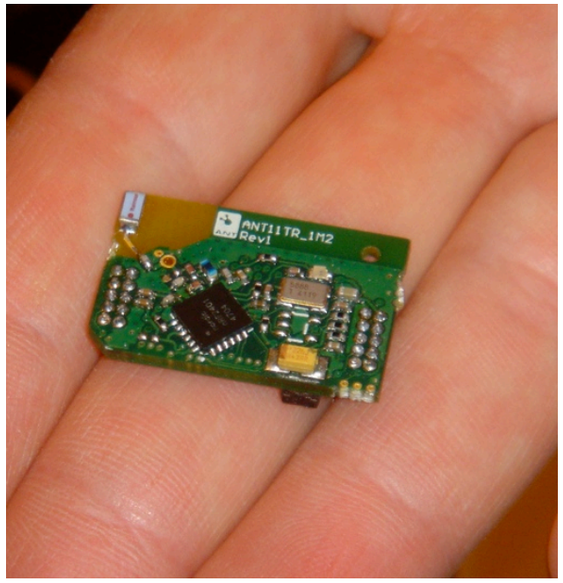
Inaugural Medical Device Connectivity Conference

September 10-11, 2009

Joseph B Martin Conference Center at Harvard Medical School

Welcome



First year

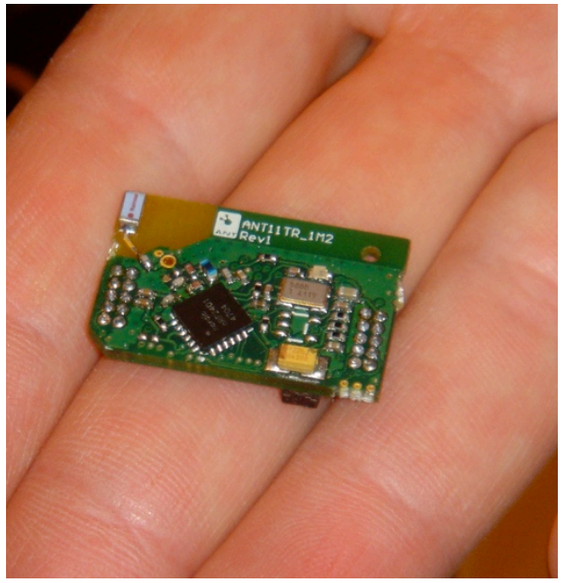
200+ attendees

9 Sponsors

10 Supporting publications

4 Supporting organizations

Welcome



Today:

Frame the topic

Industry standards

Regulatory changes

Safety issues

What does it cost?

Tomorrow - 4 tracks:

Infrastructure

Connectivity Solutions

Clinical & Workflow Impacts

Scheduled Sponsor Meetings

Agenda

Definitions

Market Segmentation

Trends

Barriers

Stimulus Impact

Connectivity

Workflow automation through the integration of medical devices and information systems

Interoperability

The ability of two or more systems or components to exchange information *and to use the information that has been exchanged*

Semantic Interoperability

Where two or more systems are capable of communicating and exchanging data

Syntactic Interoperability

The ability to automatically interpret and use the information exchanged to produce useful results as defined by the end users of both systems

Agenda

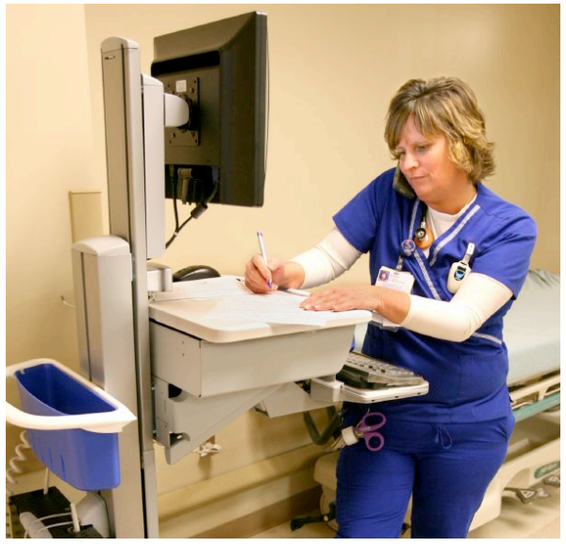
Definitions

Market Segmentation

Trends

Barriers

Stimulus Impact



Communications

Phones

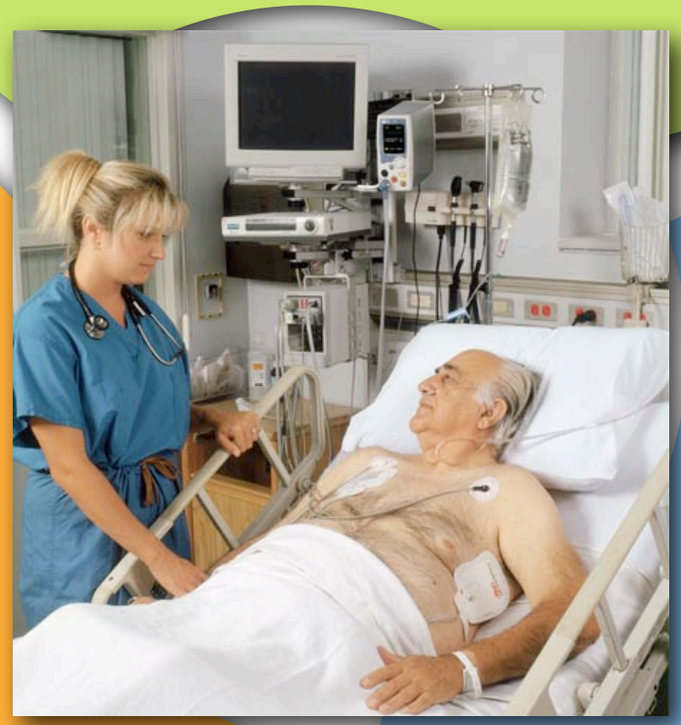
Pagers

PDAs

Computers on wheels

Overhead pages

Nurse call



Medical Devices

PoC diagnostics

Ventilators

Patient monitors

IV pumps

Telemetry packs

Spot vital signs monitors

Tasks

Patient care

Patient assessments

Alarms

Meds administration

Documentation

Coordinating care

Patient education

Communications

Phones Pagers PDAs

Computers on wheels

Medical Devices

PoC diagnostics

Ventilators

Patient monitors

IV pumps

Telemetry packs

Spot vital signs monitors

Disparate alarms
Different alarm annunciation
Different alarm classifications
Alarms at device or central station

Alarm fatigue
Failure to rescue

No single vendor solution
Vendor standardization difficult to achieve

Coordinating care

Patient education

Communications

Phones

Pagers

PDAs

Computers on wheels

Overhead pages

Nurse call

Medical Devices

PoC diagnostics

Ventilators

Patient monitors

IV pumps

Telemetry packs

Spot vital signs monitors

Two-way phone tag
Unheard calls or pages
Delayed or undelivered pages
Proliferation of devices

Noise and confusion
Unreliable communications

Delays in care delivery
Patient safety impact

Tasks

Patient care

Patient assessments

Meds administration

Coordinating care

Patient education

Communications

Phones

Pagers

PDAs

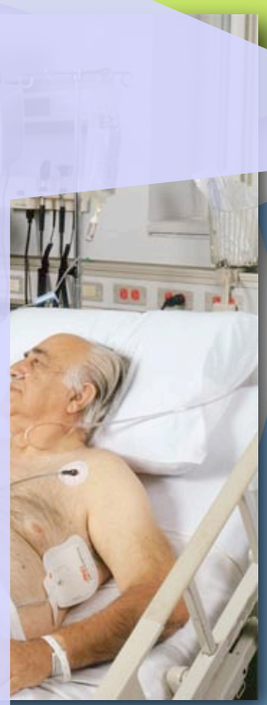
Overhead pages

Nurse call

Variable workload by patient
Direct care vs. facilitating care
Open nursing positions
Nursing skill levels

