APSF Stoelting Conference 2023
“Emerging Medical Technologies – A Patient Safety Perspective on Wearables, Big Data and Remote Care”
Las Vegas, NV Sept 6-7, 2023

Session 4: Impending Issues: Disruptors and Innovation

Remote control of Medical Devices – Are we ready?

Julian M. Goldman, MD
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Medical Director, Biomedical Engineering, Mass General Brigham
Director, MGH Medical Device Interoperability & Cybersecurity Program
Boston, MA, USA

Recent applicable US Gov Research Support

No financial conflicts to disclose

- DOD/TiDE Remote Control of Mechanical Ventilators - W81XWH-15-9-001
- DoD/Device Interoperability and Autonomy Coordinating Center (DIACC) – 1160555
- DoD/An Interoperable Platform for Real-Time In-Theater Caregiver Decision Support (RTCDS) - W81XWH-17-C-0251
- DoD/Semiautonomous Anesthesia and Sedation Devices for Military Medical Care - W81XWH-22-9-0004
- DoD/TiDE - Accelerating Medical Device Interoperability and Autonomy (MDIA)

About the MGH MD PnP Program

Medical Device "Plug-and-Play" Interoperability & Cybersecurity Program

Founded in 2004 to improve patient care by enabling innovation of advanced safe, secure, and interoperable medical devices and digital health technologies (http://mdpnp.mgh.harvard.edu/)

- Impetus: Absence of interoperability impeded innovation in MGH OR of the Future (2002)
- Convened development of ICE standard – Integrated Clinical Environment (* 2009)

  ICE = Platform + Devices + Apps
- Developed OpenICE open-source interoperability research platform (www.openice.info) (NIH U01)
- Collaborative lab prototyping and public demonstrations with industry, academia, and government
- Collaboration Agreements with FDA/CDRH, VA, and DoD/TATRC
- Industry service portfolios / lab testing

Example collaborators

*ICE Standard was originally published as ASTM F2761-09, then AAMI 2700-1

RESEARCH COLLABORATION AGREEMENT
Between
U.S. Food and Drug Administration and the Massachusetts General Hospital

FDA PI: Sandy Weininger, Ph.D.
Office/Center: FDA/CDRH/OSEL/DBP

Collaborator PI: Julian M. Goldman, M.D.
Collaborator: Massachusetts General Hospital

Effective Date: January 11, 2016
Expiration: January 11, 2027

Goals:

CDRH and MGH will collaborate to improve the safety, security, and effectiveness of medical devices used in interoperable systems, including promoting the use of Smart and Autonomous Medical Systems (SaAMS) running on Open Health Platforms (OHPs). The collaborative effort will investigate current and future interoperable medical systems including the design and proof-of-concept demonstrations in the MGH MD PnP lab and other suitable testbeds to identify clinical usage and safety scenarios, sources of interactions between devices, malfunctions and adverse events, remote control and autonomous system considerations, and test methods and standards (either existing or in need of development) across all lifecycle phases. The Parties envision that the results from the collaboration will be useful to the medical device and healthcare provider communities. Results from the collaboration will be made publicly available.

ICE Standard – "Integrated Clinical Environment"

(2009 original version of ICE)

ASTM INTERNATIONAL

F2761-09

Medical Devices and Medical Systems — Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) — Part 1: General requirements and conceptual model

(2019 version of ICE)

American National Standard

ANSI/AAMI 2700-1:2019

Medical Devices and Medical Systems—Essential safety and performance requirements for equipment comprising the patient-centric integrated clinical environment (ICE)—Part 1: General requirements and conceptual model

