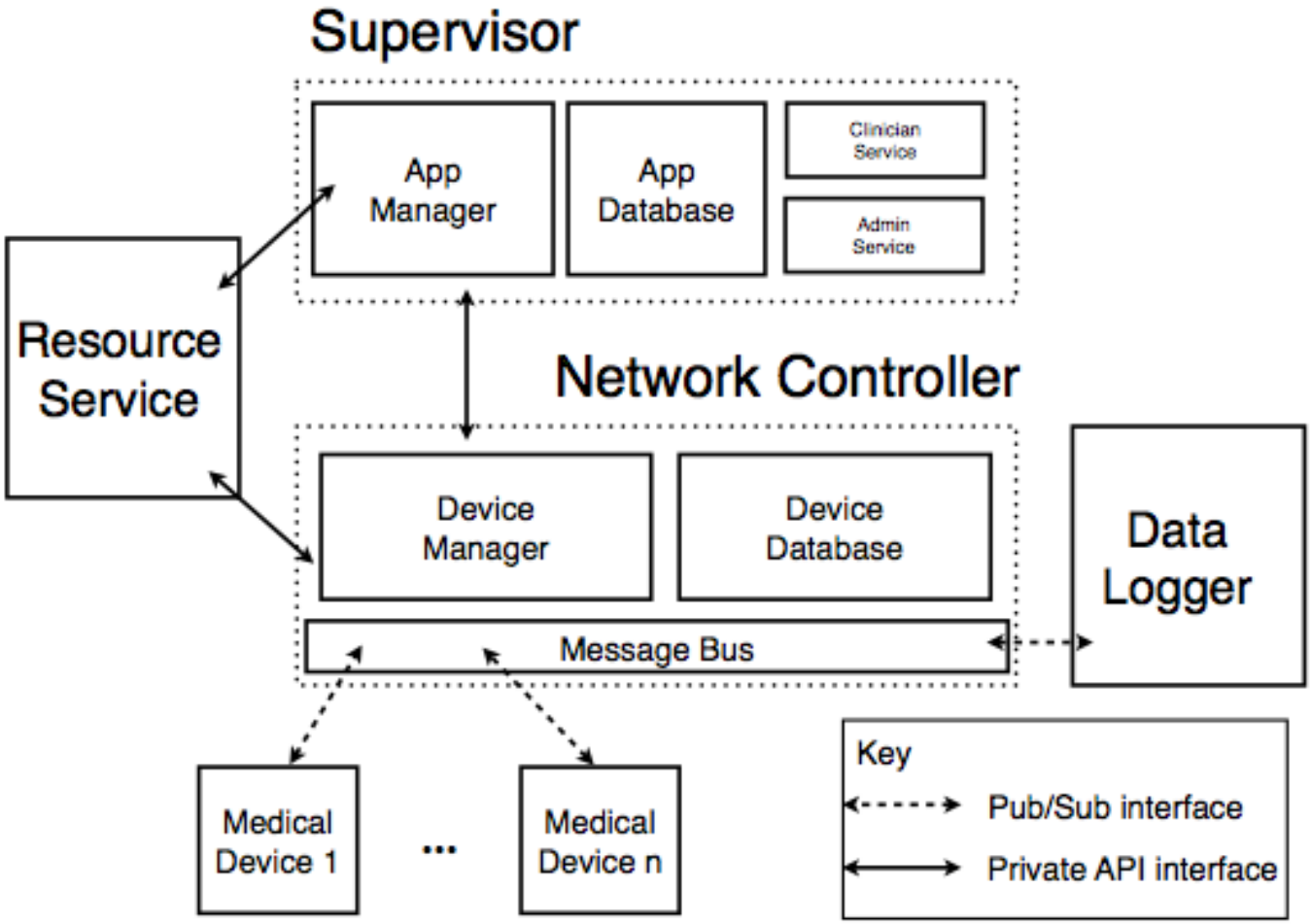
KSU Research Associate Brian Larson has developed extensive collection of artifacts for driving standards design and regulatory investigations, developed with FDA via NSF FDA Scholar-in-Residence program, builds off earlier work at U Penn

- 50+ page requirements document written following FAA Requirements Engineering and Management Handbook
- Architecture formally defined in AADL
  - Adopts a safety architecture approach
- Behavioral interface specification in BLESS
- Internal behavior and proofs of correctness in BLESS
- Associated hazard, risk management, and regulatory artifacts
  - One focus is formal definition and risk assessment associated with ICE interface



MDCF / ICE Organization

See paper for a brief overview of how MDCF modules are used to support (partial) ICE functionality

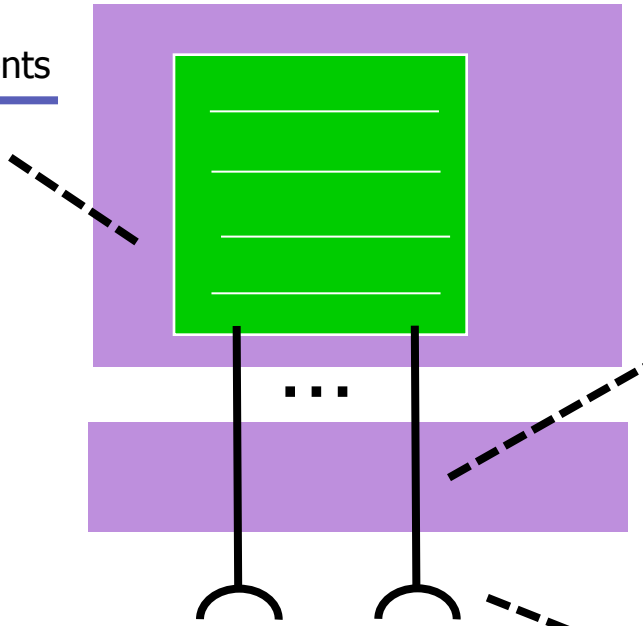


Trust via Staged Checking

App declares its requirements for devices, communication, execution. A Priori third-Party certification evaluates safety/correctness of app wrt those declarations.

App's Supervisor Requirements

Scheduling Units
Unit Periods, etc.
Memory Requirements

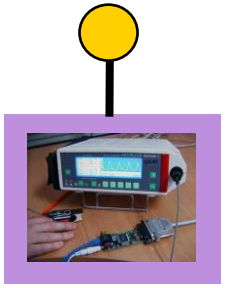


App's Network Controller Requirements (derived)

Bandwidth
Latency, etc.