Interrupt-driven environment
Direct care sometimes lags

Delays in care delivery
Tasks poorly aligned with devices, and IT



Tasks

Patient care

Patient assessments

Alarms

Meds administration

Documentation

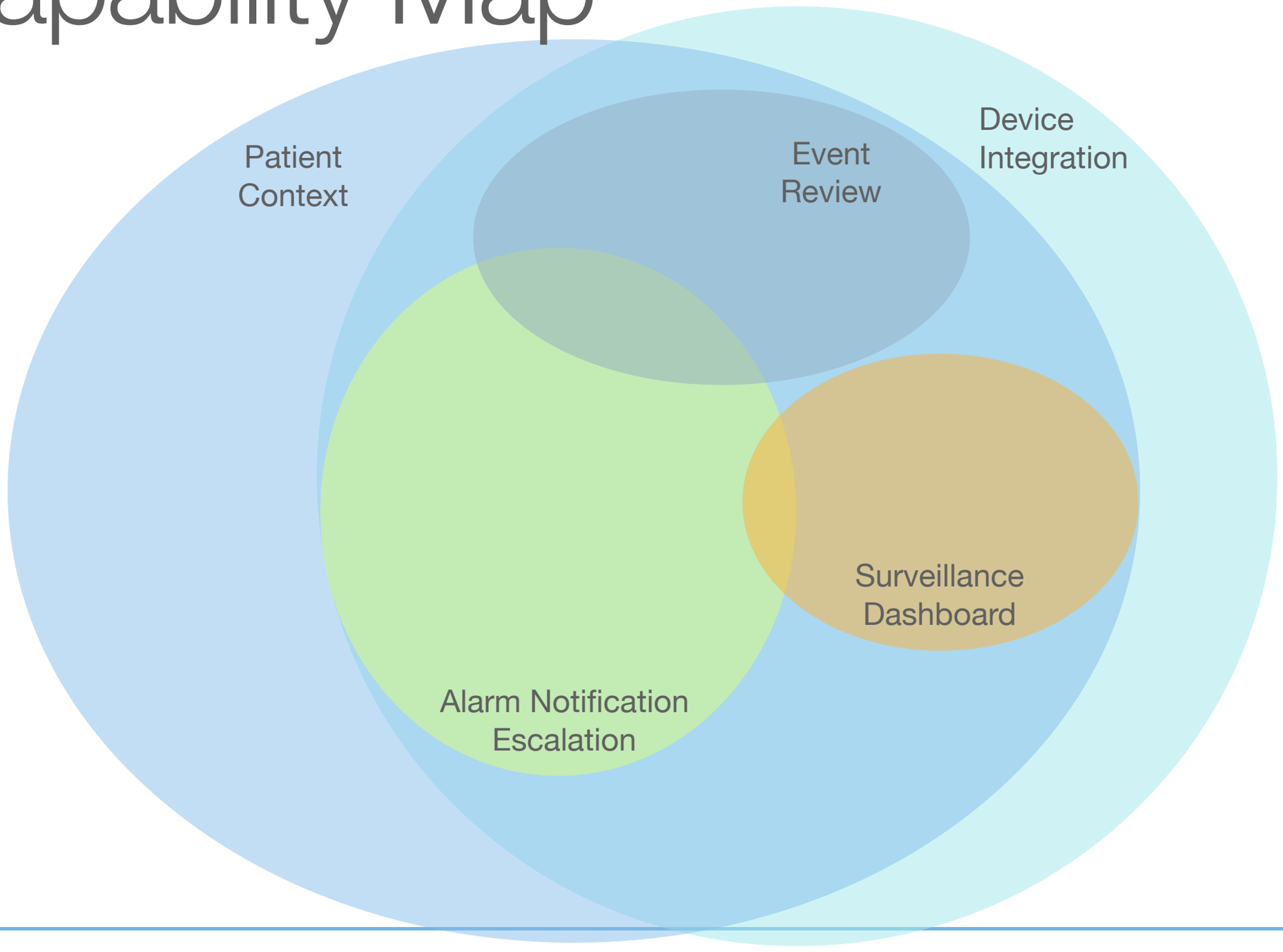
Coordinating care

Patient education

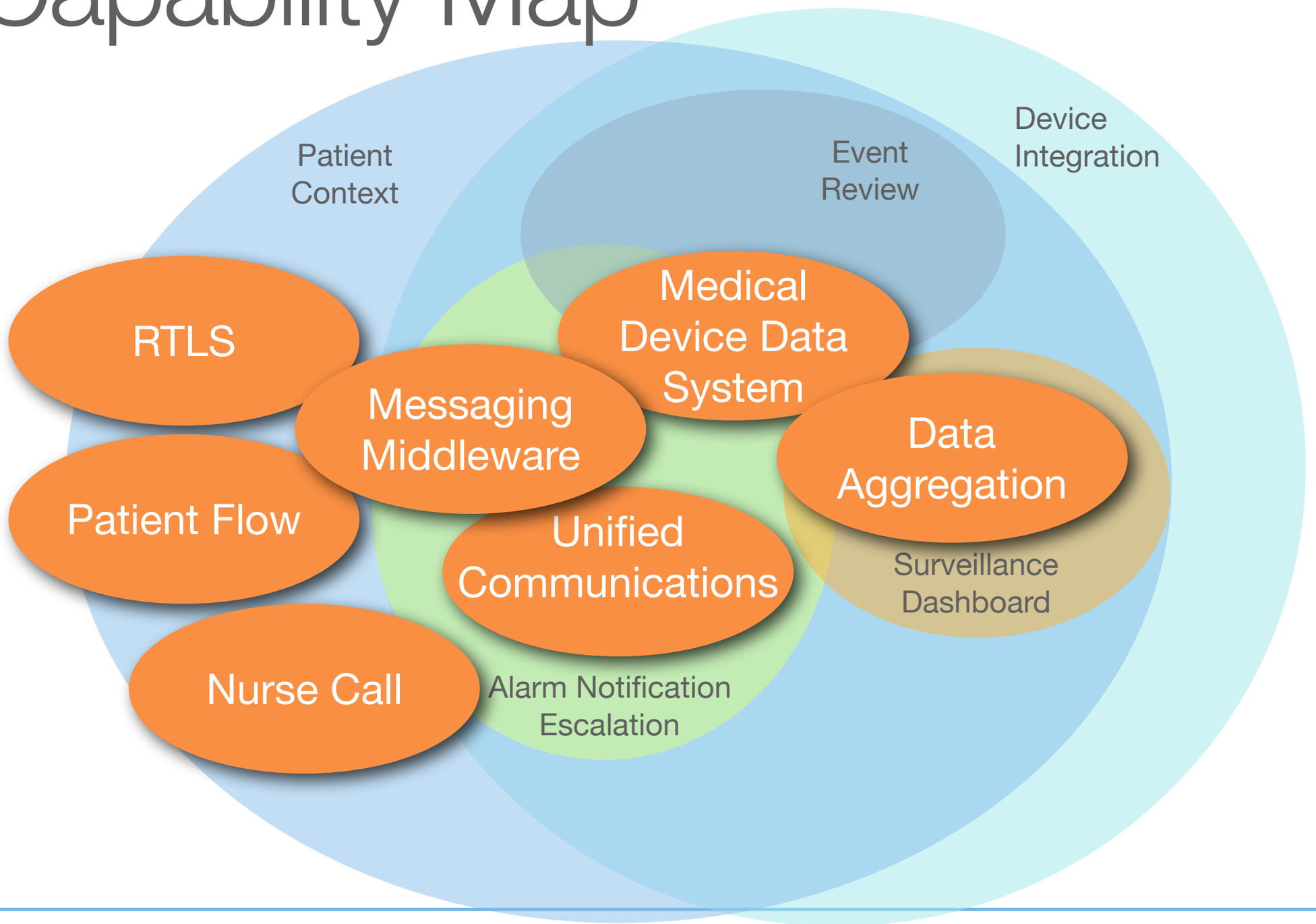
Devices

Spot vital signs monitors

Capability Map



Capability Map



Dashboard

Web Server

Rules Engine

Messaging Engine

Interface Engine

ESB/SOA

DBMS

Data Acquisition

Evolving Architecture

Agenda

Definitions

Market Segmentation

Trends

Barriers

Stimulus Impact

Conventional Medical Devices

"Embedded system"