AAMI
Advancing Safety in Health Technology

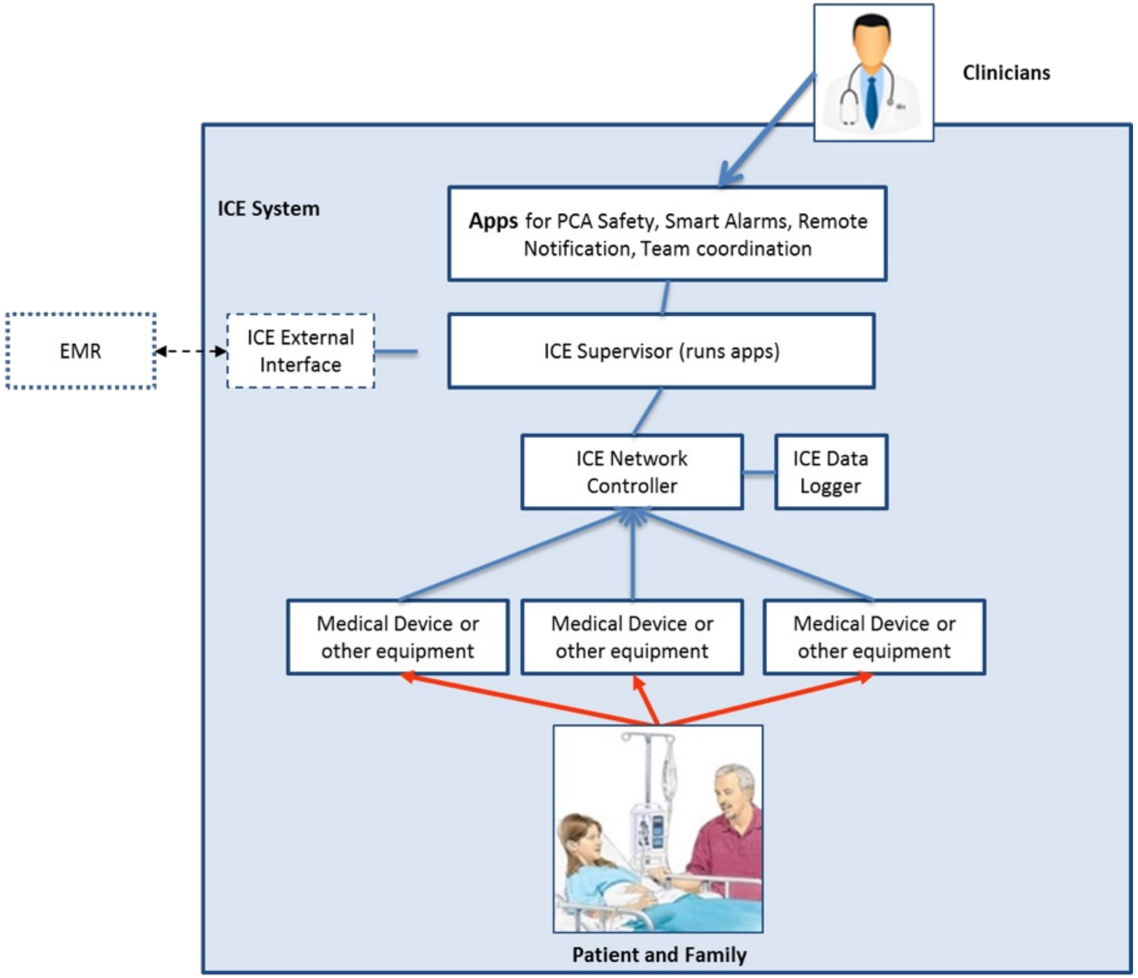
Recognized by the FDA 08/2013

Integrated Clinical Environment Architecture (ICE)

"Essential <u>safety</u> requirements for equipment comprising the patient-centric Integrated Clinical Environment ”

ICE provides an architecture and requirements to help provide:

- 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 (AAMI 2700-2-1 data logging)
- Builds on medical device interoperability
- Leverages standards

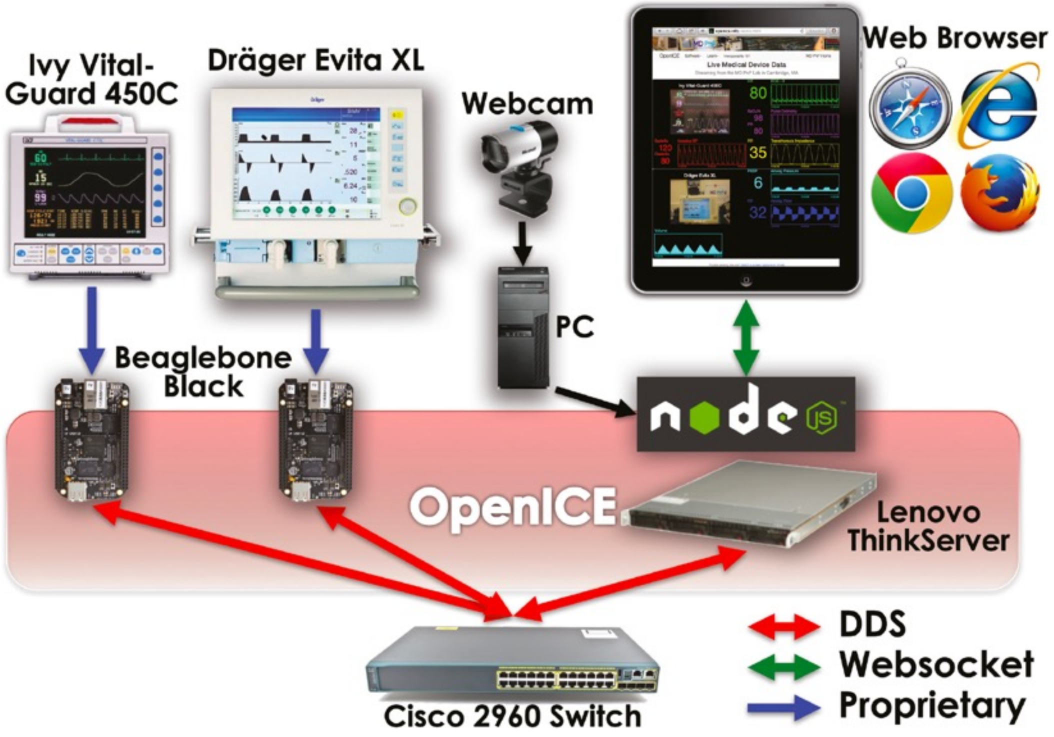


http://mdpnp.mgh.harvard.edu/projects/ice-standard/

Standard recognized by FDA in August 2013

OpenICE – Open-Source Interoperability Research Platform

- An open-source reference implementation of the Integrated Clinical Environment - developed under NIH U01 in 2012
- Provides a development and environments and suite of test tools
  - Built-in simulated medical devices
  - Built-in apps and tools
  - Serial and network connected devices
  - Date visibility and export



OpenICE Architecture

Open Medical Device and Data Integration Platforms to support the management of Ebola Virus Disease

Oct 17, 2014 - Nov 6, 2014

- Friday Oct 17th the White House OSTP Requested an Ebola Care Medical-Technology Response
- First call -> FDA, then to medical device manufacturers and academic collaborators
- Over a 20 day period 19 organizations collaborated to develop and prototype innovative solutions at the MGH MD PnP Lab
- More project details and videos available at

  https://mdpnp.mgh.harvard.edu/astra-portfolio/ebola-response/

Remote Control prototyped for Ebola Response (2014)

WCVB 5 abc
MENU
3 ALERTS
58° WEATHER
SEARCH

BREAKING NEWS: Coronavirus crisis in Massachusetts: The latest map and data
2 / 3

RECOMMENDED

Couple holds special adoption ceremony over Zoom

Massachusetts men arrested in connection with smuggling ex-Nissan executive out of Japan

Restaurant opens for last time because of pandemic's toll on business

Gov. Charlie Baker visits Braintree company converted to producing protective equipment

AR-15 stolen from Maine state trooper in 2018 recovered in Boston

Police find body of missing former WWE star Shad Gaspard

Coronavirus crisis in Massachusetts: The latest map

Local researchers testing remote control Ebola care

Researchers hope prototypes will soon be in medical centers

Share

WCVB 5 | Updated: 7:09 PM EST Nov 6, 2014

Kelley Tuthill

SOURCE: Kelley Tuthill/WCVB

BOSTON — If a television can have a remote control, why can't a medical device?

