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Getting connected for patient safety™

CCC Workshop, Assured Autonomy #1
Arlington, VA
Oct 16, 2019
Panel on Safety, Verification, Certification

Healthcare challenges, gaps, & needs to inform the Assured Autonomy Research Agenda

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Medical Director, Partners HealthCare Biomedical Engineering

Contact and bio: www.jgoldman.info
MD PnP Program: http://mdpnp.mgh.harvard.edu/

Conflicts – none

Patient Safety
Exploring Quality of Care in the U.S.

How Many Die From Medical Mistakes in U.S. Hospitals?

https://www.cdc.gov/nchs/fastats/deaths.htm

Leading Causes of Death (2017):

1. 647,457 Heart Disease
2. 599,108 Cancer
3. *210,000-440,000 Deaths Due to Preventable Medical Errors (not listed on CDC web site)**
4. 169,936 Accidents
5. 160,201 Chronic lower respiratory diseases
6. 146,383 Stroke
7. 121,404 Alzheimer's disease
8. 83,564 Diabetes
9. 55,672 Influenza &Pneumonia
10. 50,633 Kidney diseases
11. 47,173 Intentional self-harm (suicide)

45 patients every hour!

*http://journals.lww.com/journalpatientsafety/Fulltext/2013/09000/A_New,_Evidence_based_Estimate_of_Patient_Harms.2.aspx (2013)
* https://www.bmj.com/content/353/bmj.i2139 (May 2016)

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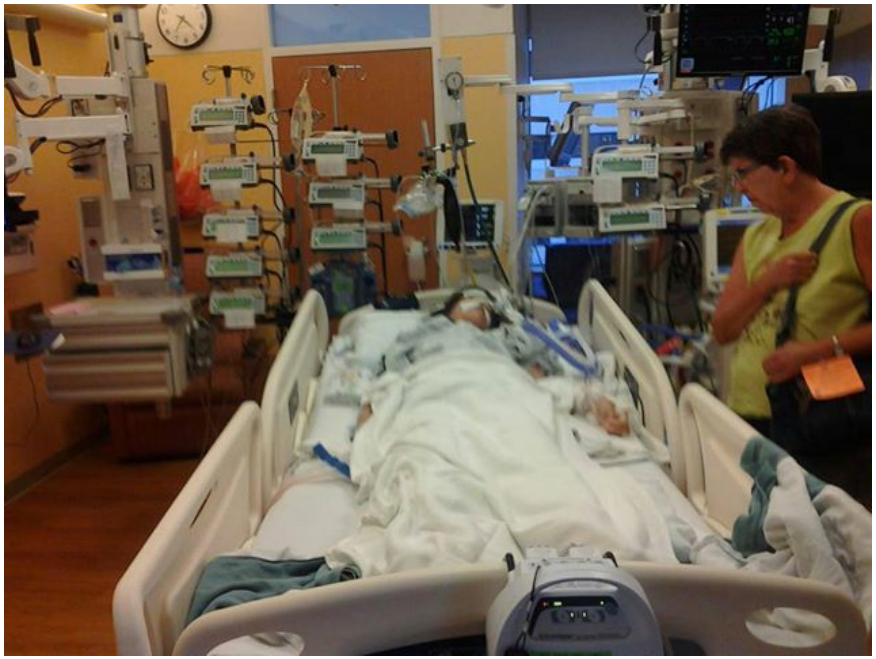
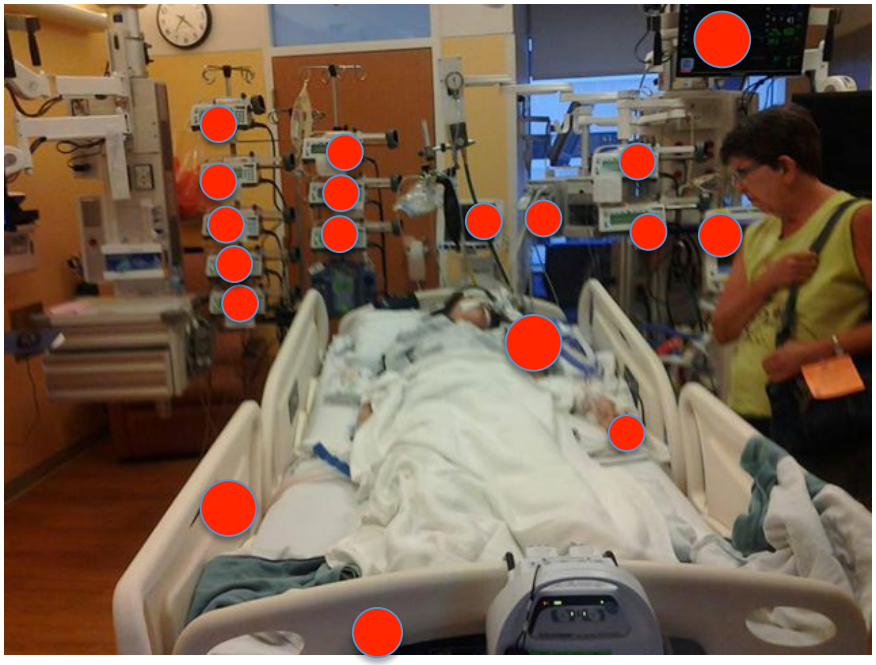
Medical devices proliferate, complexity increases
Caregivers must maintain vigilance, manually integrate data …