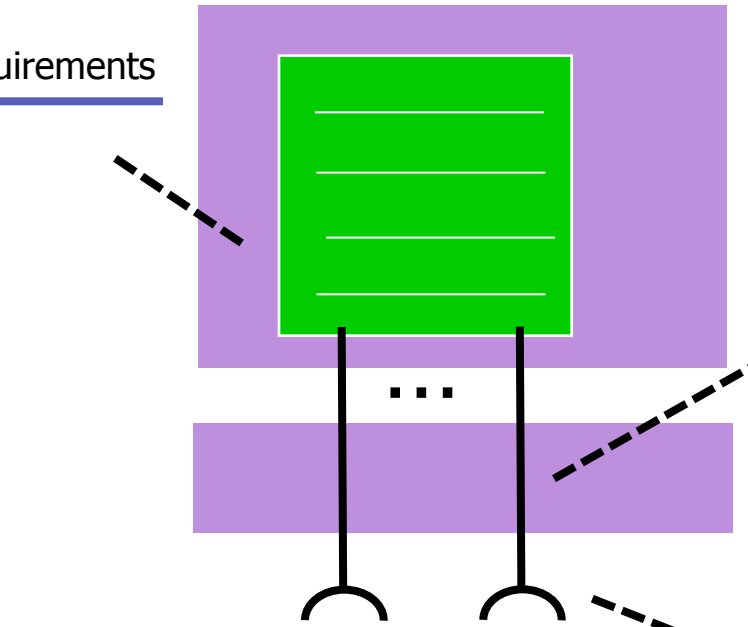
App's Device Requirements

Clinical Data
Control Functions
QoS / RT Constraints
Safety Modes
Hazards Handled
Access & Security Constraints



Trust via Staged Checking

Device declares its capabilities for supplying clinical data control functions, safety modes, QoS/RT properties. A priori third-party certification evaluates safety/correctness of device wrt those declarations.



App's Supervisor Requirements

Scheduling Units
Unit Periods, etc.
Memory Requirements

App's Network Controller Requirements (derived)

Bandwidth
Latency, etc.

App's Device Requirements

Clinical Data
Control Functions
QoS / RT Constraints
Safety Modes
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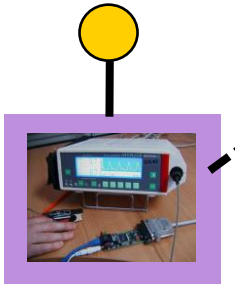
Access & Security Constraints

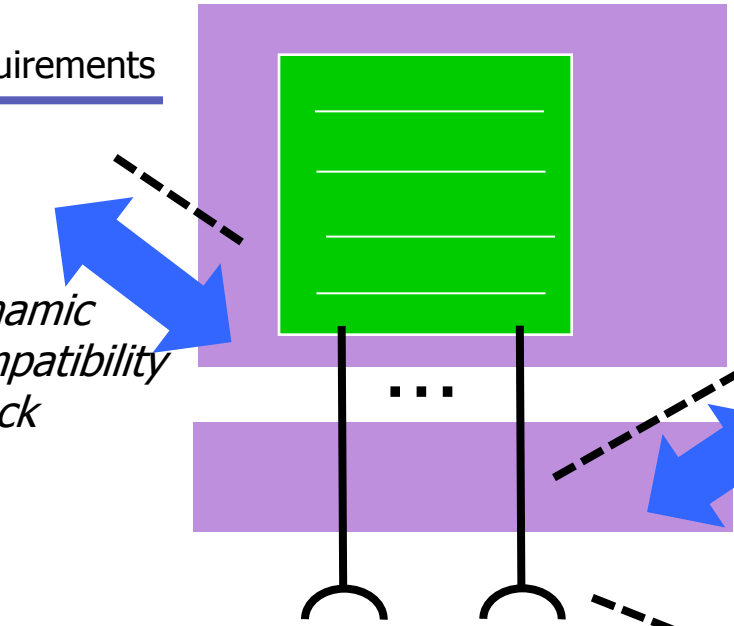


Device Capabilities

Clinical Data
Control Functions
QoS / RT Constraints
Safety Modes
Hazards Generated
Access & Security Constraints

Trust via Staged Checking

At app launch time, platform services check to see whether platform and attached devices can satisfy requirements stated by the app. If so, app is launched. If not, app is not allowed to run.



App's Supervisor Requirements

Scheduling Units
Unit Periods, etc.
Memory Requirements

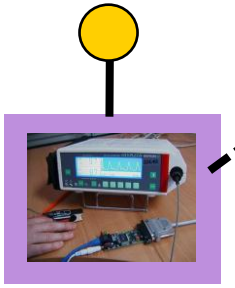
Dynamic compatibility check

App's Network Controller Requirements (derived)

Bandwidth
Latency, etc.

App's Device Requirements

Clinical Data
Control Functions
QoS / RT Constraints
Safety Modes
Hazards Handled
Access & Security Constraints



Device Capabilities

Clinical Data
Control Functions
QoS / RT Constraints
Safety Modes
Hazards Generated
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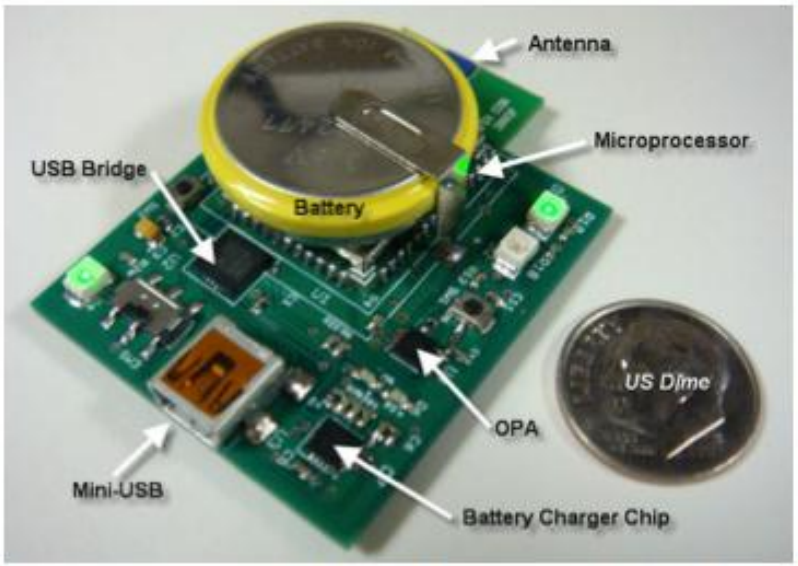
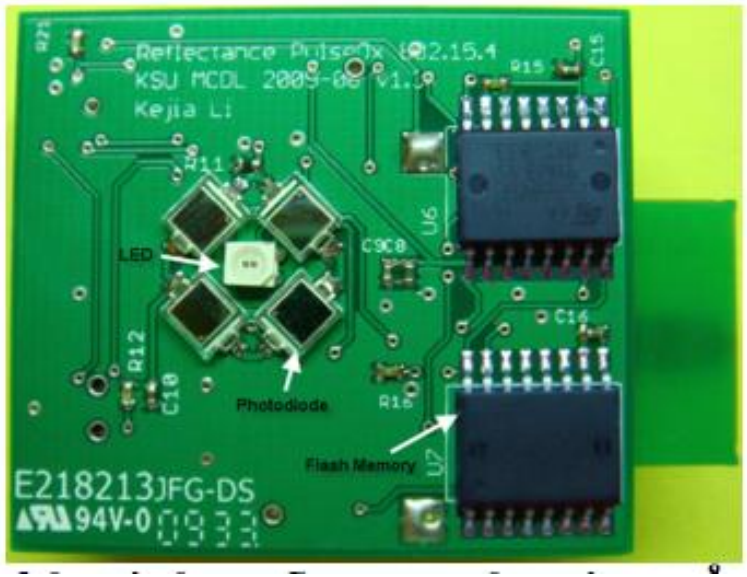
Medical Platform-Oriented Devices