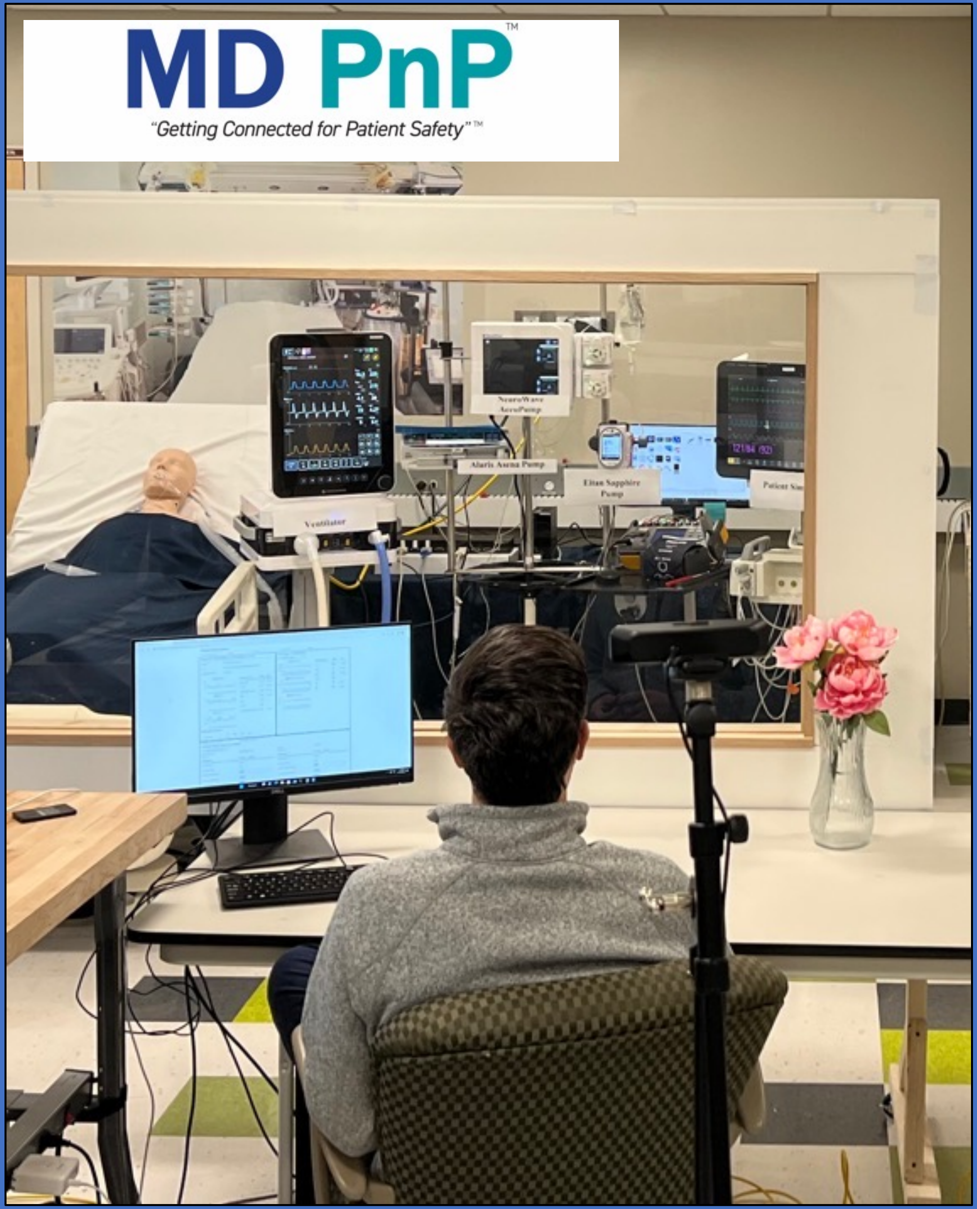
Watch the report

Potential benefits of remote control:

- More rapid response to urgent patient needs (e.g. increase $FiO_2$from outside room)
- Reduce room entries
- Reduce PPE consumption
- Assess patients more quickly
- Project supported under NIH/NIBIB U01 grant, and NSF Smart America Closed-Loop Healthcare[2]

1. https://www.wcvb.com/article/local-researchers-testing-remote-control-ebola-care/8211393# in MGH MD PnP lab. See video.
2. https://www.nsf.gov/discoveries/disc_summ.jsp?cntn_id=132204

Medical Device Plug-and-Play Interoperability & Cybersecurity (MD PnP) Lab



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Letter of support from Jeffrey Shuren, MD, JD, Director, FDA CDRH

Participation of the US FDA was a powerful incentive for medical device manufacturers to explore innovative medical technology solutions, especially those benefiting from interoperability and collaboration between manufacturers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Room 5447, Building 66
Silver Spring, MD 20993-0002

November 3, 2014

Julian M. Goldman, MD
Director, Medical Device Interoperability Program
65 Landsdowne Street
Cambridge, MA 02139

Dear Dr. ~~Goldman~~ Julian,

Thank you for reaching out to the Center for Devices and Radiological Health (CDRH) via our Emergency Preparedness/Operations and Medical Countermeasures (EMCM) Program.

We understand that The Medical Device "Plug-and-Play" (MD PnP) Interoperability Program, under your coordination, has been asked by the White House Office of Science and Technology Program to mobilize resources among medical device manufacturers and the clinical community, so as to design and demonstrate proof of concept for an interoperable platform that would enable critical care of Ebola-infected patients in an isolation environment with reduced exposure to health care workers.