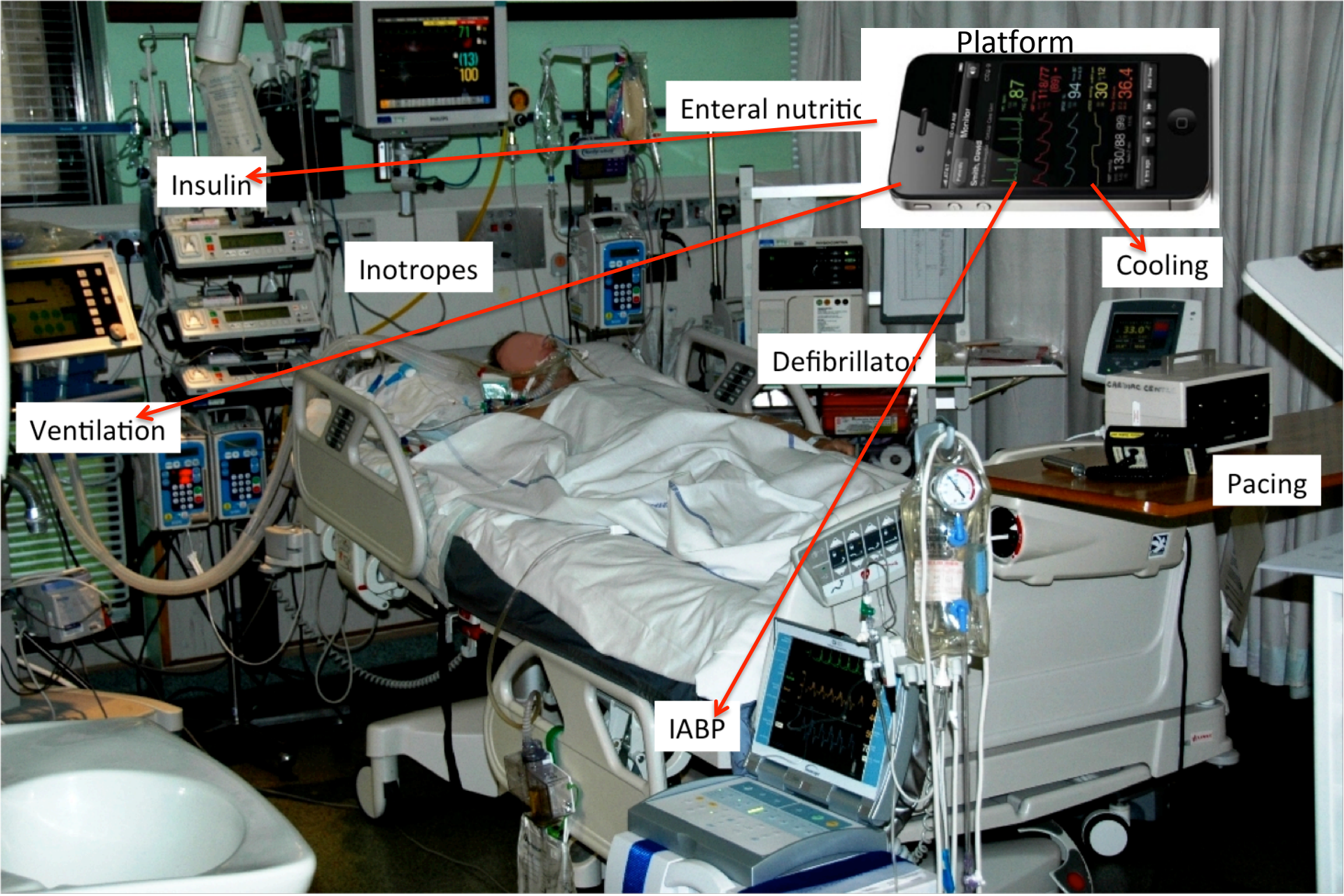
- Clinical environments are not engineered
  Devices are not designed to be integrated to deliver new system capabilities