Analog or digital

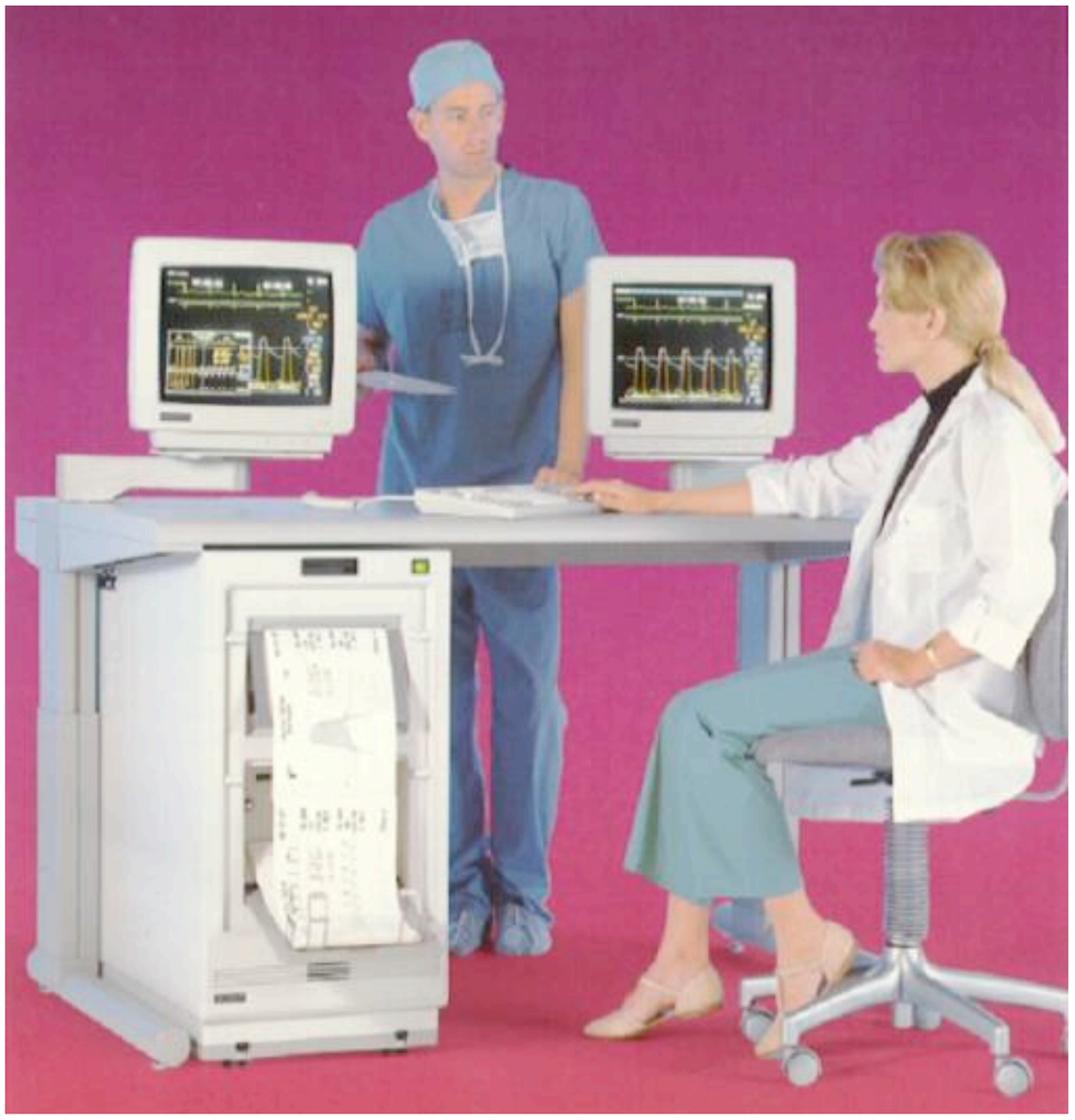
Manufactured by vendor

Serial port for printing

Virtualized Medical Device

- Extending embedded systems to general purpose computing platforms
  - Patient monitoring central stations, ICU flowsheets
  - Cath lab data analysis, reporting
  - PACS
  - Smart pumps DERS