FDA recognizes the importance of implementing strategies that minimize direct exposure of clinical personnel to patients infected with Ebola virus. We understand that MDPNP, along with its collaborators, are developing potential approaches that would include comprehensive data access and potential remote control of medical devices in the isolation environment, thereby reducing the risk of healthcare worker exposure to the virus.

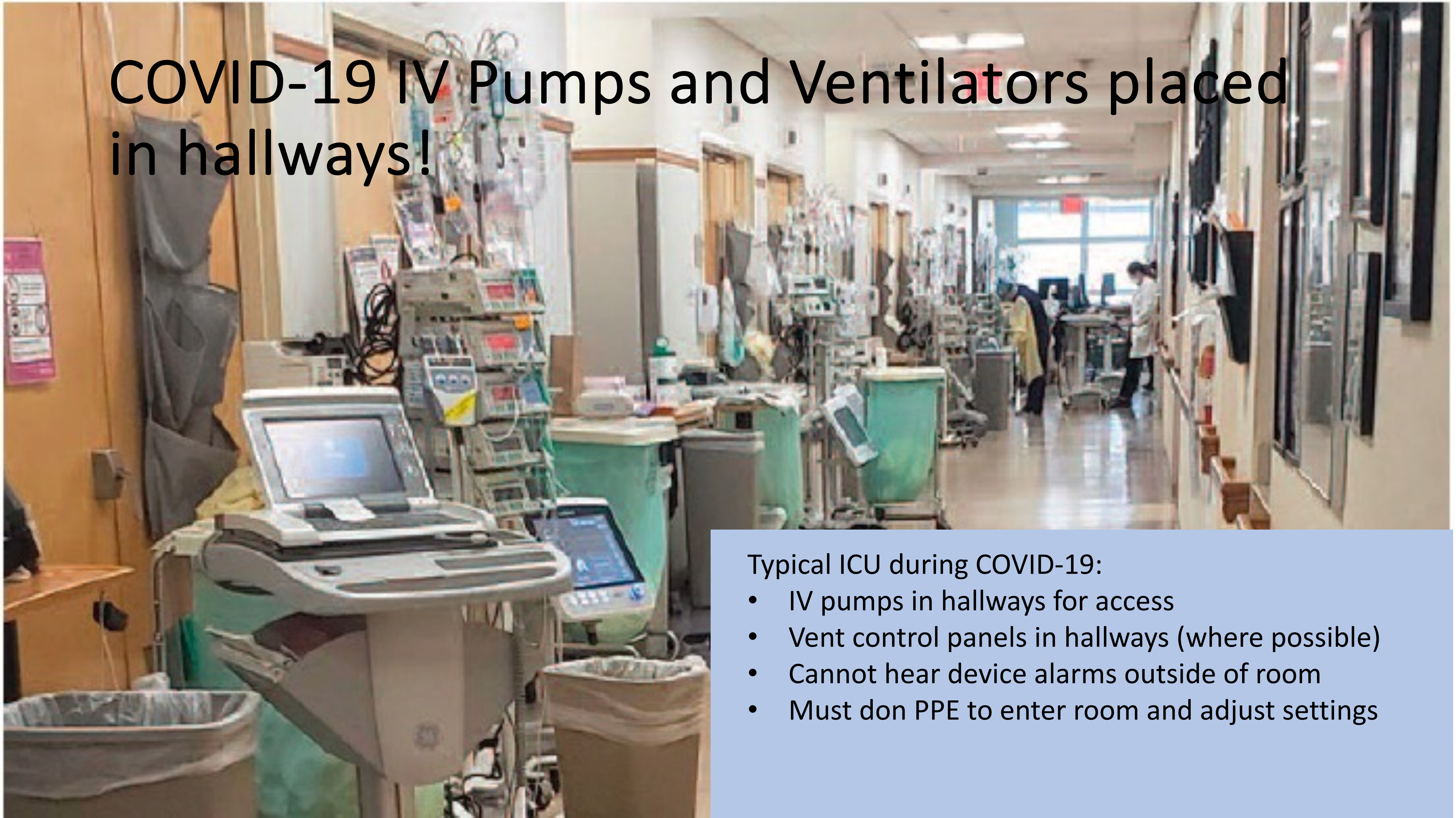
CDRH recognizes the importance of these efforts and is ready and willing to collaborate with you, the clinical community and your industry partners to demonstrate the potential of this technology in serving this particular public health emergency. We are eager to observe the demonstration taking place Friday November 7th for OSTP, and we look forward to participating in the development of next steps with MDPNP and your medical device partners so as to do our part in enabling advancement of technology that can protect our healthcare workers who put themselves on the front line to promote the public health mission.

Sincerely,

Jeffrey Shuren

Jeffrey Shuren, M.D., J.D.
Director
Center for Devices and
Radiological Health

COVID-19 IV Pumps and Ventilators placed in hallways!