Medical Device (Electronic)



Has this scenario changed in the last 25 years?

Automated and autonomous systems could reduce cognitive workload and enable implementation of best practices.



What if… Integrating Clinical Environments can enable Apps to rapidly and safely implement solutions?

Smart and Secure Medical Device Systems can Enable Healthcare Transformation

- Future health environments need secure, integrated apps, sensors, actuators, and rich data to improve patient safety and enable new care delivery models.

Video funded in part by NIH/NIBIB "Quantum Interoperability" grant

PCA – Patient Controlled Analgesia

Current State and Future State with Autonomy

Current State:

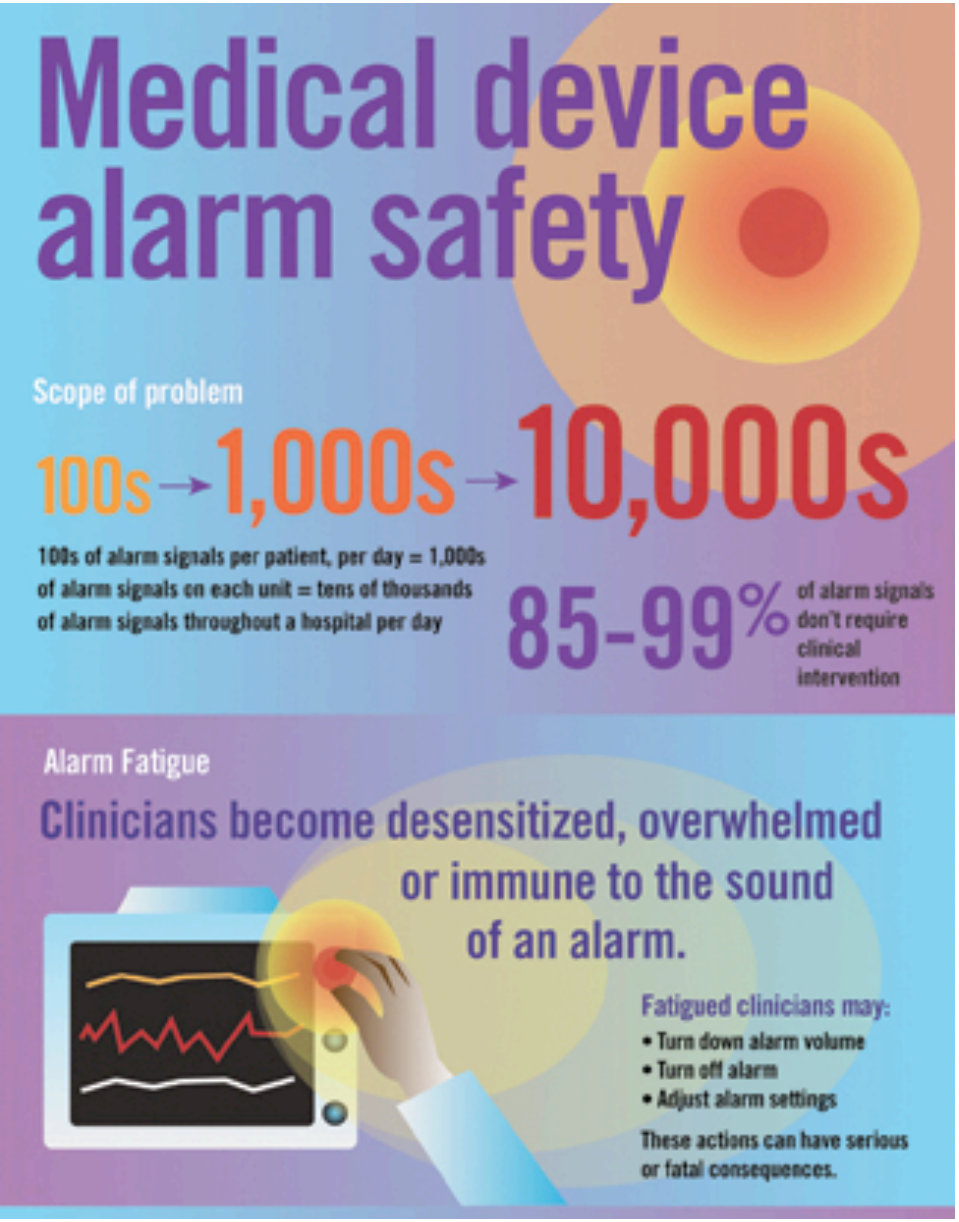
https://vimeo.com/66589116

Proposed State

https://vimeo.com/66589115

10,000s of alarms / hospital / day

85-99% don't require intervention ➔ alarms are NOT meaningful inputs to autonomous systems