Headless, wireless, pulse oximeter developed by Dr. Steve Warren at KSU EECE…

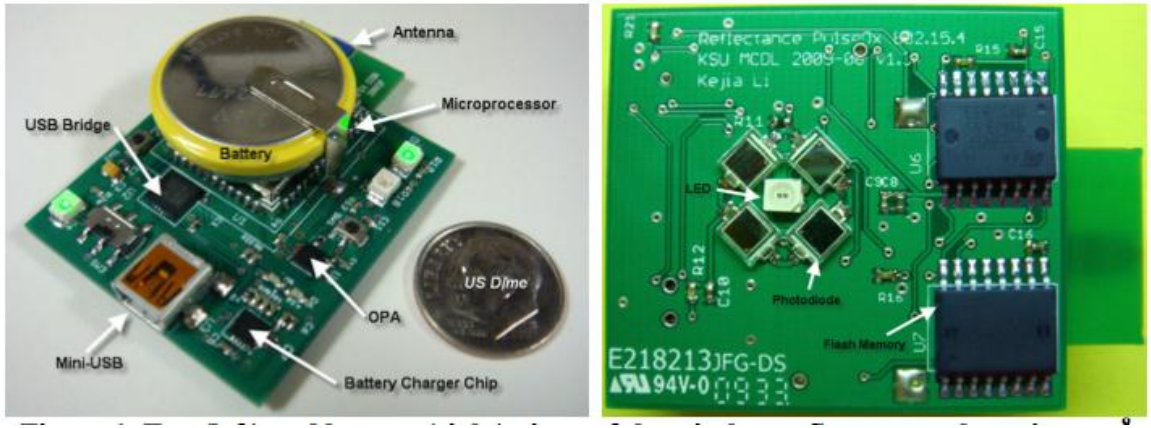




- Thinking about what devices would look like if they were designed from scratched to be integrated with the MDCF (or iBus)
- Headless, small form-factor devices that transmit raw waveforms
- Computation is done in apps, leading to highly (re)configurable devices

Medical Platform-Oriented 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

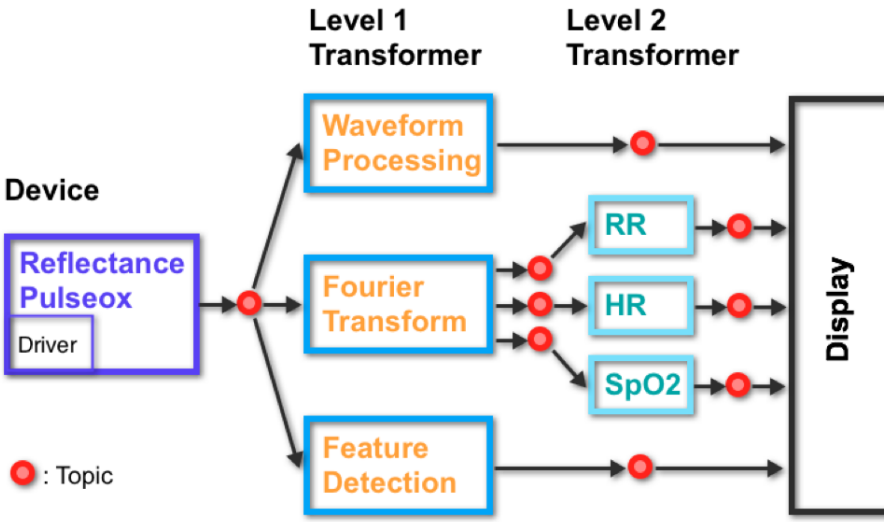
- Systolic, diastolic, BP
- Stroke volume (SV)
- Cardiac output (CO)
- Respiration rate (RR)
- Peak-to-peak time (PPT)
- Pulse wave velocity (PWV)
- Arterial elasticity (AE)
- Stiffness index (SI)
- Reflection index (RI)
- Perfusion index (PI)
- Patient activity/motion
- Patient identity
- Ambient light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

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)

Medical Platform-Oriented Devices

MDCF + apps + sensors/actuators = reconfigurable medical devices

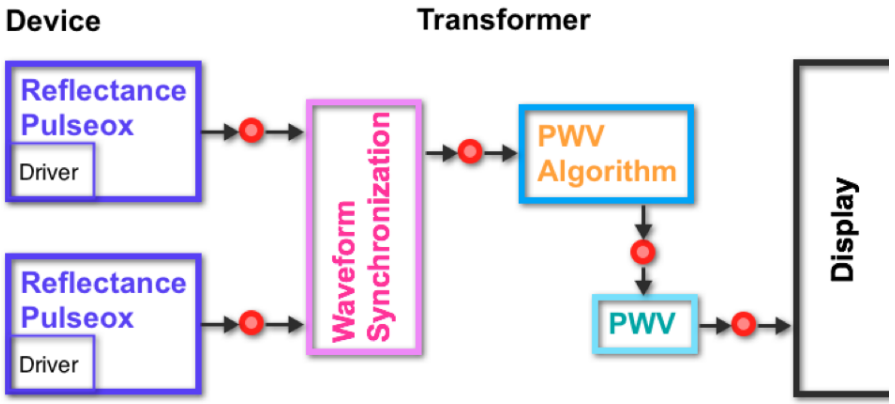
Example 1: App to extract HR, SpO_2, and RR with moving averages, display smoothed waveforms.



Medical Platform-Oriented Devices

MDCF + apps + sensors/actuators = reconfigurable medical devices

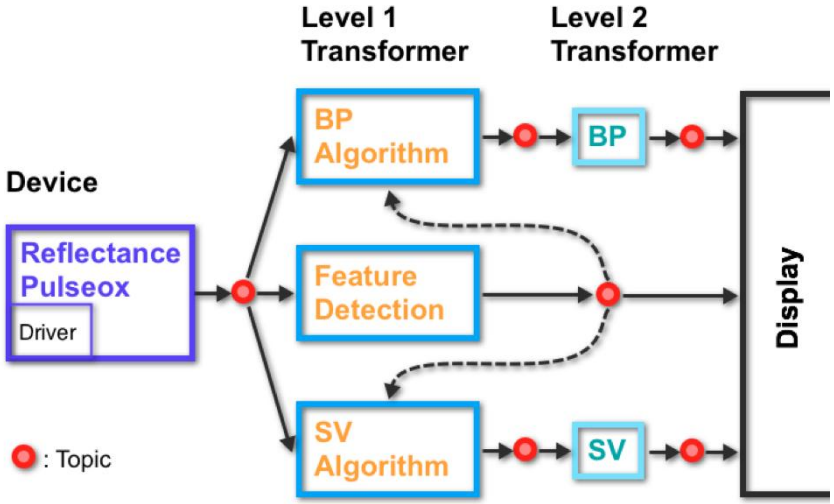
Example 2: App using two MPOD POs (positioned at the wrist and finger of the same hand) to extract pulse wave velocity. The Waveform Synchronization transformer aligns the PPGs received from the two devices using timestamps in the messages. The synchronized waveforms are then streamed to the central 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.