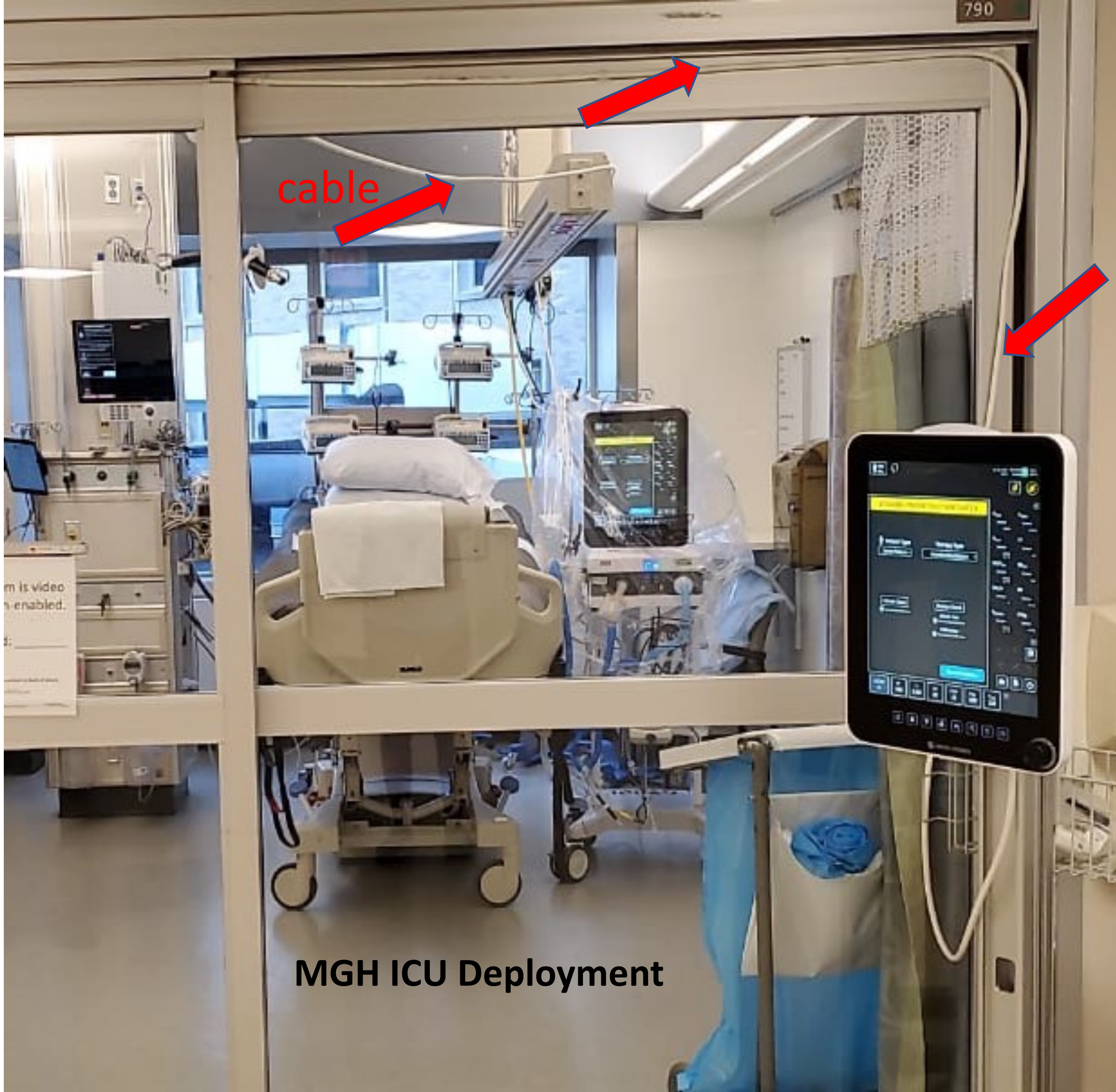
Typical ICU during COVID-19:

- IV pumps in hallways for access
- Vent control panels in hallways (where possible)
- Cannot hear device alarms outside of room
- Must don PPE to enter room and adjust settings

2019 state of the art:
Near-patient remote control
Nihon Kohden Orange Med NKV-550 Ventilator

Second Active Screen / GUI

- FDA 510K Cleared (prior to pandemic)
- Full ventilator operation (except power on/off)
- Connected through doorway with 10m cable
  - <u>line of site deployment</u>



FDA Immediate in Effect Guidance 2020

"… Hardware and/or software modifications implementing the capability for remote monitoring and remote adjustment of ventilator parameters" may be added without the need for 510k submission

https://www.fda.gov/media/136318/download
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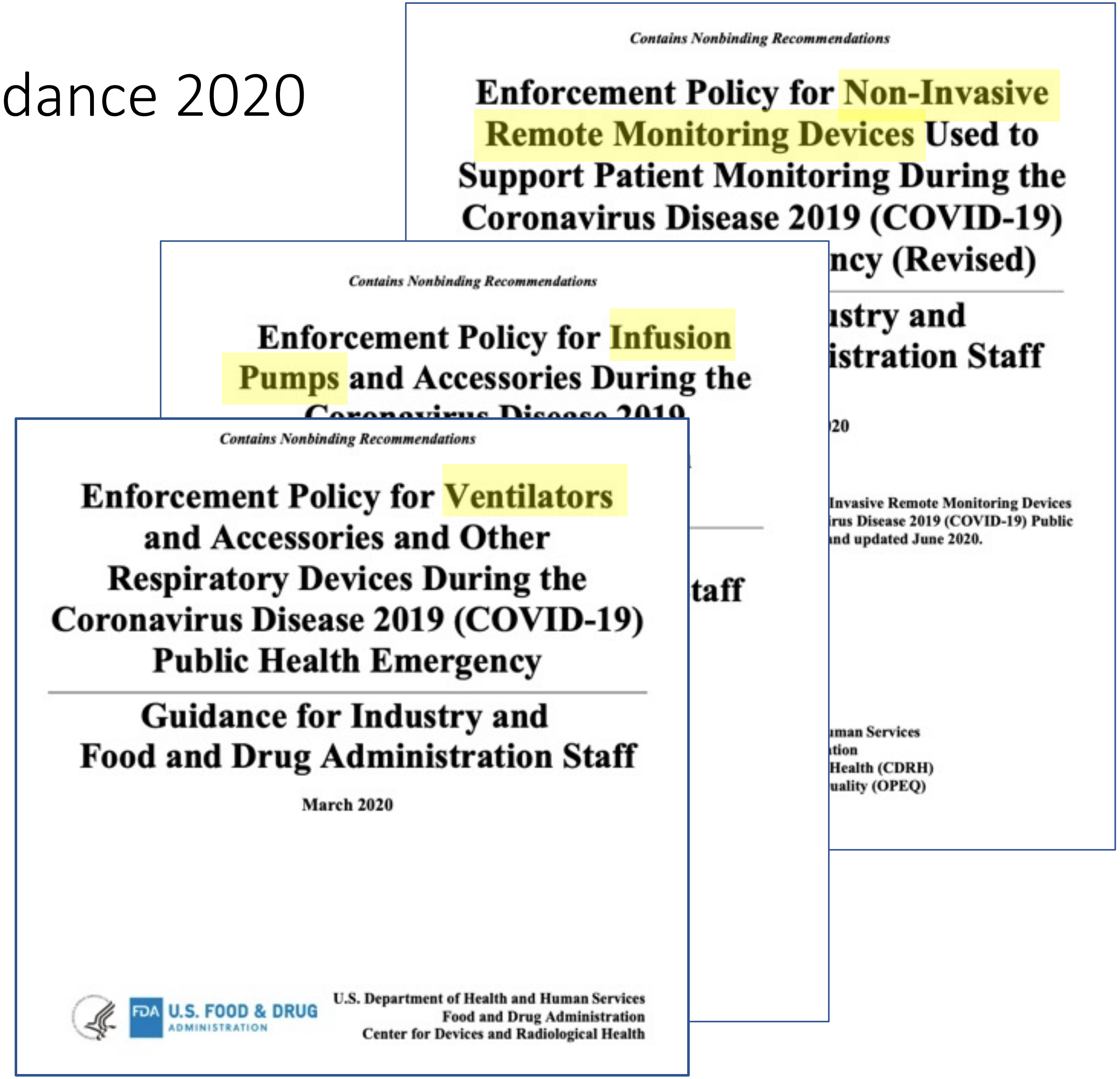


