



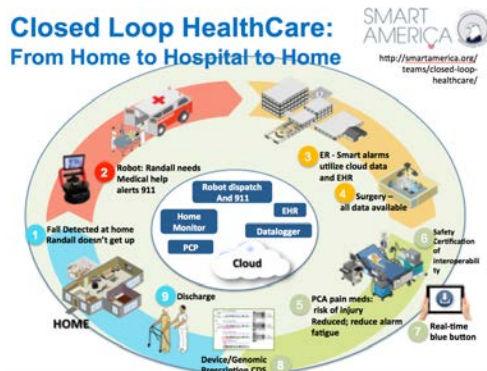
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“Procuring Safety” Through Medical Device Interoperability *to Transform Healthcare Delivery*

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Health environments need integrated technologies and rich data to improve patient safety and enable learning and transformational care delivery models.

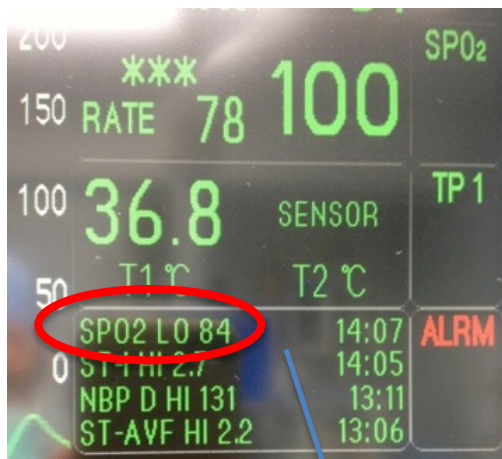
- Program established 2004 at Mass General Hospital/Partners Healthcare
- Lab opened 2006 for research on achieving safe, secure interoperable medical systems (standards, technologies, products). Expanded 2017.
- Clinical, biomed, computer science, and IT subject matter experts
- Publish research to enable safe interoperability
- Develops OpenICE open-source interoperability research platform www.openice.info
- \$22M research funding primarily from DOD, NIH, NSF, DHS
- Multiple collaborative lab prototyping and public demonstrations with industry, academia, and government
- Developed foundational content for standard ASTM F2761 on the Integrated Clinical Environment ("ICE") , AAMI-UL 2800, and other standards
- FDA “pre-submission” on safe platform-based interoperability, publicly shared
- All above being leveraged for commercial products