Medical Platform-Oriented Devices

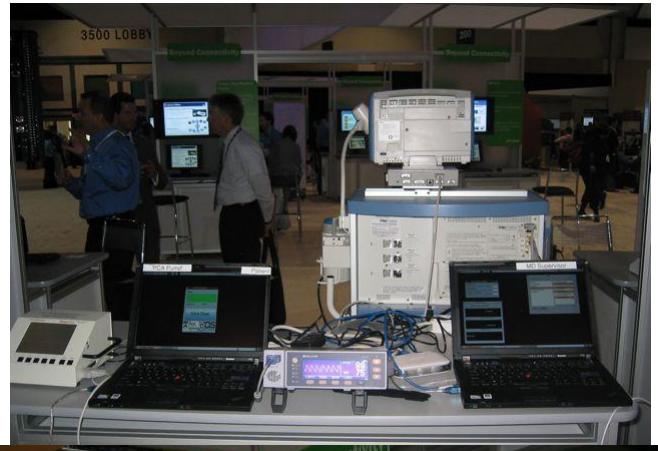
MDCF + apps + sensors/actuators = reconfigurable medical devices

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



MDCF in Action

- MDCF is definitively a prototype, but it has been used to support demos of MAP concepts at several industry events
  - HIMSS 2012, Device Connectivity 2011, Cerner Health Conference 2011
- Through NSF FDA Scholar-in-Residence program, working directly with FDA engineers on app development environment, safety arguments
- Supporting investigations related to UL 2800 – Underwriter Laboratories standard on device interoperability
- Supporting investigations on NIH/NIBIB Quantum project
- Interfacing with Continua devices, hand-built interfaces, etc.
- See project web-site for additional application papers



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

Summary

- Described the concept of *Medical Application Platforms* – one vision for introducing cyber-physical systems of systems functionality into health care delivery
- This work flows out of a large multidisciplinary team of…
  - Clinicians, device integrators, national testing and standards organizations, regulatory authorities
  - …drawn from NIH/NIBIB Quantum project and Medical Device Safety Interoperability Working Group
- Collaborating on solution technologies, regulatory pathways, business model / ecosphere for MAPs
  - Medical Device Interoperability Safety Working Group
  - UL 2800 Device Interoperability Standards
- ASTM ICE standard (initiated by Dr. Julian Goldman at CIMIT) is providing a foundation for organizing technical work and regulatory issues
- The Medical Device Coordination Framework (MDCF) from KSU/U Penn is providing a platform for experimenting with MAP/ICE concepts and illustrating proposed safety and regulatory artifacts

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

From *Connectivity* to *Systems*

Looking ahead…

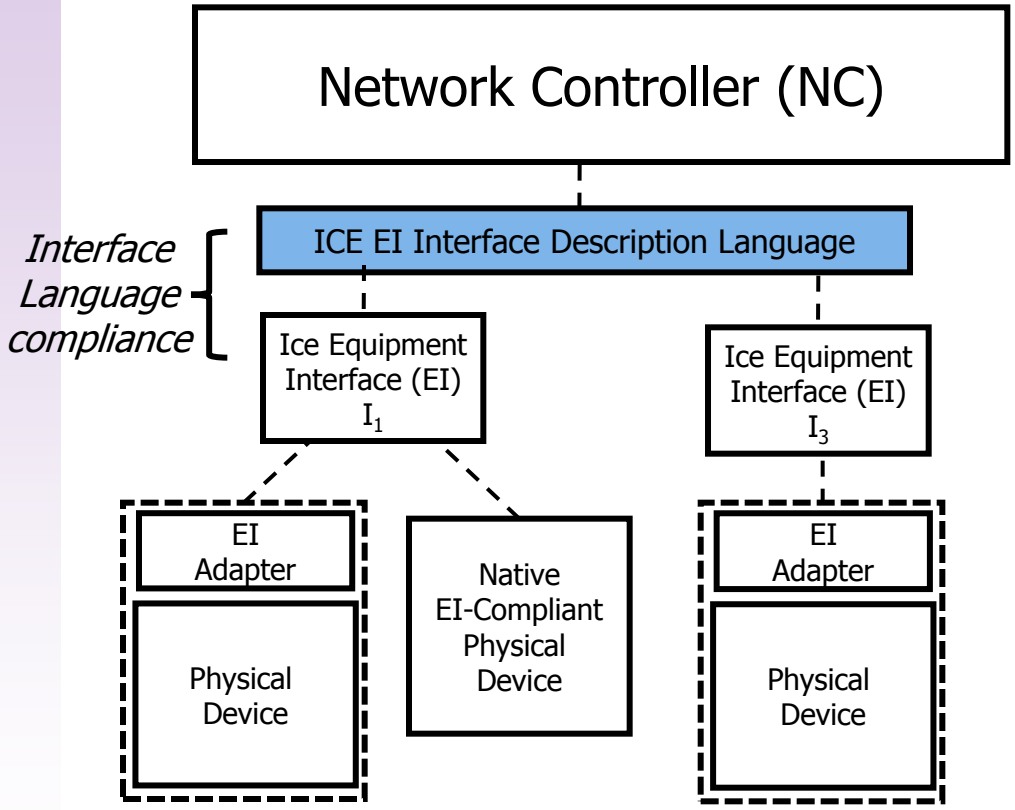
- Delivering modern medical care involves complex cyber-physical systems…
  - many medical devices, electronic medical records, clinicians/care-givers …all working together to achieve a goal

- 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

How might health care delivery benefit if devices and EHR databases could function as components of automated systems?

For ICE: "Component-wise"

The ICE vision emphasizes compositional or "component-wise" clearance – current regulatory authorities still need to be convinced that this approach can assure safety and effectiveness.