Medtronic PB 980 network–enabled remote control provided under FDA COVID-19 FDA enforcement policy

- Medtronic developed a firmware upgrade for the PB980 that allowed remote operation using proprietary software
- Tested in the MGH MD PnP lab in preparation for clinical proof-of-concept deployment in 2020
  - Interoperability
  - Cybersecurity
  - Clinical workflow
  - Installation requirements
  - Assessed role of video to replace line-of-sight connection

Medtronic PB 980 Remote-controlled ventilator evaluation - prior to clinical deployment for COVID-19 care

Monitoring & Control Computer

Webcam

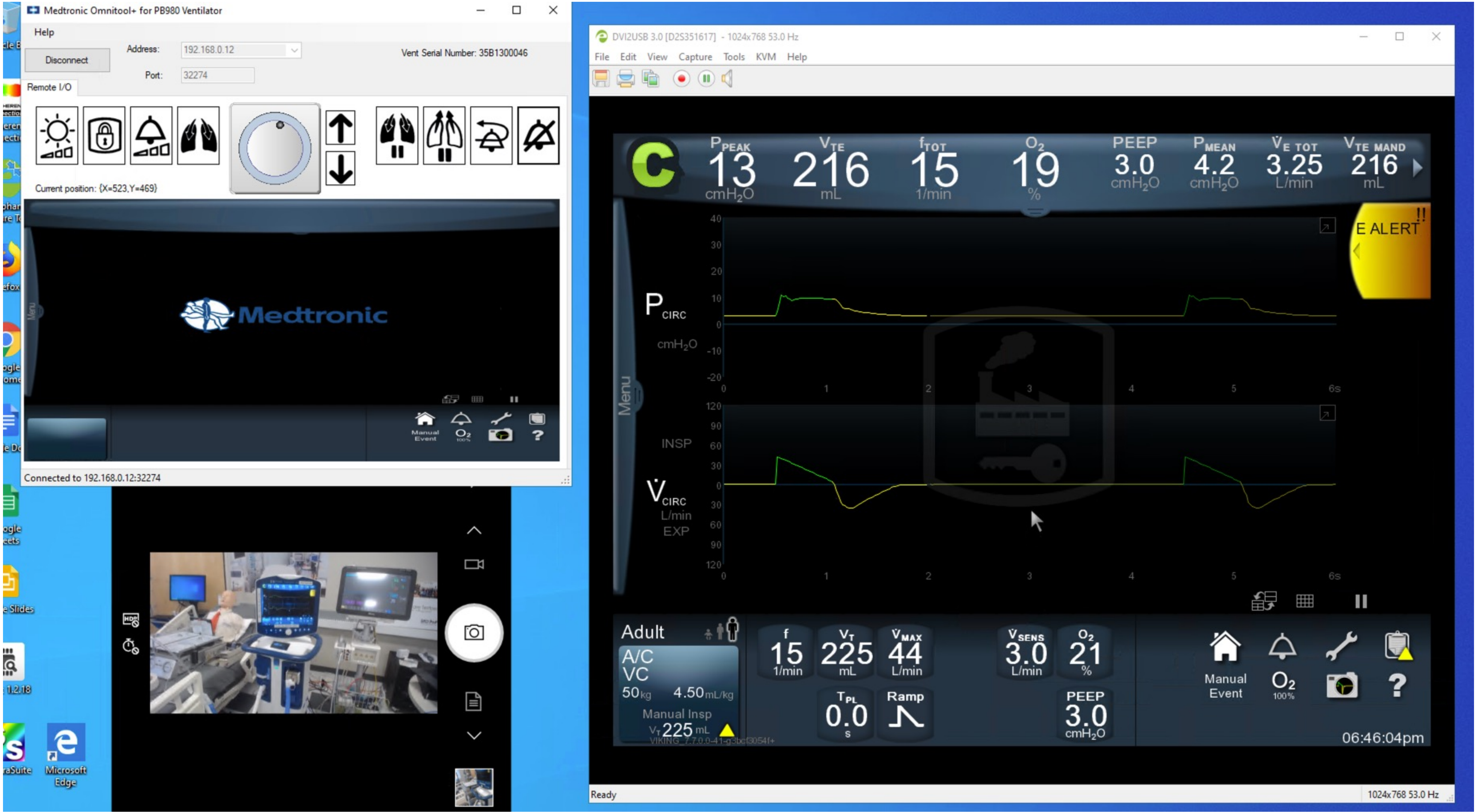
HDMI Capture

Ventilator

https://vimeo.com/419942297

MD PnP™
Getting connected for patient safety™

Medtronic PB 980 Ventilator controlled over secure connection 8 miles away



COVID-19 Resources from the Field

https://www.aami.org/news-resources/covid-19-resources

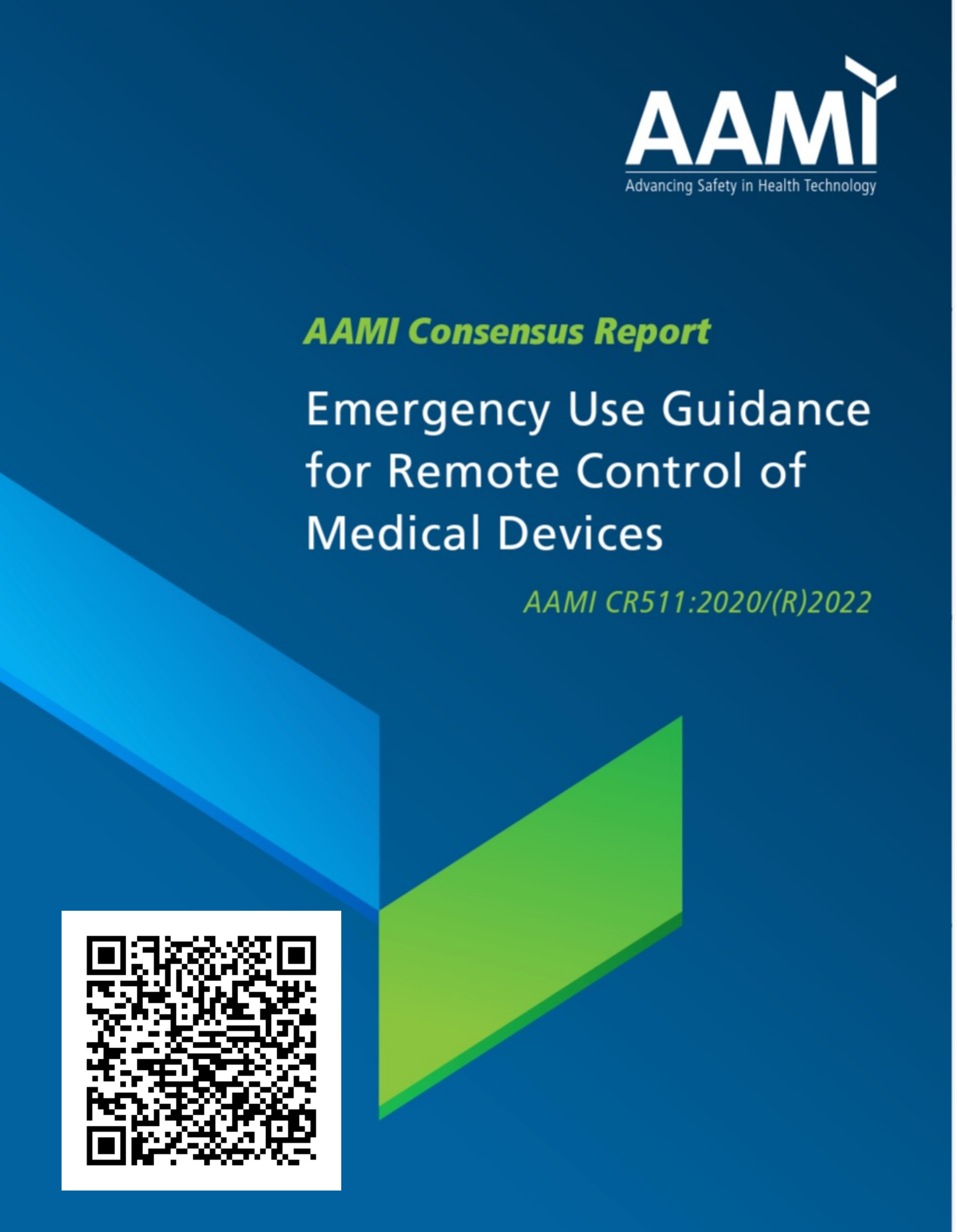
As the COVID-19 pandemic continues to impact global health care, AAMI is providing this curated collection of resources to assist the health technology field. While AAMI finds these sources to be credible and has compiled this collection as a service to the field, these references are not endorsed by AAMI and the inclusion of any reference or resource should not be construed as endorsement, promotion, or support of any organization.

To request new or updated information, resources and links, please contact Colleen Elliott at celliot@aami.org.

Ventilators/Resuscitators/CPAP/BiPAP