Asystole. Really???

JM Goldman, MD / MGH

http://www.theamericannurse.org/wp-content/uploads/2013/10/medical_device_alarm_safety_infographic.jpg

Medical devices

A ticking time-bomb

May 23rd 2012, 10:46 by M.H. | SEATTLE

The Economist

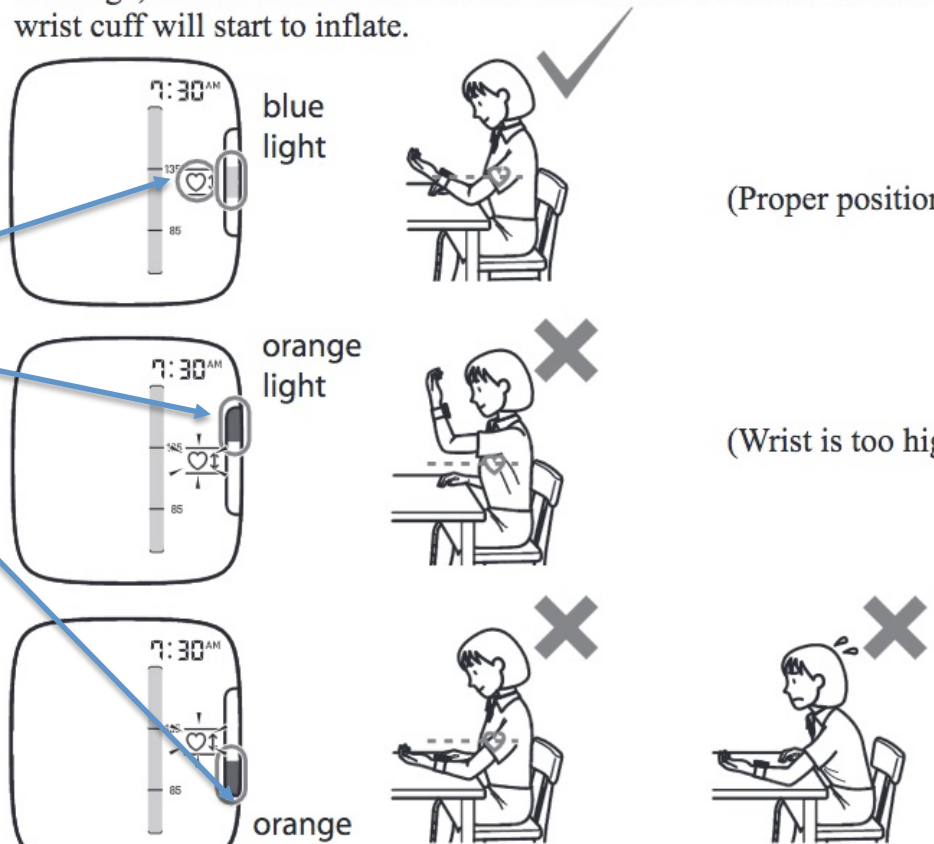
A MAN with one clock knows what time it is, goes the old saw, a man with two is never sure. Imagine the confusion, then, experienced by a doctor with dozens. Julian Goldman is an anaesthetist at Massachusetts General Hospital in Boston. Like many modern health care facilities, it has become increasingly digitised and networked, with hundreds of high-tech medical devices feeding data to a centralised electronic medical record (EMR), which acts as both a permanent repository for health information and a system that can be accessed instantly by doctors to assist with clinical decisions.