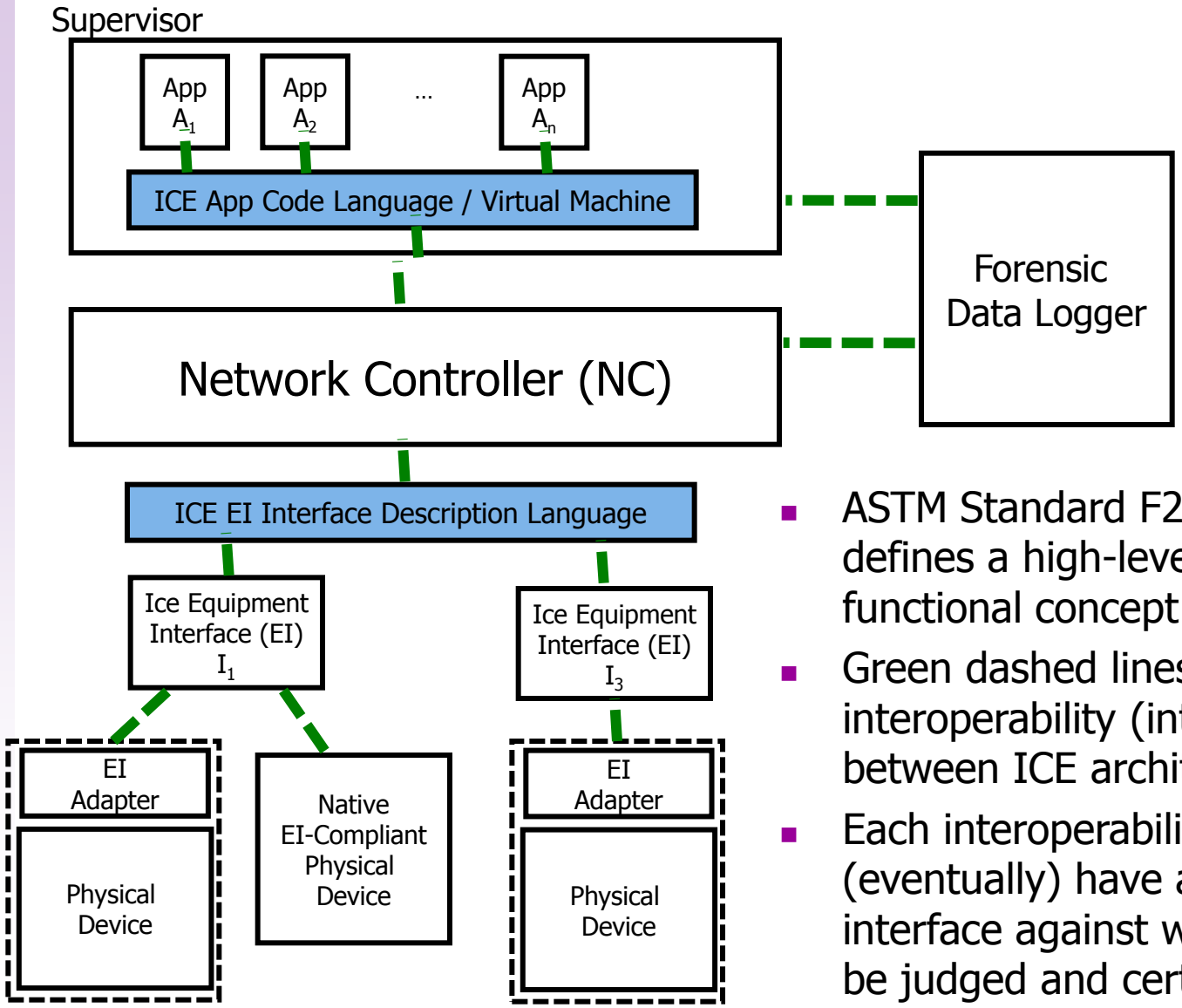


In ICE, all possible interfaces between NC and devices are cannot be known *a priori.* We need to support "variable interfaces" – interfacing between NC & devices that allows device interfaces to be different.

Variable interfacing will be achieved by defining an ICE Interface Description Language. A NC is cleared against the ICE IDL (showing that it can interface with any device whose interface is correctly describing using the IDL).

Using a fixed interfacing approach between NC and devices would either limit the devices that could be attached or would require standard to be changed and NCs to be re-cleared when new device types were incorporated.

Interoperability Points



- ASTM Standard F2761-2009 for ICE defines a high-level architecture and functional concept
- Green dashed lines represent interoperability (interfacing) points between ICE architecture component
- Each interoperability point must (eventually) have a standardized interface against which compliance can be judged and certified

ICE Standard

- ASTM Standard F2761-2009 for ICE defines a high-level architecture and functional concept
- Subsequent standards are intended to provide specific functional and interfacing requirements for components
- The ICE architecture standard is the focal point for FDA's evaluation of bus-based app concepts in future medical systems
  - A key element of this evaluation is moving from regulation of "systems as a whole" to component-wise regulation

Closed Loop Control

Example Use-Case: PCA Monitoring

- Patients are commonly given patient-controlled analgesics after surgery
  - …better outcomes than nurse administered opioids
- Administers analgesics such as morphine, fentanyl, and hydromorphone
  - constant basal rate of infusion
  - bolus does delivered when patient pushes button

PCA Pump

Opioid Side-Effects -- Respiratory Depression

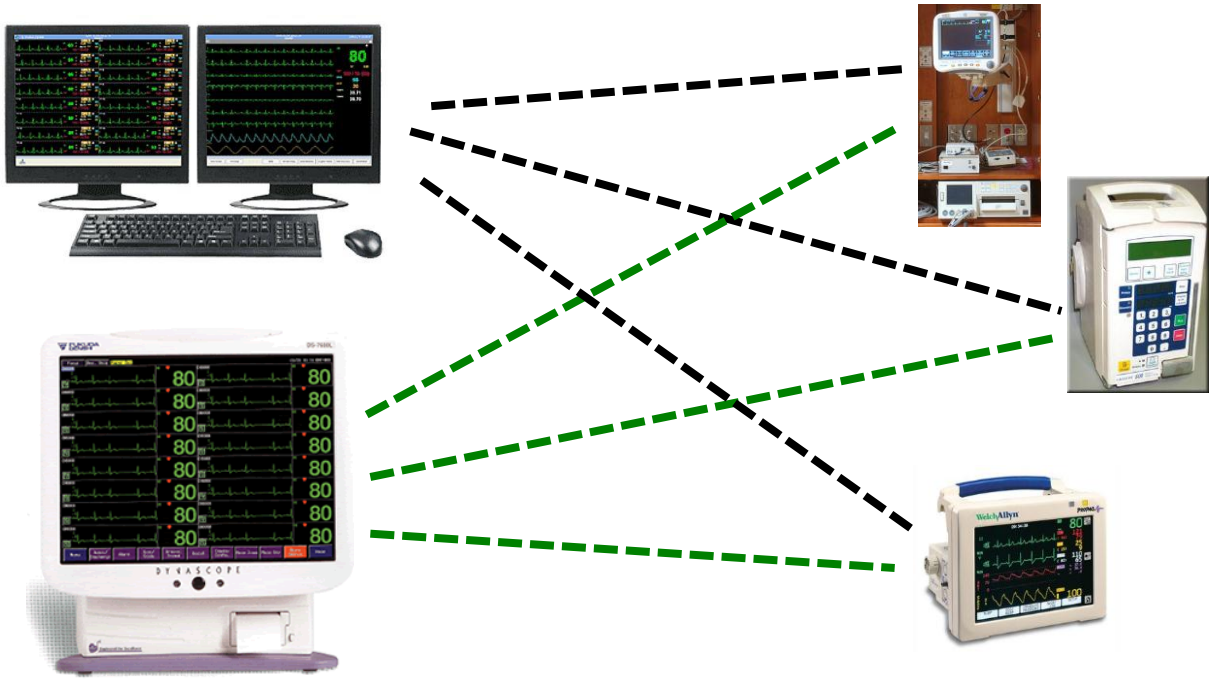
- decreased respiratory rate, decreased oxygen saturation, increased end tidal carbon dioxide
- detect by monitoring
  - heart rate, respiration rate, blood pressure
  - pulse oximeter (oxygen saturation)
  - capnography (CO_2 exhalation)

PCA Hazards

- operator error (wrong drug, wrong dosage)
- PCA by proxy
  - e.g., relative pushes button for patient
- monitoring device alarms tends to lag time of overdose

Needed: New Regulatory Approach

Current regulation of integrated systems (e.g., central station monitors) requires **"pair-wise" clearance**: whenever a new type of device is added to the monitoring platform, the entire infrastructure must be re-cleared.