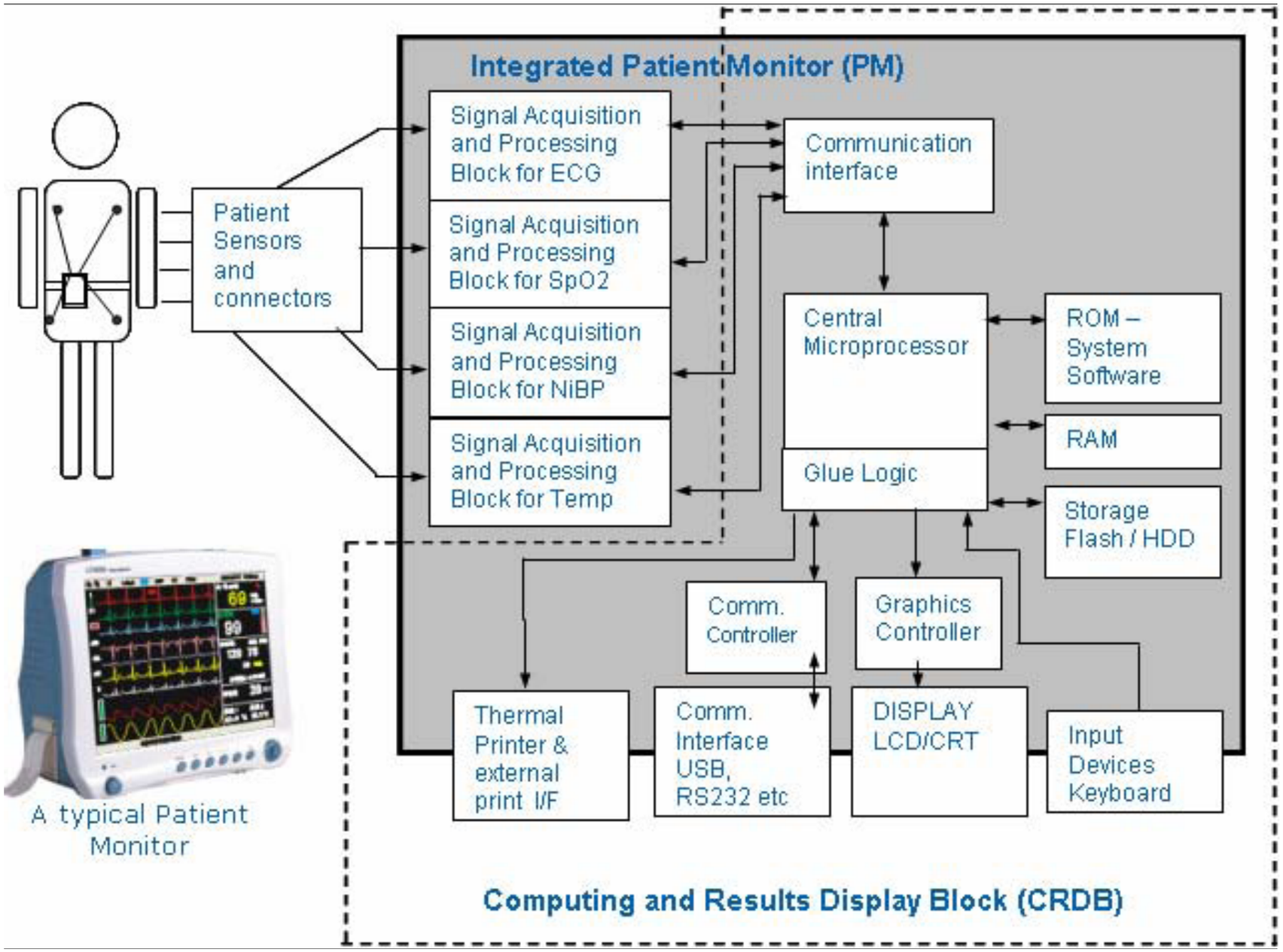
MacLab



Cath recorder market owned by Electronics for Medicine

Marquette automated data analysis and reporting

Utilized off-the-shelf Personal Computers



A typical Patient Monitor

Intel Digital Health

Device Virtualization

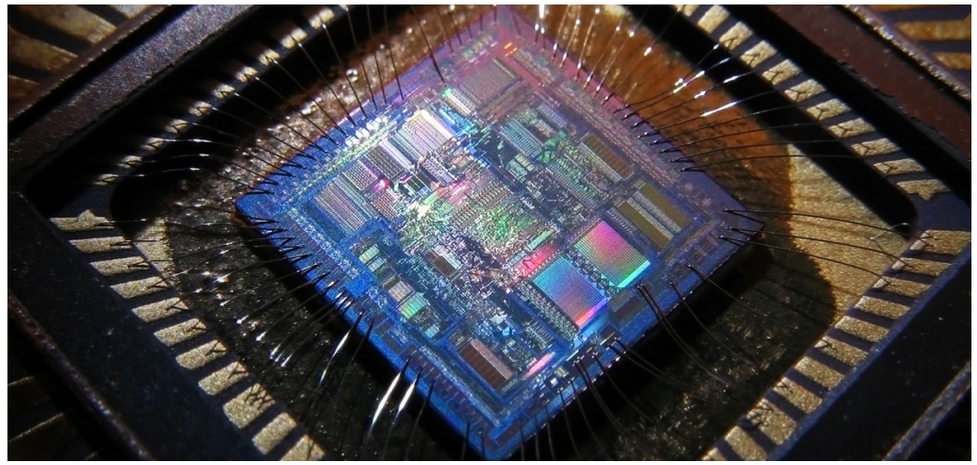
Spirometry

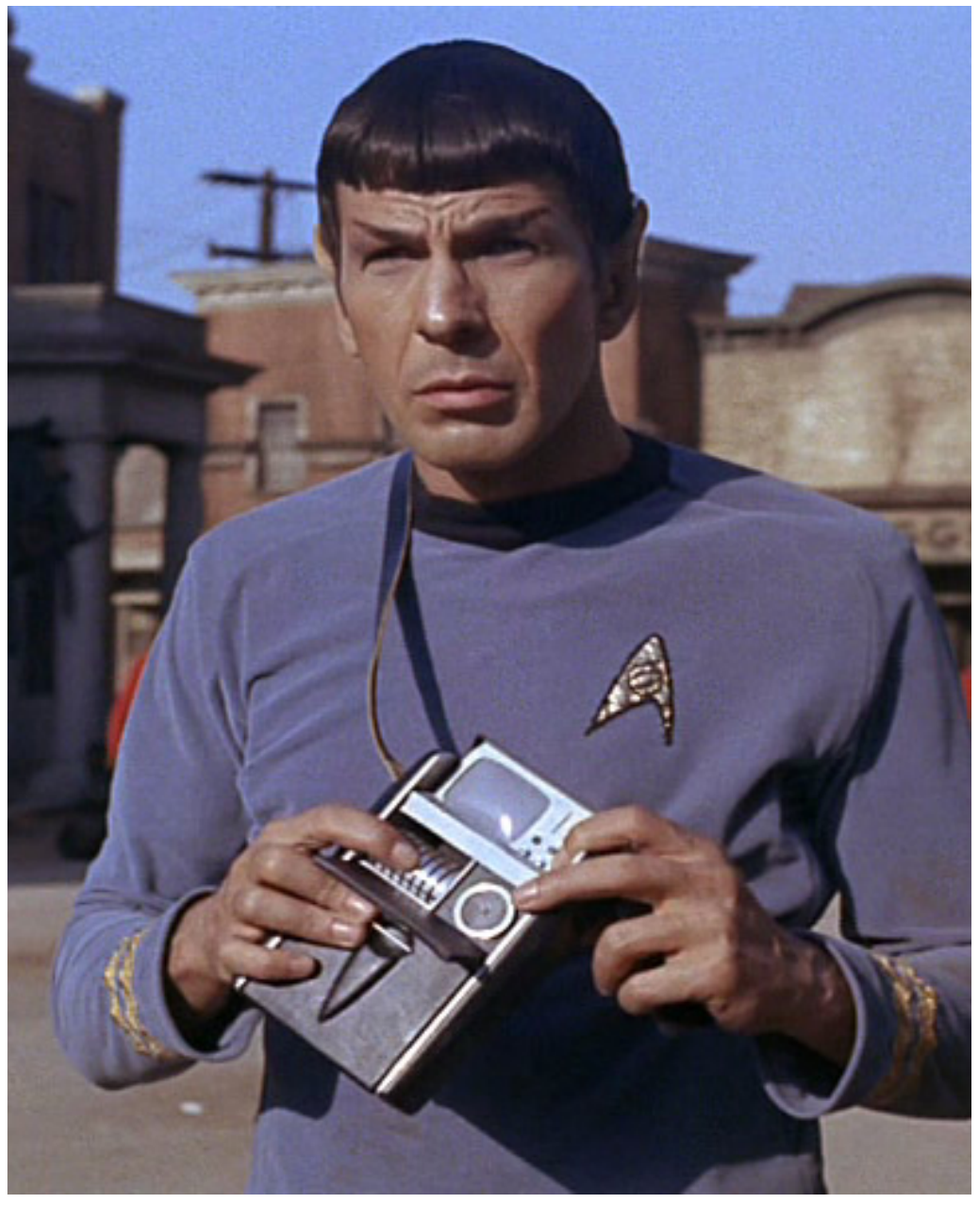
PoCT

ECG testing

Diagnostic ultrasound

What's Next?