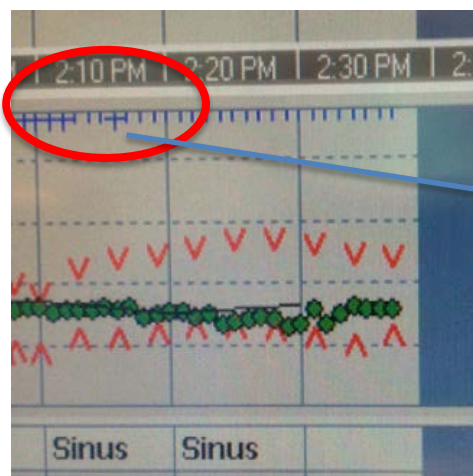
Example of collaborators



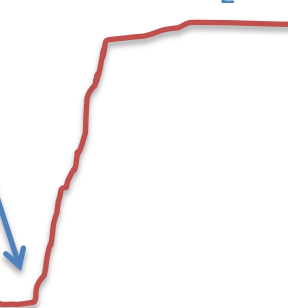
Missing low SpO₂ event in EMR



Monitor Displays Low SpO₂ Alarm "84%" at 2:07

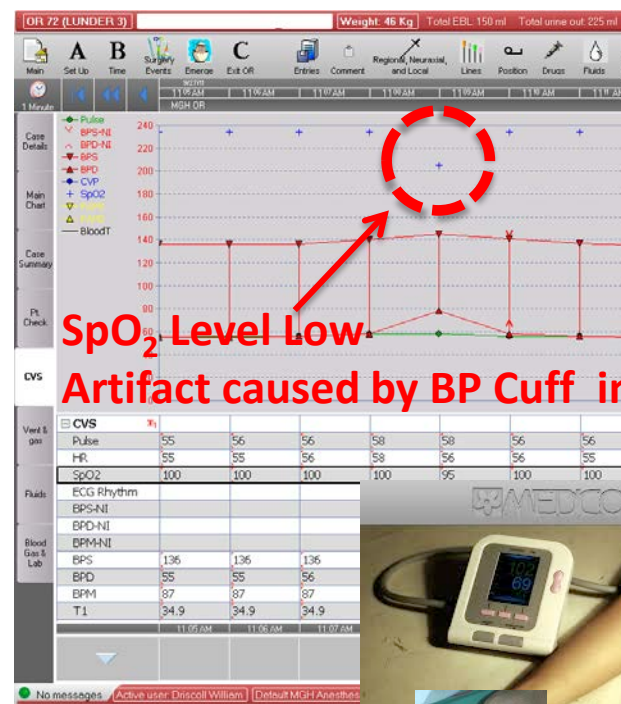


Real-time SpO₂

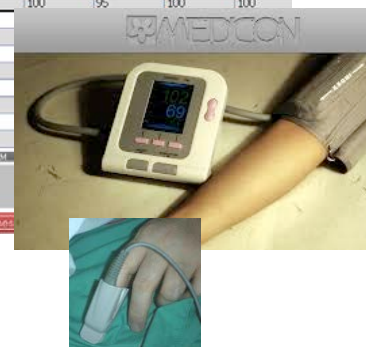


No evidence of 84% SpO₂ in EHR
(Blue ticks represent SpO₂ values)

Falsely low SpO₂ data in EMR



SpO₂ Level Low
Artifact caused by BP Cuff inflation



Spurious SpO₂ data would interfere with PCA safety algorithm

- Solution: include NIBP metadata about cuff inflation status

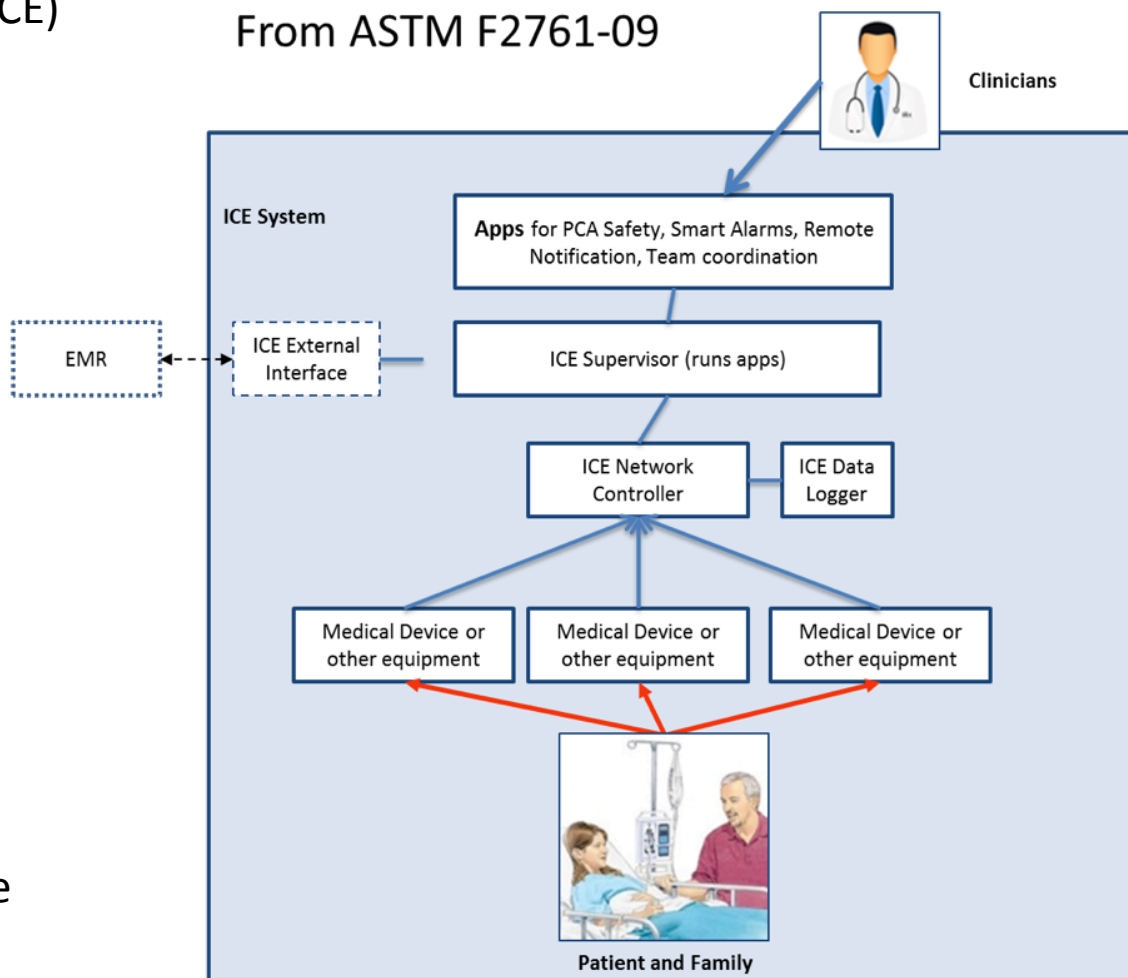
Integrated Clinical Environment Architecture (ICE)