Omron BP654

TAKING A MEASUREMENT

Positioning Indicator - The monitor has a built-in positioning indicator that is used as an aid in determining if the monitor is at the correct height. It has been designed to work with most people so that when your wrist is at the correct position relative to your heart, the positioning indicator will be blue. If the positioning indicator changes to orange, the device may not be at the correct height relative to your heart. Due to difference in individual size and physique, this feature may not helpful in all cases and you may wish to turn off this feature. If you feel the position of the wrist according to positioning indicator's guidance does NOT match your heart level, please turn off this feature and follow your judgement. It can be disabled, see "Turn OFF (ON) the Positioning Indicator".

NOTE: Even if the device is not positioned properly and the positioning indicator is orange, after 5 seconds the monitor will start the measurement and the wrist cuff will start to inflate.



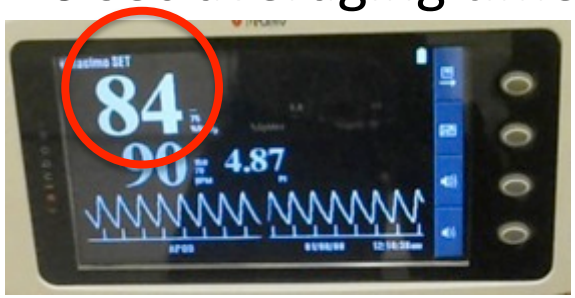
"Position" Indicator (tilt)

Position metadata is included in hx
Is their a standards-based term for tilt?

What is the real O_2saturation?
Effect of Averaging Time Setting on Measured Value (and need for Metadata)

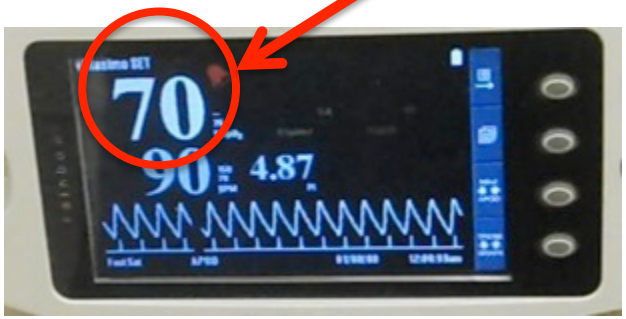
Pulse Ox is set to:

16 sec averaging time

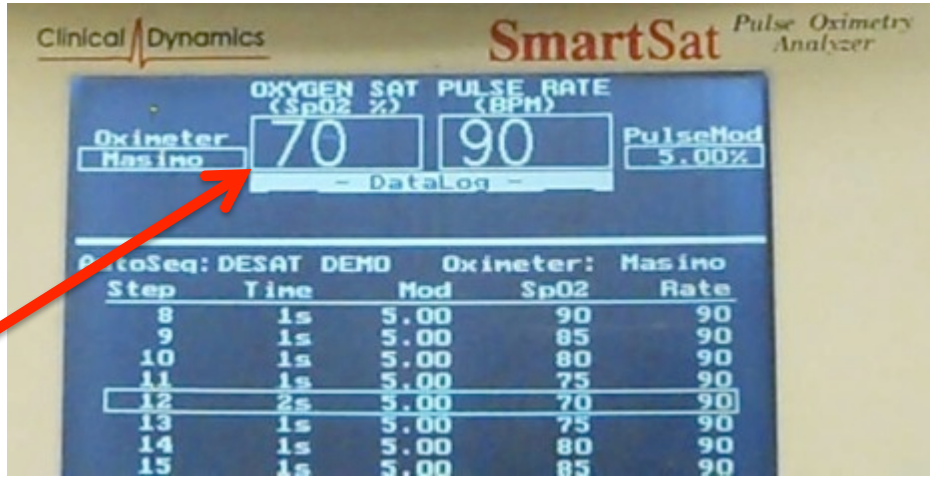


8 sec averaging time

2 sec averaging time



Experiment: Simulator is set to create transient desaturation from 99%->70%->99%



Only the device set to 2 sec averaging time accurately captures the lowest sat created by the simulator.