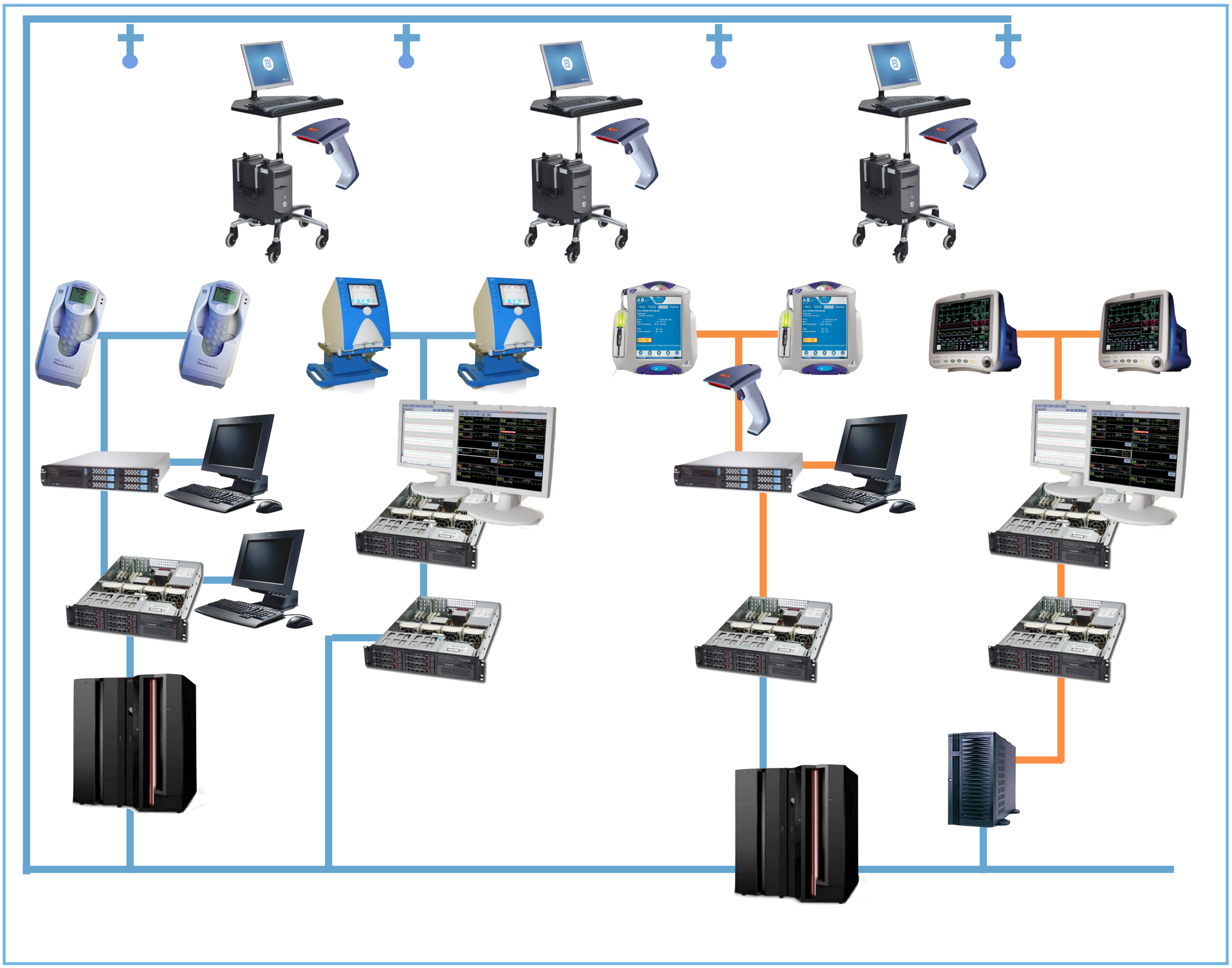




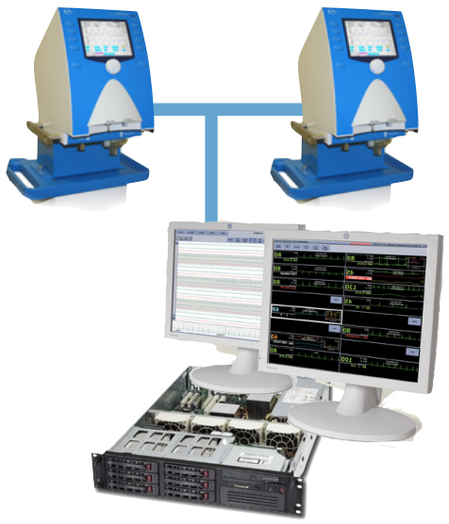
Systems of System

- The combination of separate products or monolithic systems into an overall system
- Optimize interacting legacy and new systems brought together
- Intended to satisfy multiple objectives
- Risk: extensibility and flexibility over time
- Risk: safety impact from unintended consequences

How They're Deployed



How They're Tested

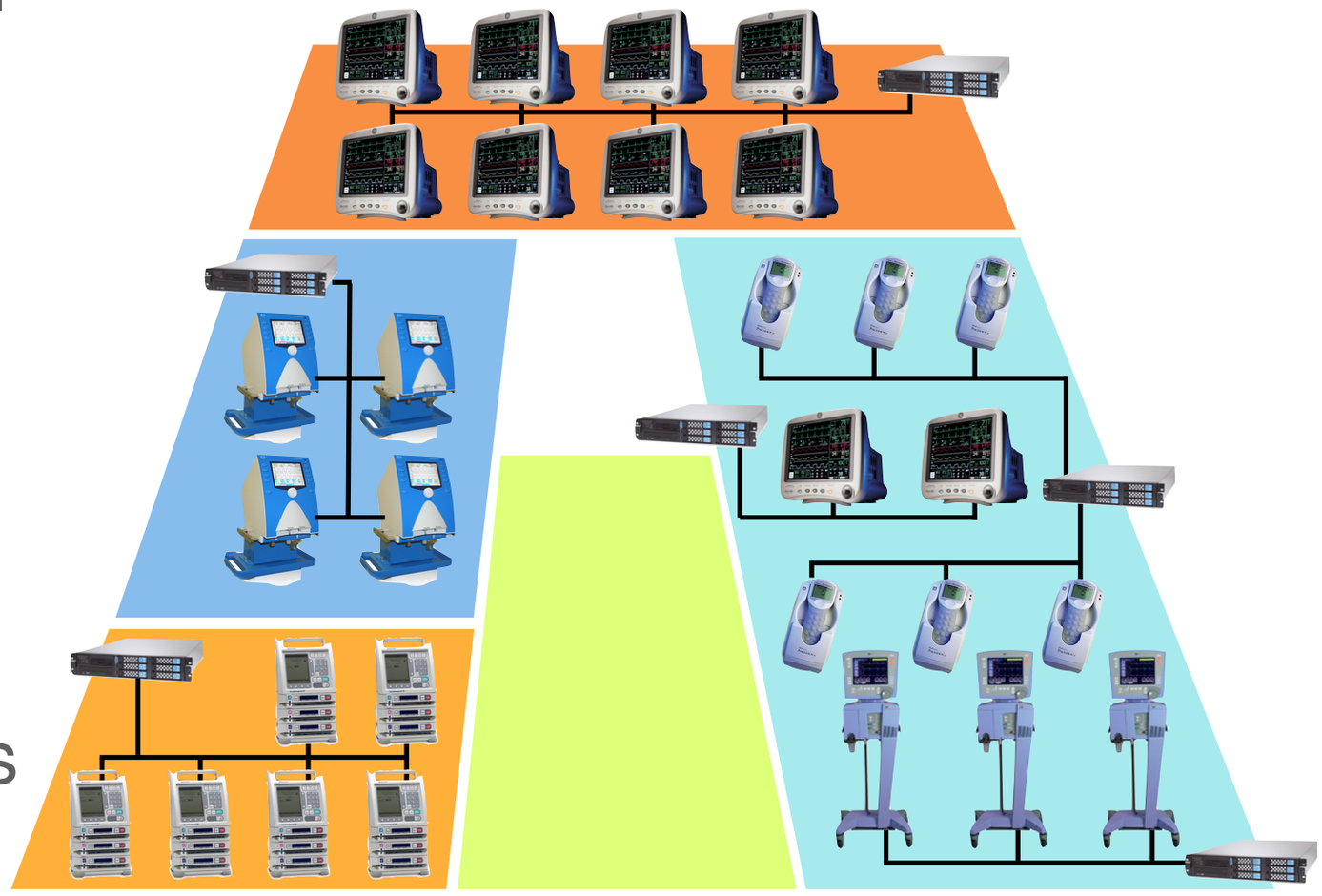


Safety Risks

Multiple stakeholders	Effective coordination and consensus building across organizations difficult to achieve
Multiple selection criteria	Definition and evaluation of systems to deliver ultimate capabilities often not determined
Sequential adoption	Integrating initial phase systems with subsequent phases prone to unanticipated change and cost
Integration risk	Integration risk is often not explicitly evaluated
Functional performance risk	Functional performance risk across systems often not explicitly evaluated
Interface complexity	Difficult to evaluate interface complexity across systems and accurately asses risk

Private Device Networks

- Separate physically or routed
- Controlled and supported by vendor
- Easier to support
- Lower R&D costs
- Ideal for stand-alone departmental systems