These guidance documents have been developed by the AAMI COVID-19 Response Team, made up of manufacturers, clinicians and FDA representatives, to respond to the ventilator shortage emergency.

- AAMI CR501:2020/(R)2022, *Emergency Use Ventilator (EUV) Design Guidance* (8 April 2020, Revision 1.2)
- AAMI CR502:2020/(R)2022, *End User Disclosures for Emergency Use Ventilators (EUVs)* (17 April 2020, Revision 1.2)
- AAMI CR503:2020/(R)2022, *Emergency Use Resuscitator Systems Design Guidance* (8 April 2020, Revision 1)
- AAMI CR504:2020/(R)2022, *End User Disclosures for Emergency Use Resuscitator Systems* (17 April 2020, Revision 1.1)
- AAMI CR505:2020/(R)2022, *Emergency Use CPAP/BiPAP Design Guidance* (15 April 2020, Revision 1)
- AAMI CR506:2020/(R)2022, *End User Disclosure for CPAP/BiPAP* (17 April 2020, Revision 1.1)
- AAMI CR507:2020/(R)2022, *Basic Safety of Emergency Use Medical Devices* (6 May 2020, Revision 1)
- AAMI CR508:2020/(R)2022, *Emergency Use Ventilatory Assistance Helmet (VAH) Design Guidance*(16 July 2020, Revision 1)
- AAMI CR509:2020/(R)2022, *End User Disclosures for Emergency Use Ventilatory Assistance Helmet (VAH)*(16 July 2020, Revision 1)
- AAMI CR511:2020/(R)2022, *Emergency use Guidance for Remote Control of Medical Devices*(16 December 2020, Revision 1.1)



Task Group representation

Association for the Advancement of Medical Instrumentation

COVID-19 Response Team Members

This AAMI Consensus Report (CR) was developed by a task group under the auspices of the AAMI COVID-19 Response Team.