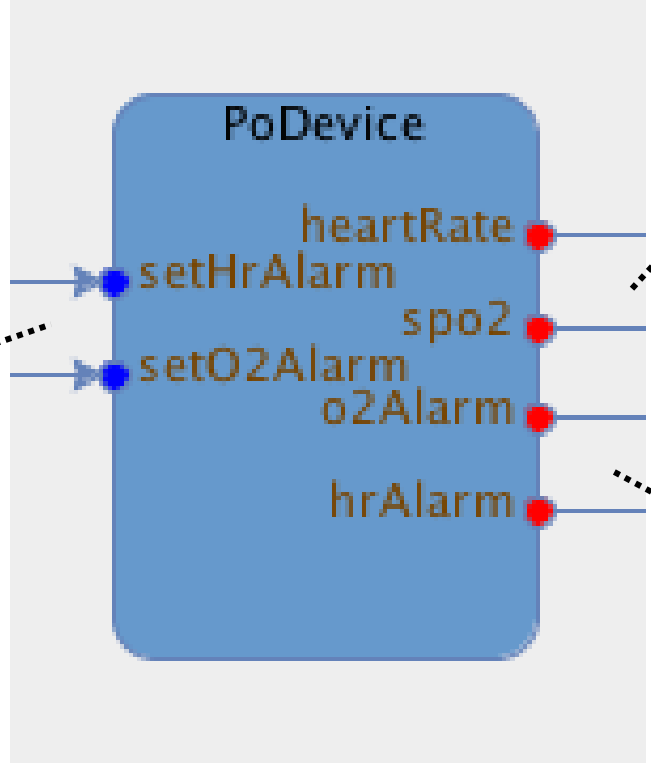


Following the existing "pair-wise" clearance approach will significantly limit the applicability of MAPs and will inhibit the development of development of a commodity market of MAP components.

Following the existing "pair-wise" clearance approach will significantly limit the applicability of ICE and will inhibit the development of development of a commodity market of ICE components.

Replay Mock Pulse Oximeter

Device Interface



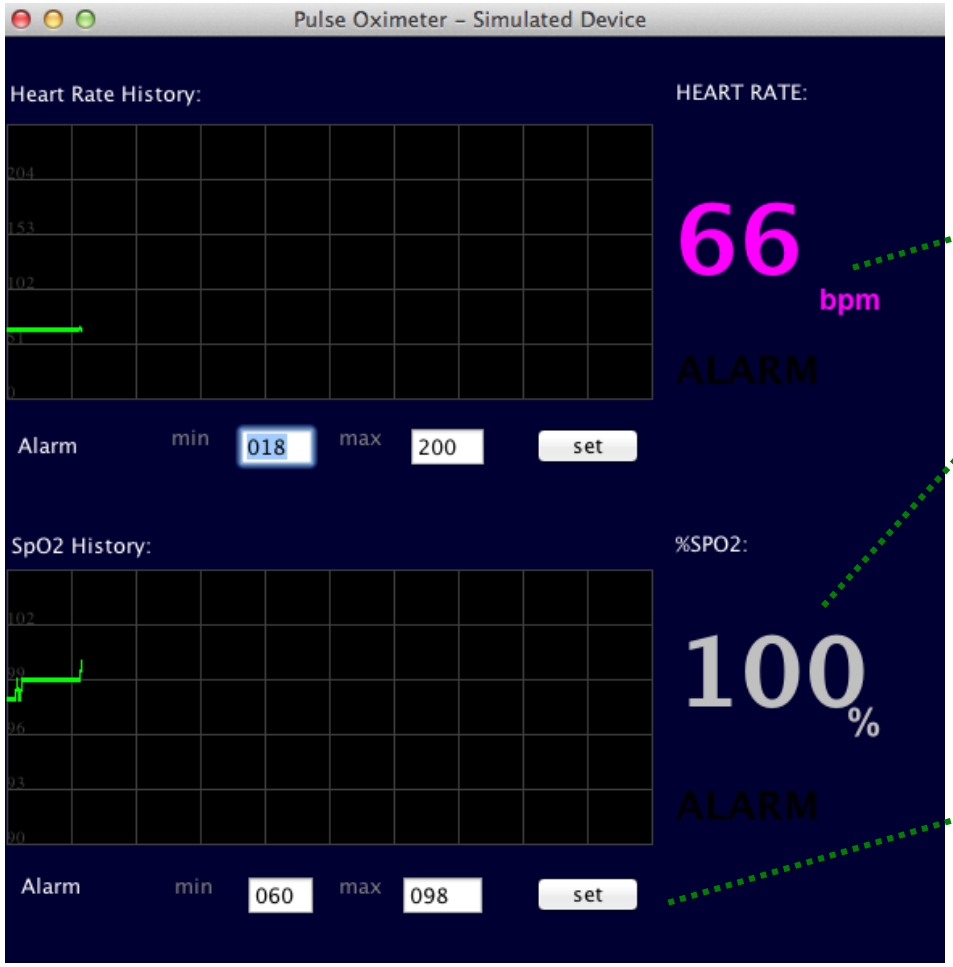
Output data streams for heart rate and SpO2 values

Input commands to set the upper/lower limits for alarms

Output event ports for signaling alarms based on violations of upper/lower limits for heart rate and SpO2

Replay Mock Pulse Oximeter

Swing UI – simulates the "front panel" of a real pulse oximeter



Output readings for heart rate and SpO2 values

Mechanism for setting alarm limits

ICE and the MDCF

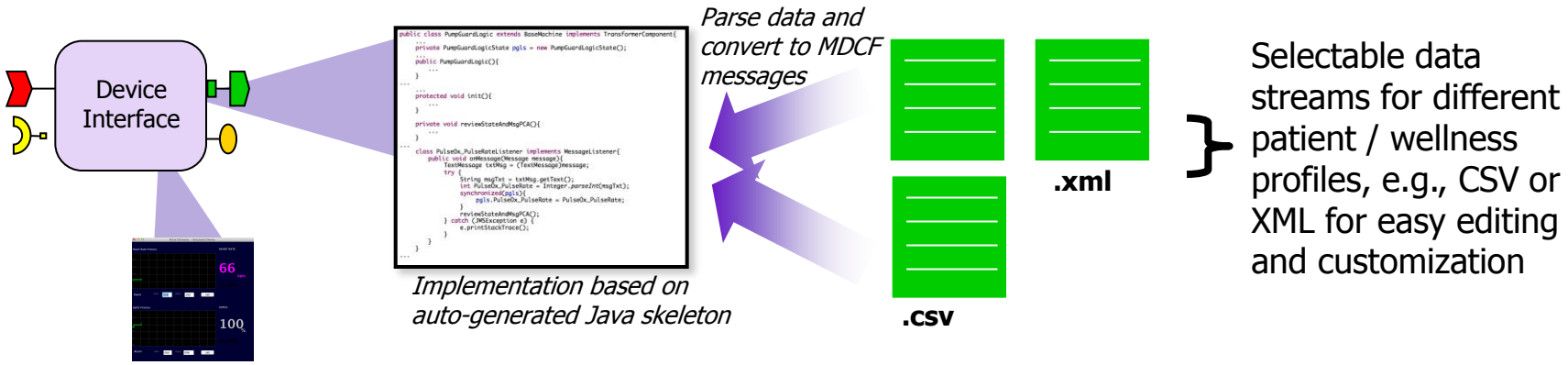
- The Medical Device Coordination Framework, jointly developed by KSU and U Penn provides a prototype implementation of ICE
- MDCF is designed to serve as a test-bed to illustrate issues related to…
  - Functional concepts
  - Safety
  - Security
  - Verification and Certification technology
- Subsequent lectures will present the details of the MDCF

Mock Device Strategies

Data Replay mock devices

- One of the easiest ways to build a mock device with an element of realism is simply to replay data streams / waveforms captured from real devices
- The PhysioNet open source database provides a variety of medical device waveforms and data streams
  - ECG, blood pressure, respiration, gait, brain stimulation, etc.