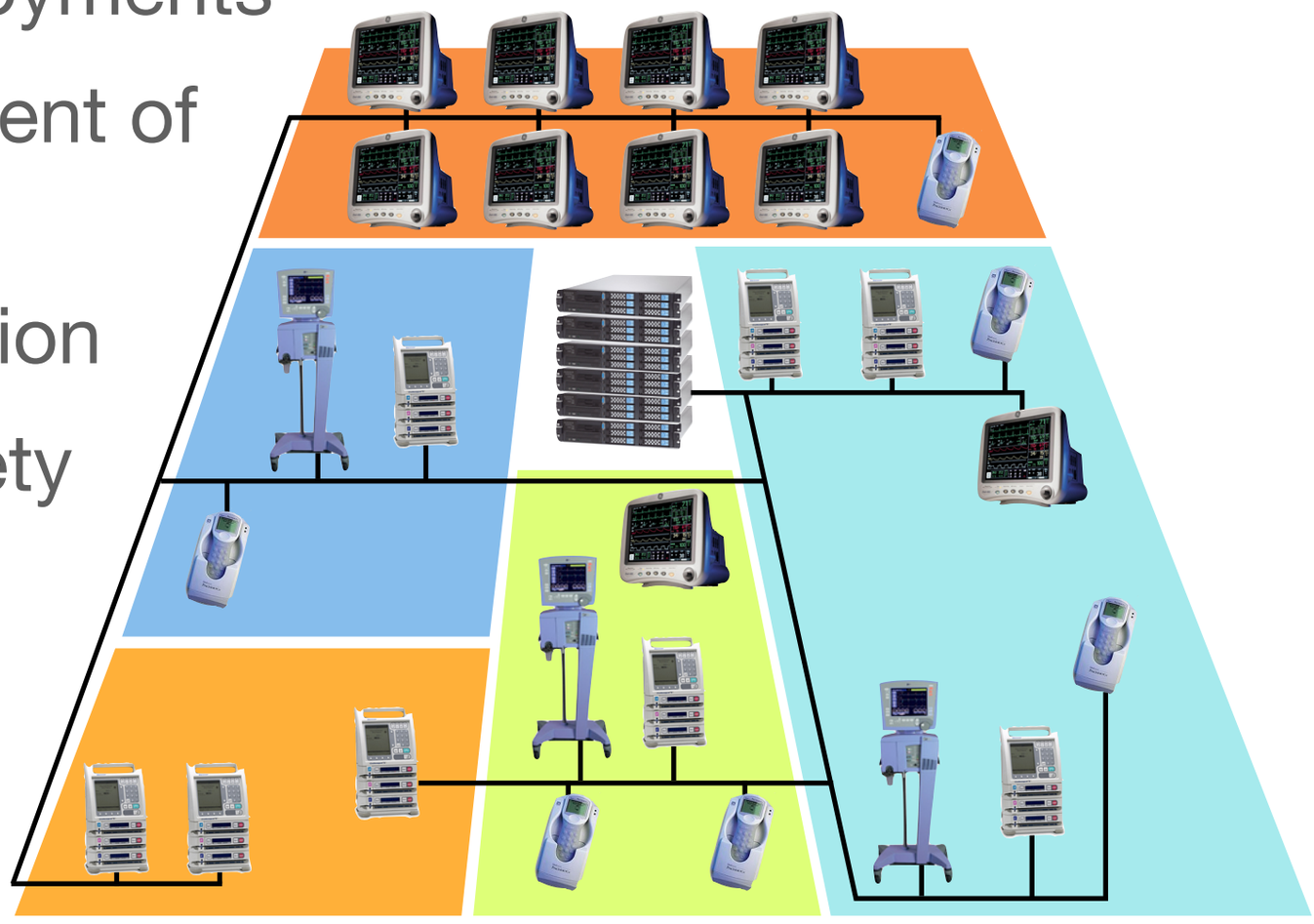
Private Network Limits

- Create “islands of information”
- Sometimes include discontinued third party products
- Not kept current with evolving network/computer technology
- Proliferate widely
- Barrier to enterprise deployment
- Customer sees unnecessary complexity, duplication and cost

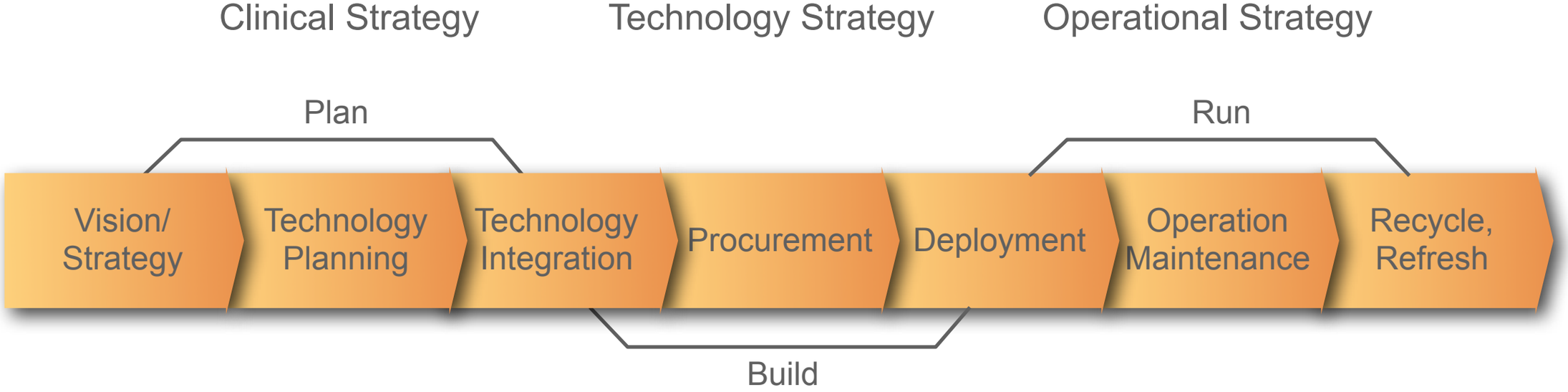
Bob Metacalf, Ethernet inventor holding ThickNet network cable

Medical Device As Information Appliance

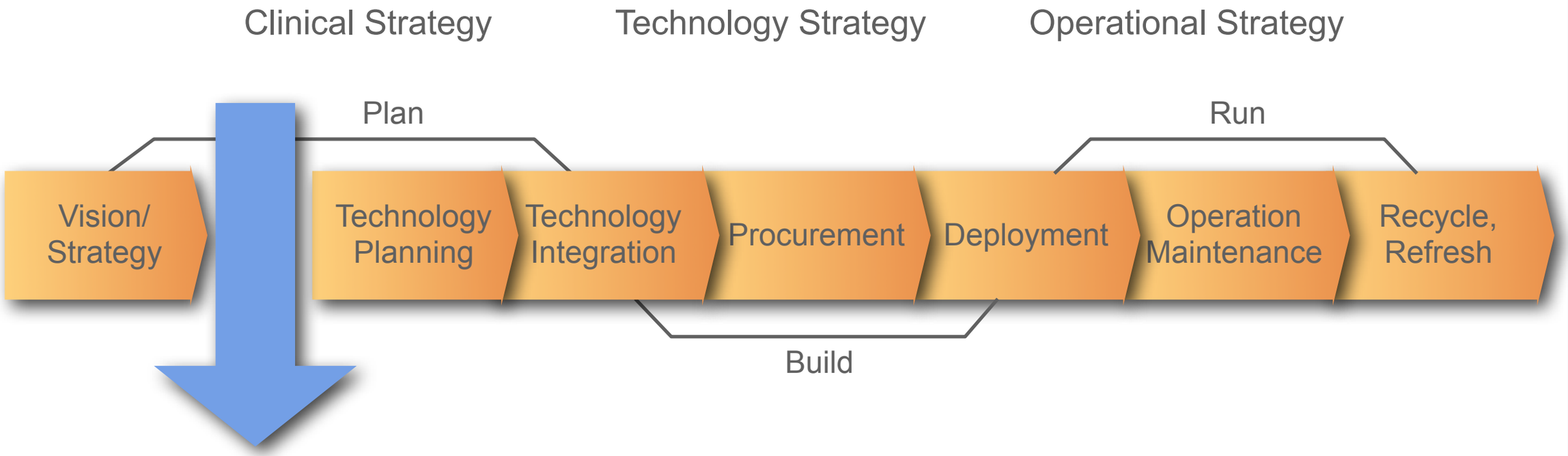
- Enterprise-wide deployments
- Overlapping deployment of different devices
- Driven by EMR adoption
- Driven by patient safety applications