Example demonstrates importance of <u>averaging time METADATA in data set to interpret data</u>

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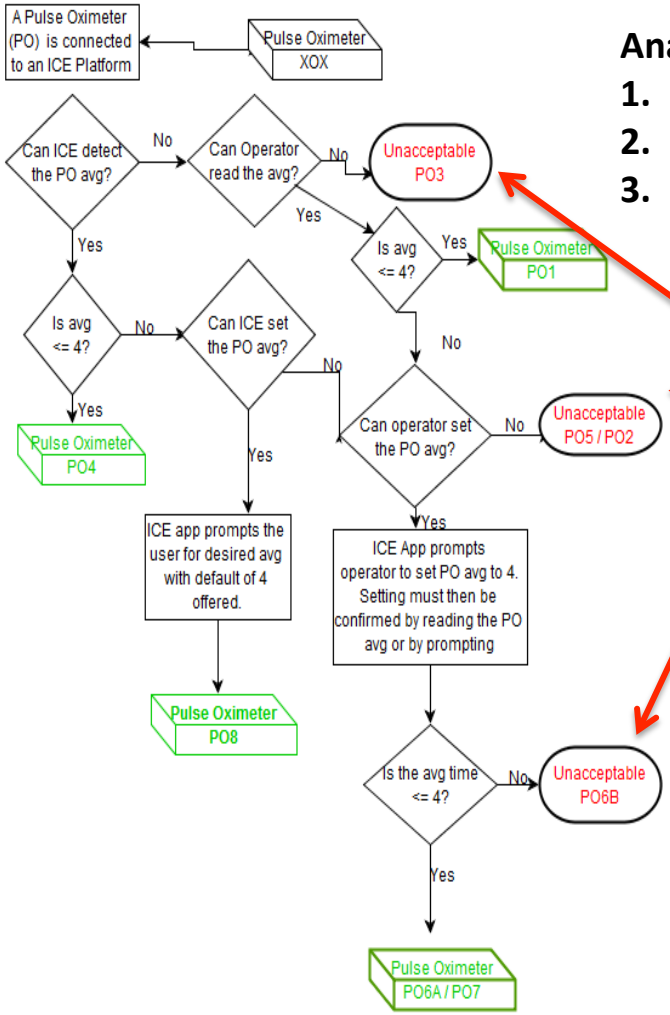
Pulse Oximeter (PO) Capability Decision Tree



Analysis of multiple POx "types" based on avg time attributes:

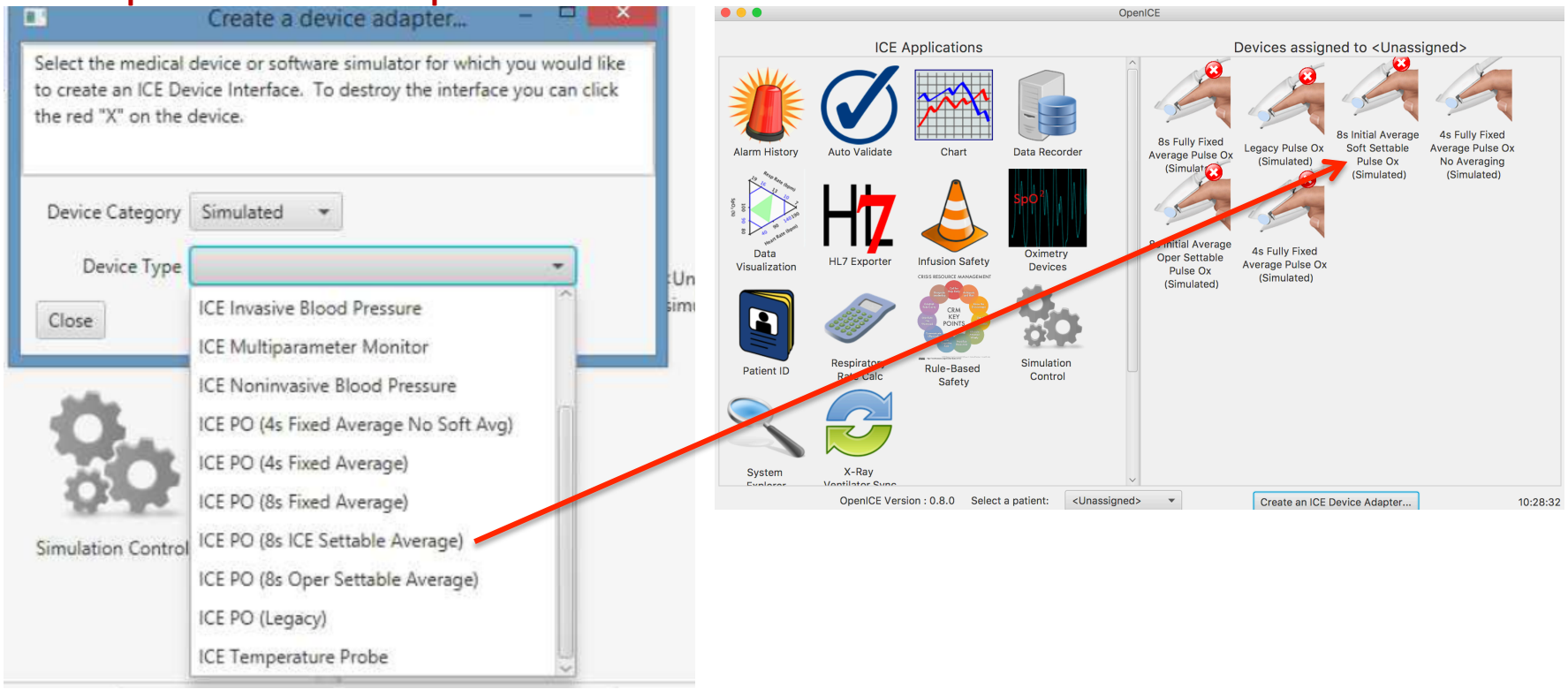
1. **Adjustability of avg time (fixed or adjustable?)**
2. **Avg time availability via the interface? Can app read avg time?**
3. **Availability for operator to see and/or adjust avg time**

"Unacceptable" = POx is not suitable for use with the Resp Depression app
If avg time > 4sec, not adjustable, or unknown

Use case: App requires PO signal averaging time of <= 4 sec to detect transient O2 desaturations (e.g. OSA)									
Does not address patient or use environment.									
	Examples of Pulse Oximeters (PO) with varying data display, setting, and communication capabilities								
	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6 Case A (typical)	PO 6 case B	PO 7 (typical)	PO 8 (Ideal)
Device UI fx/operator capabilites									
Operator can read (access and see) Signal Averaging time	Y	y	N	Y	Y	Y	Y	Y	Desirable (not req)
Operator can change avg time (example - range of 4 - 16 sec)	N	N	N	N	N	Y	Y (device is c	Y	Desirable (not req)
Operator cannot change averaging time (set to =<4 sec)	Y	N		Y	N	N	N	N	
Operator cannot change averaging time (set to > 4 sec)	N	Y		N	Y	N	N	N	
Device Interface fx/App capabilities									
App can read avg time via device interface	N	N	N	Y	Y	Y	Y	N	Y
App can set avg time via device interface	N	N	N	N	N	N	N	N	Y
PO data acceptable for use by this app?	Y	N	N	Y	N	Y	N	Y	Y

Simulated Pulse Oximeters in OpenICE

OpenICE – Device setup



https://www.openice.info/demo.html

Gaps/Needs

- Adverse medical events are not shared and analyzed at national level (no **HITSA*, NTSB)
  - FDA oversight limited to medical devices
- How can emergent hazards of heterogeneous point-of-care composable systems (sensors, actuators, platforms, apps) be identified?
- Empower healthcare sector to improve safety through technology innovation
  - See HITRD RFI & Listening Session (7/19) [1]