General approach



Note: sometimes difficult to incorporate concepts of device *control* into the "replay" paradigm.

How to Achieve the MAP Vision?

- A rigorous architecture oriented to compositional safety/trust
- Precise/formal interface specifications capturing a variety of properties
  - Including real-time and resource constraints
- Formal verification techniques for checking interface compatibility and implementation compliance to interfaces
- A well-developed ecosphere to support community-based design of architecture and interfaces
- Rigorous third-party certification of compliance to architecture/interfaces
- Regulatory Pathway
- Examples, examples, examples

ICE Architecture Goals/Concepts

- Partition desired ICE functionality into components that may be implemented by different vendors and composed to form a functioning system
  - The determination of components within the architecture will define the granularity at which one chunk of an ICE implementation can be swapped out and replaced by another
- Component boundaries are characterized by precise standardized interfaces for which it is possible to determine/certify compliance
- Open-ended wrt devices and apps
- Enable the development of a commodity market of component implementations
- Regulation of ICE systems occurs component-wise
  - Individual components are submitted for regulatory approval
- The ICE architecture provides sufficient safety and security guarantees such that composing components to form an *instantiation* of the ICE architecture at the point of care is not a regulated activity
  - Composing components should never result in a system failure

Market Forces Impacting Approach

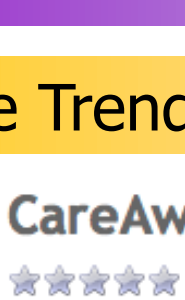
- Well-designed open platforms can encourage innovation and give rise to an explosion in lightweight apps providing highly targeted functionality
- There will likely be a flood of ICE apps and device interfaces submitted for marketing clearance — significantly more than the number of Class II & III device approvals that are submitted now.
- Safety issues in open systems are much more challenging.
  - apps will need to work with devices with which they have previously not been tested,
  - it will be easier for "fly by night" operators to "roll their own" apps/interfaces, etc.

Conclusion: existing regulatory process needs to be assessed with the goal of developing strategies for ICE-related submissions to better support (a) increased speed in processing submissions, and (b) increased scrutiny of safety and functional/security claims.

Current Trends

Example Trend: Cerner MDDS iAware App Store

CareAware iAware® Application Platform

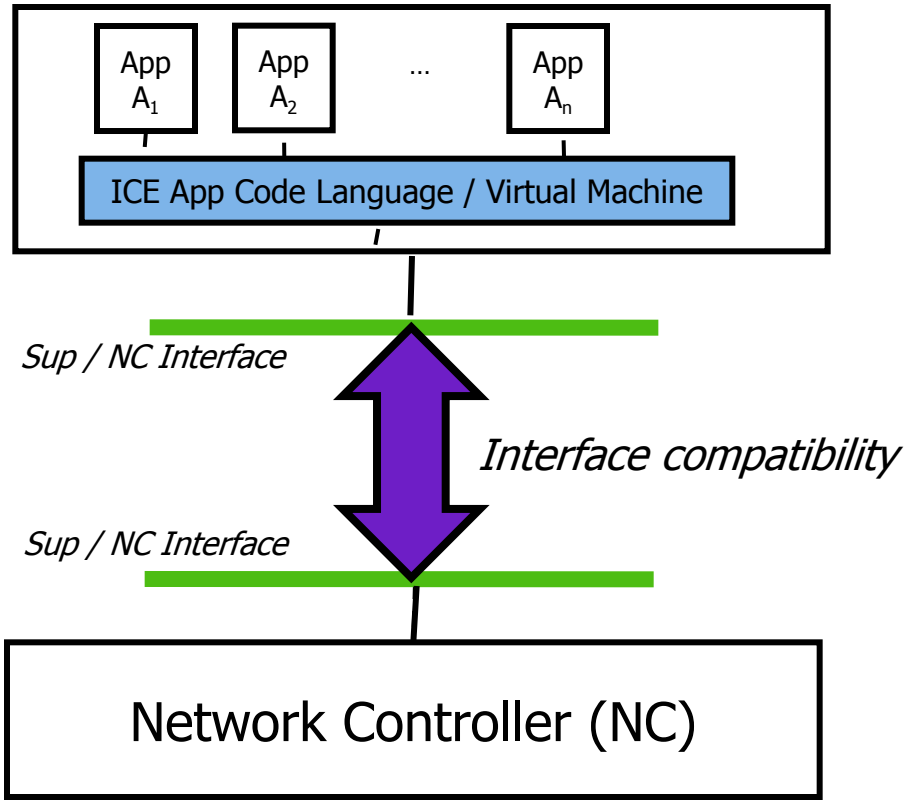


"Organizations are able to purchase gadgets and perspectives from the Cerner Store as well as write and publish their own gadgets. The iAware platform supports the ability to plug these gadgets and perspectives into views to create a customized application based on the needs of a specific organization, role or venue." – Cerner Marketing Material

Note: iAware is an MDDS (data forwarding) platform, not a full device coordination (ICE-like) platform.

For ICE: "Component-wise"

The ICE vision emphasizes compositional or "component-wise" clearance – current regulatory authorities still need to be convinced that this approach can assure safety and effectiveness.



In ICE, standardized interfaces are defined between components, e.g., the Supervisor / Network Controller Interface

For Supervisor, instead of being cleared against a specific model of Network Controller (as required in the "pair-wise"), in component-wise clearance the Supervisor is cleared against the ICE standard Supervisor / NC interface.

This is an example of what we call "fixed interfacing": the interface between the Sup & NC is known *a priori*