Technology Management

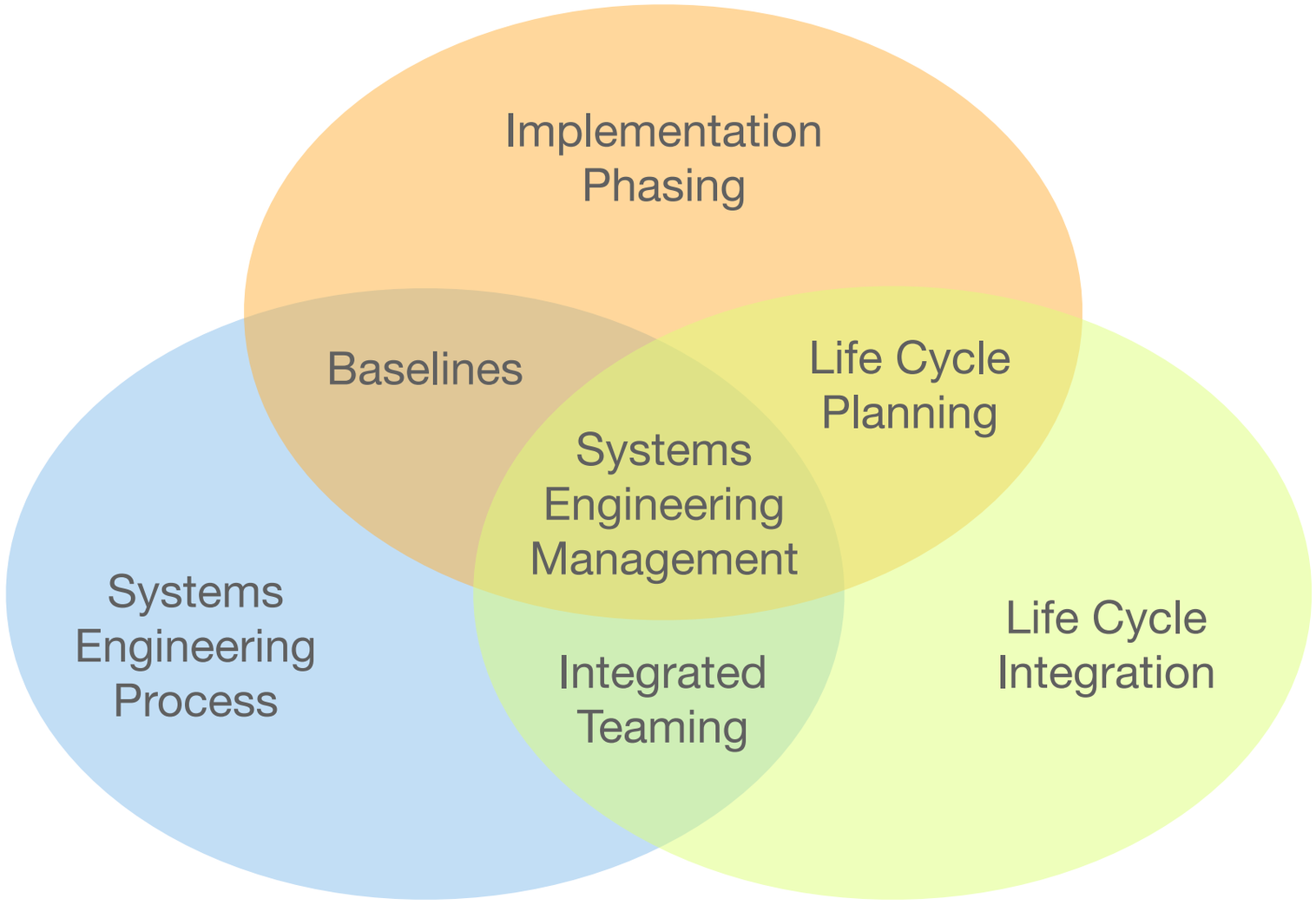


Technology Management

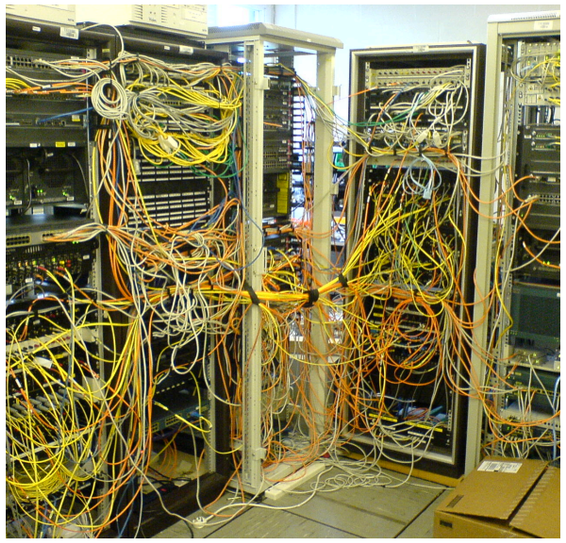


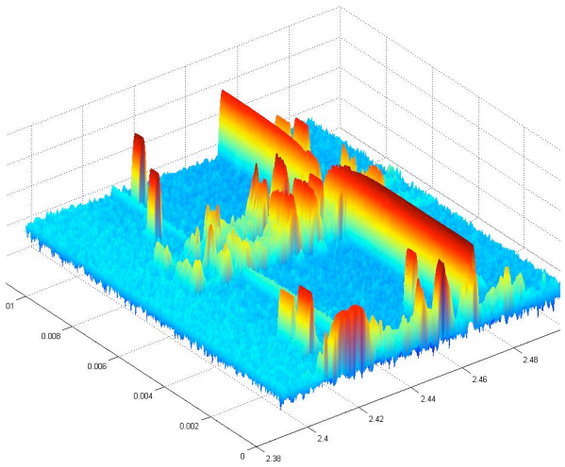
Needs assessment?

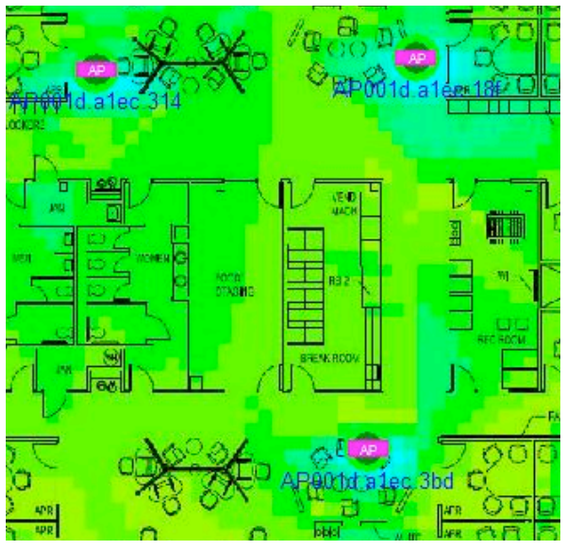
Technology Management



Wireless Uncertainties







Agenda

Definitions

Market Segmentation

Trends

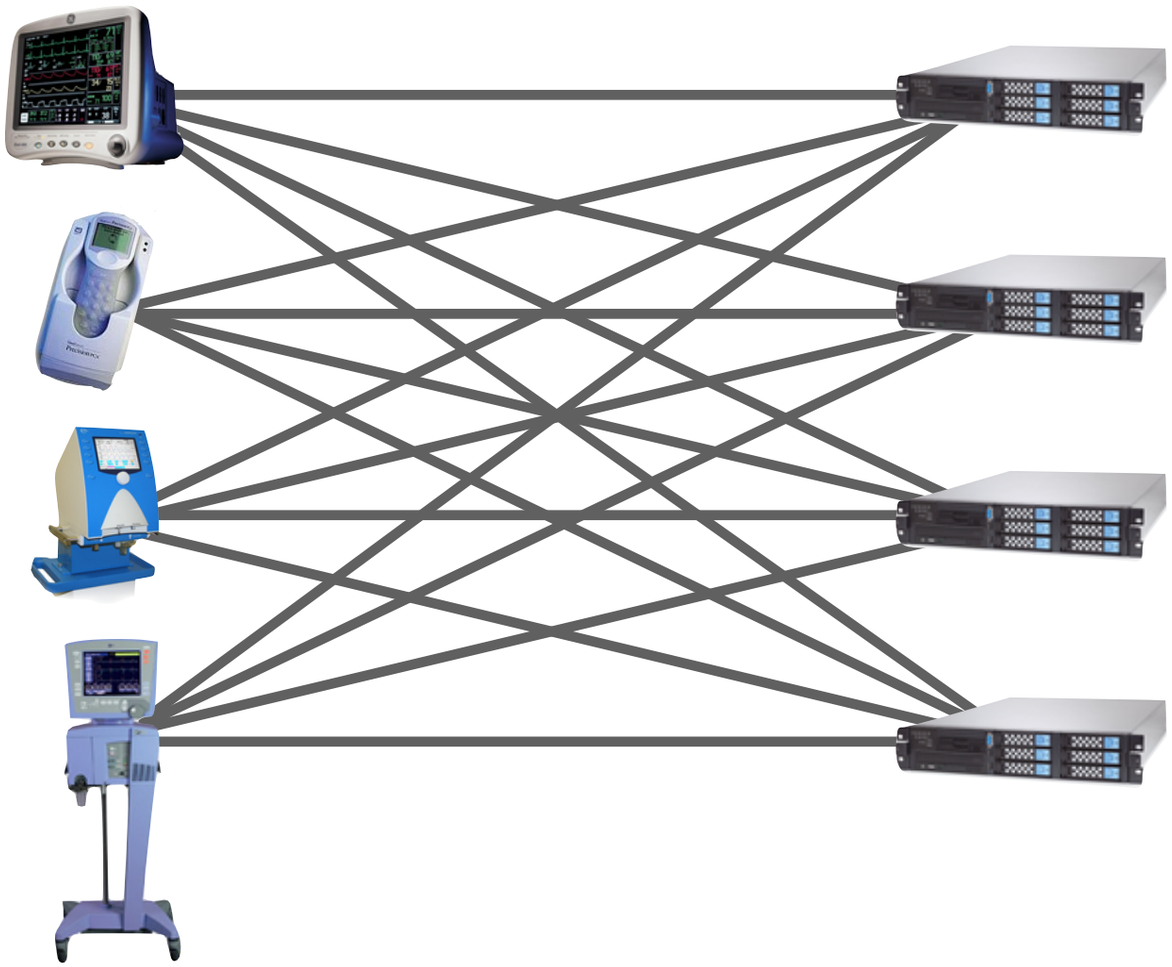
Barriers

Stimulus Impact

Connectivity Barriers

- Absence of standards
- Complex systems integration
- Proprietary APIs
- Unnecessary duplication of effort
- Higher costs and prices