[1] https://www.federalregister.gov/documents/2019/02/15/2019-02519/request-for-information-action-on-interoperability-of-medical-devices-data-and-platforms-to-enhance
[2] https://mdpnp.mgh.harvard.edu/projects/hitsa/

The Networking and Information Technology Research and Development Program

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Federal Listening Session on Interoperability of Medical Devices, Data, and Platforms to Enhance Patient Care

A Networking and Information Technology Research and Development (NITRD) Program workshop organized by the Health Information Technology Research and Development (HITRD) Interagency Working Group (IWG).

https://www.nitrd.gov/nitrdgroups/index.php?title=Medical-Device-Interoperability-2019

Presentations:

- Jeffrey Shuren, MD, JD, Director, FDA CDRH - conveyed support for interoperability
  - Interoperability Listening Session: Federal Vision, Sandy Weininger, July 17, 2019.
  - Medical Autonomous Systems for Improving Healthcare Delivery, Loretta Schlachta-Fairchild, July 17, 2019.
  - The Medical Interoperability Reference Architecture Research Collaboration (video), Defense Health Agency, DOD. Presented by Loretta Schlachta-Fairchild at Federal Listening Session on Interoperability of Medical Devices, Data, and Platforms to Enhance Patient Care on July 17, 2019.

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https://www.nitrd.gov/nitrdgroups/index.php?title=Medical-Device-Interoperability-2019#Presentations

Gaps/Needs

- Medical device interoperability: not just a "*data sharing*" or "*openness*" issue. Components must emit data required to achieve and assure performance within system.
- Standards are incomplete and may not be complementary (need comprehensive framework)
- Need comprehensive list of clinical scenarios in which safety/efficiency would benefit
  - E.g. RCA of the 400,000 preventable deaths / year
- "Black box recorder" is essential for risk management
  - AAMI 2700-2-1 under development
- Security …

[1] https://www.federalregister.gov/documents/2019/02/15/2019-02519/request-for-information-action-on-interoperability-of-medical-devices-data-and-platforms-to-enhance
[2] https://mdpnp.mgh.harvard.edu/projects/hitsa/

Supporting research/tools

- MD PnP Lab virtual hospital “sandbox”
- MDIDS – Medical Device Interface Data Sheets (define required interface elements)
- Clinical Scenario Repository - pilot of guided web tool to identify technology system gaps and solutions to improve clinical care
- OpenICE open-source interoperability platform (www.OpenICE.info)

Supporting research/tools

- Standards for physiologic closed-loop control systems (IEC 60601-1-10)
  - Operator must be provided with a mental model of system operation (for safety)
  - Distributed system (sensors, actuators, apps, platform) is permitted
- Integrated Clinical Environment standard ("ICE", AAMI 2700-1) – architecture for platform based medical systems
  - Standard - ICE Data Logger (Black Box Recorder) under development AAMI 2700-2-1
- UL 2800 interoperability standard family
- HIT communication standards (IEEE, HL7, etc.)
- Expert clinical-engineering workshops (STA, NAVAt, IAMPOV) – Use cases, requirements, hazards,
  - E.g. detect spurious data from motion, sensor interaction, etc.

Medical Autonomous Systems for Improving Healthcare Delivery

Loretta Schlachta-Fairchild, RN, PhD, FACHE, LTC(ret), US Army Nurse Corps
Health Information Technology/Informatics Research Program Area Manager
Medical Simulation and Information Sciences/Joint Program Committee-1 (JPC-1)
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Note – MHS slides have been approved for public release

Medical Device Interoperability (MDI) Reference Architecture Research Collaboration

Award:

- Prime Performer: Johns Hopkins University Applied Physics Laboratory (JHU-APL)
- Clinical Principal Investigator: Julian Goldman MD, Massachusetts General Hospital
- Period of Performance: 24 months (start: SEP-2018)

Objectives:

- Advance MDI to improve patient safety through standardization of healthcare delivery
- Identify a collaborative Federal/industry approach in pursuing answers to the questions
- Conduct multiagency/multi partner collaborative research to develop a sustainable framework of autonomous /closed loop prototypes for military health care which are dual use for the civilian healthcare system