The PCA and other clinical scenarios identified a need for a platform-based medical device interoperability architecture

ASTM F2761 "Essential safety requirements for equipment comprising the patient-centric Integrated Clinical Environment "(ICE)

ICE provides an architecture to help address:

- App platform for clinical care and device management
- Safety and performance of the system
- Security (sandboxing)
- Patient ID-data binding
- Correct time stamp-data binding
- Data logging for forensic, QA, and liability
- Builds on medical device interoperability
- ICE systems are using applicable existing standards



Standard recognized by FDA in August 2013

MD FIRE – Medical Device Interoperability Procurement Language

- Focused on providing capabilities to improve patient safety
- Requirements are based on clinical scenarios from providers
- Procurement concept based on Kaiser’s approach
- Endorsed by VA and American Society of Anesthesiologists
- Version 1 was developed by a collaboration of 5 groups from Partners, Kaiser, and Hopkins:
 - Clinicians
 - Purchasing/Procurement
 - IS/IT
 - Biomed
 - Legal
- Currently adding adoption pathway and Cybersecurity content.

Medical Device Free Interoperability Requirements for the Enterprise (MD FIRE)

| | |
|--|------------------------|
| Medical Device Interoperability for Patient Safety: Driving Procurement Changes | Issued October 2008 |
|--|------------------------|

Medical Device Plug-and-Play (MD PnP) Program Massachusetts General Hospital / Partners HealthCare System Johns Hopkins Medicine Kaiser Permanente

This paper discusses the requirements for medical device interoperability in the modern healthcare environment. These requirements are changing the way in which we procure medical devices. An appendix provides shareable RFP and contract language examples.

Background

Medical devices, essential for the practice of modern medicine, have been traditionally designed to operate independently using proprietary protocols and interfaces for system integration. With the increasing complexity of the healthcare environment, stand-alone, proprietary devices and systems no longer provide an acceptable solution. Medical devices and systems must easily integrate with other vendors' equipment, software and systems in order to improve patient safety.

Essential improvements in patient safety and healthcare efficiency in high-acuity clinical settings require system solutions that can be implemented using standardized, interoperable medical devices and systems.^[1] Clinical societies and the FDA now endorse the potential of medical device interoperability to lead to "improvements in patient safety and clinical efficiency".^{[2][3]}

<http://mdpnp.mgh.harvard.edu/projects/md-fire/>

Original version of MD FIRE

Acknowledgments

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