One-Off Integration



Integration Costs

- Initial integration - per integration half
  - 4 to 6 months
  - $300,000 to $500,000
- Sustaining engineering - per integration half
  - 1 to 4 months
  - $200,000 to $400,000

Company Impact

- 2 product lines, 4 interfaces each = 8 interfaces
- $3.2 million initial integration ($400k x 8)
- $2.4 million sustaining ($300k x 8)
- 5 year cost: $15.2 million

Industry Impact

- 20 manufacturers
- $64 million initial integration ($3.2m x 20)
- $48 million sustaining ($2.4m x 20)
- 5 year cost: $304 million ($15.2m x 20)

Connectivity Costs

- Connectivity costs 30% - 40% device purchase price; ~ $10,500 per bed for basic EMR connectivity
- Upgrade costs can equal replacement costs
- Proprietary systems (e.g., WMTS) raises changing costs

What, Me Worry?

- Clear market demand
- Ongoing commitments
- Opportunity cost
- Standards efforts

Agenda

Definitions

Market Segmentation

Trends

Barriers

Stimulus Impact

ARRA & HITECH

Reimburse provides a portion of investment in certified Electronic Medical Records

Meaningful Use

The requirements that must be met to qualify for reimbursement

Payment Year	Payment Amount ($) * or Penalty (%) ** per provider based on First qualifying year										
	Now-2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	Unimplemented
2011	$15,000	-	-	-	-	-	-	-	-	-	-
2012	$12,000	$15,000	-	-	-	-	-	-	-	-	-
2013	$8,000	$12,000	$15,000	-	-	-	-	-	-	-	-
2014	$4,000	$8,000	$12,000	$12,000	-	-	-	-	-	-	-
2015	$2,000	$4,000	$8,000	$8,000	$8,000	-	-	-	-	-	-
2016	$0	$2,000	$4,000	$4,000	$4,000	$0	1%	1%	1%	1%	1%
2017	$0	$0	$2,000	$2,000	$2,000	$0	$0	2%	2%	2%	2%
2018	$0	$0	$0	$0	$0	$0	$0	$0	3%	3%	3%
2019	$0	$0	$0	$0	$0	$0	$0	$0	$0	3-4% ***	3-4%
2020+	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	3-5%
Totals	$41,000	$41,000	$41,000	$26,000	$14,000	$0	$0	$0	$0	$0	-

* - Maximum amount possible, actual amount is 75% of allowed charges for professional services under Medicare.

Roadmap

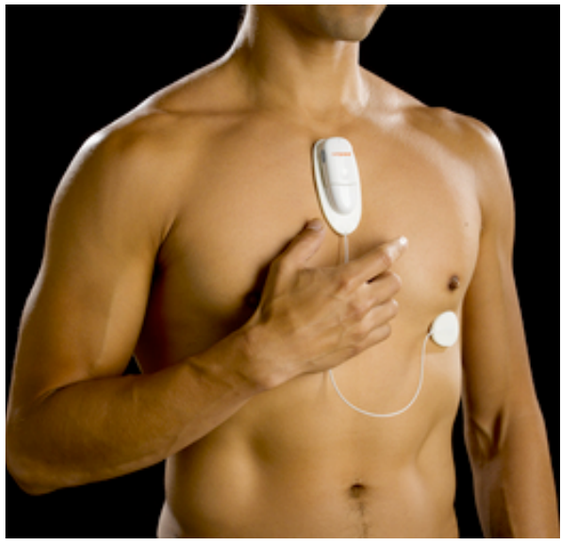
Medical device interoperability

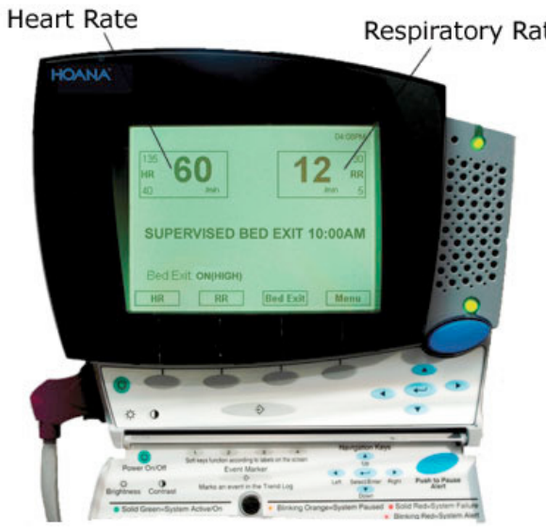
2015 Objectives

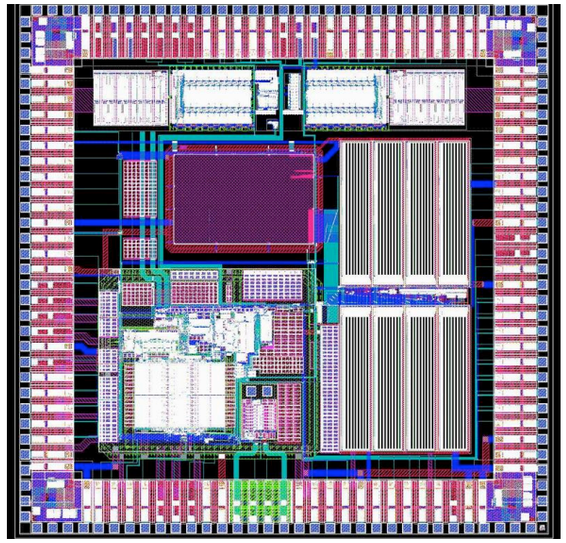
- Improve quality, safety, and efficiency
  - Achieve minimal levels of performance on quality, safety, and efficiency measures
  - Implement clinical decision support for national high priority conditions
  - Achieve medical device interoperability
  - Provide multimedia support (e.g., x-rays)

2015 Objectives

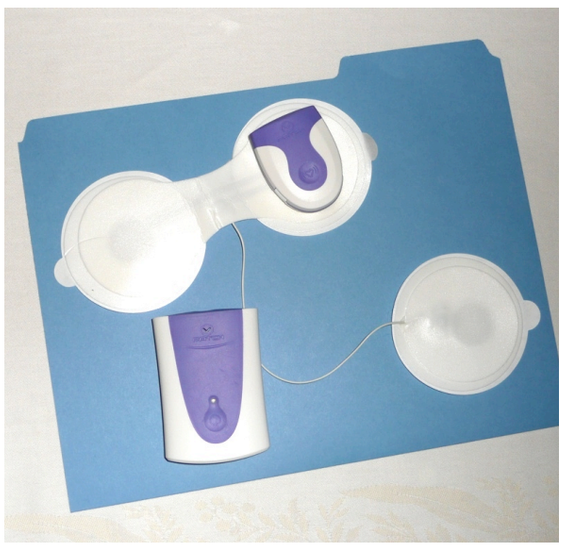
- Improve quality, safety, and efficiency
  - Achieve minimal levels of performance on quality, safety, and efficiency measures
  - Implement clinical decision support for national high priority conditions
  - Achieve medical device interoperability
  - Provide multimedia support (e.g., x-rays)




Heart Rate
Respiratory Rat
HOANA
60
12
SUPERVISED BED EXIT 10:00AM
Bed Exit ON(HIGH)
HR
RR
Bed Exit
Menu



B +ve
SMS



Bibliography

FDA Proposed MDDS Rule

IEC 80001 - An Introduction

Medical Device Connectivity - Why Bother?

Device/EMR Integration - Basic Components and Market Segmentation

Cisco Stumbles in Health Care

Is ISO/IEEE 11072 a Viable Standard?

Secondary vs. Primary Alarm Notification

Why Connect Medical Devices?

Patient Safety, Medical Devices, and Interoperability

Barcoding and Patient Context

Distributed Antenna Systems

Hospital Network Management

Network Management Improves for Medical Devices