Cerner SmartRoom

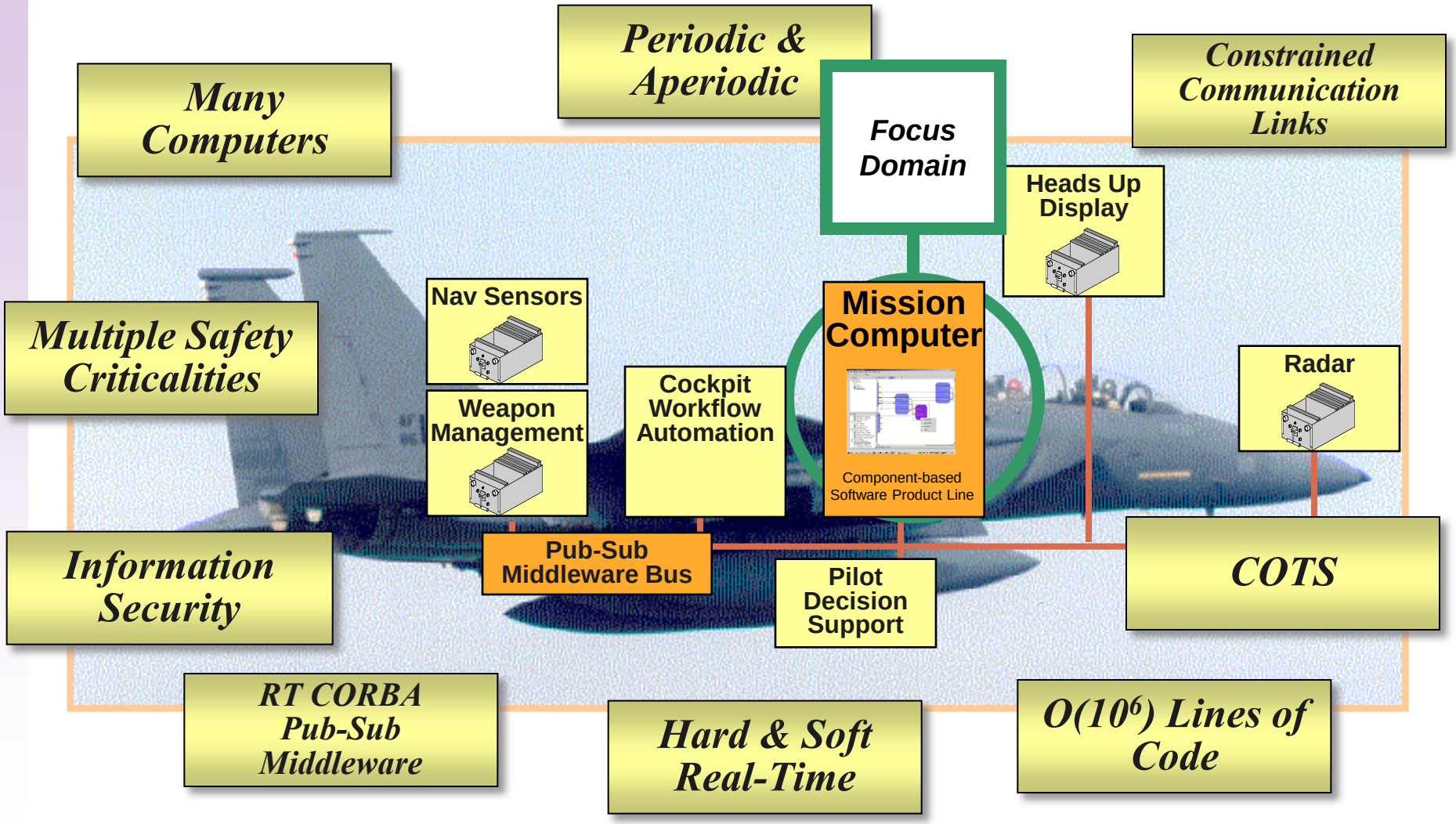
Integrated displays with views customized for caregiver

Networked Devices

Enterprise Service Bus

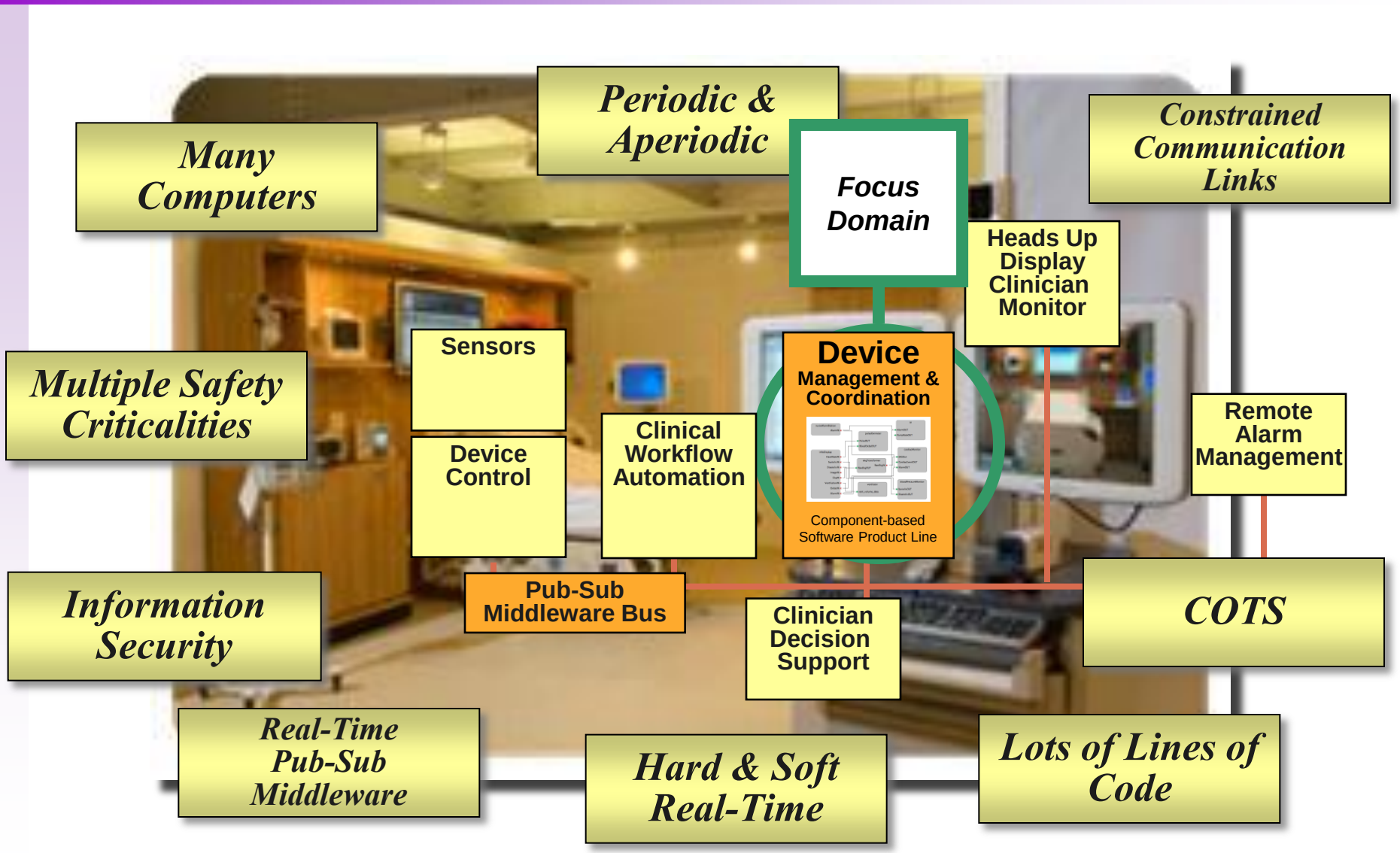
Electronic Patient Medical Record

Boeing Bold Stroke Platform



Previous KSU work on development tools for mission control software product line for Boeing F-18 platform family.

Looking Ahead?



Can we really start to imagine an integrated Cyber-Physical Systems of Systems view for health-care delivery?

Medical - Just Connectivity

Many modern medical devices have some form of connectivity, but do not implement standardized protocols for device discovery and communication...

RxStation / Ethernet

Anesthesia Machine
Ethernet

Ethernet /
802.11b

RS-232 to
Ethernet Adapter

Portable Monitor
802.11b

ECG Cart
Ethernet

How is this connectivity being leveraged in emerging commercial products?

Example of a Backbone Architecture with FlexRay