The **AAMI COVID-19 Response Team** had the following members:

Cochairs:

Jennifer Danieley
David Feinstein
Julian Goldman
Sandy Weininger

Members:

Simona Bancos, FDA/CDRH
Andrew Bath, ResMed Inc.
Brandon Blakely, FDA/CDRH
Brad Bonnette, ECRI Institute
Caitlin Brady, Intertek
David Busch, UT Southwestern Medical Center
Anthony Ciccarello, Philips
Steven Dain, University of Western Ontario
Rakhi Dalal, FDA/CDRH
Jennifer Danieley, FDA/CDRH
Andy Doering, Medtronic
Simon Dunham, Weill Cornell Medicine
Leonard Eisner, Eisner Safety Consultants
David Feinstein, American Society of Anesthesiologists (ASA)
Anura Fernando, UL LLC
Bruce Friedman, GE Healthcare
Adrian Gelb, University of California, San Francisco
Hamed Ghods, FDA/CDRH
Julian Goldman, Mass General Brigham
Ralf Heesch, Draeger Medical Systems Inc.
Eric Hudson, Medline
Fernando Isaza, Philips
Michael Jaffe, Cardiorespiratory Consulting LLC
Robert Kopotic, Edwards Lifesciences
Hubertus Lasthaus, VitalAire Germany
Ponleaarun Le, FDA/CDRH
Ken LeDez, Memorial University of Newfoundland
Ed Madsen, Avanos Medical
Phoebe Mainland, Alfred Health
Jeff Mandel, Society for Technology in Anesthesia
Benoit Marchal, Air Liquide
Thomas Marmet, GE Healthcare
Debra Milamed, Harvard University
Cyndy Miller, Medtronic Inc Campus
Bryant Moeller, ResMed Inc.
Curtis Morgan, 3M Health Care
Akito Ohmura, Teikyo University-Mizonokuchi Hospital
David Osborn, Philips

7 Safety requirements and risk control measures

Risk management shall be performed to ensure that risk has been reduced to an acceptable level, or failing that, determining that the benefits of using the remote control system outweigh the risk that remains after reducing the risk as low as reasonably practicable.

7.1 Disclosure of communication architecture

The architecture of communication shall be disclosed with sufficient detail in the Instructions for Use to allow the healthcare delivery organization to verify implementation and acceptably manage risk.

Disclosed information shall include whether the remote control system annunciates audible alarm signals.

Note 1 Implementation details may be dependent on both the device manufacturer and the health delivery organization's infrastructure. Sufficient detail in this context includes the aspects of the safety requirements in this section.

Note 2 Remote control systems may be constructed from constituents from different manufacturers – those manufacturers may address use hazards somewhat differently, e.g., they may provide (1) different ways of informing the operator about the current state and (2) different controls for operating their respective devices.

Note 3 The signal pathways in the remote-control system that are relevant to this guidance document are the four paths listed below. The details of the IT network other than those relating to cybersecurity will not be addressed.

a) Direct Wire (point to point) — A direct wired connection is a point to point connection with a single cable or multiple cables that transmits bi-directionally the signals required for monitoring and control of the equipment. This type of connection may use pass-through connectors inside and outside the patient room to maintain a negative room pressure.

b) Network Connected-Private/Isolated — A network connected (Private/Wired) connection is a connection where the medical electrical equipment inside the room and/or the auxiliary HMI is connected with a cable to a local area network.

c) Wireless-Private/Isolated — A wireless local connection is a wireless connection of the equipment inside the room and/or the auxiliary HMI to each other through a network that is isolated from other networks. This connection is typically a Wi-Fi (See IEEE 802.11x) connection.

d) Wireless/Wired-Shared network connection

Note 4 Example of factors affecting risks for different signal pathways listed above include: EMC, QoS, Cybersecurity, Co-existence, Connector and cabling reliability, Primary/Auxiliary identification.

Note 5 Protocols that allow components to transmit information between them can be used to support levels of interoperability (e.g., syntactic, semantic, conceptual). (See ISO/IEEE 11703-10201)

7.1.1 Degradation or loss of information

Means shall be provided to prevent unacceptable risk arising from degraded or loss of information that is exchanged between the remote control system and the primary medical device.

Connection/disconnection of the remote control system shall not interfere with the intended use of the primary medical device.

Note 1 Causes of degradation can include physical interference with the signal (e.g., electromagnetic in origin (EMC), physical integrity (cable issues)

Note 2 Causes of QoS degradation can include bandwidth, latency, jitter, packet drop.

Note 3 The loss of function of the remote control system whether through loss of mains power or failure of the power supply, or other cause, will disable the auxiliary HMI and potentially lose the display of information, device control, and alarm display and annunciation. Similarly, loss of auditory or visual alarms may reduce the ability of the clinicians to respond in a timely manner.

7.1.2 Conflicting commands

There shall be a means for ME EQUIPMENT to prevent or resolve conflicting control arising from user action on the remote control system.

7.1.3 Authorization of the remote control system communications

When the remote control system communicates with the primary medical device for the first time, there shall be a means to confirm that the auxiliary HMI has the authority to remotely control the primary medical device.

7.2 Component issues and physical hazards

7.2.1 Basic safety

Means shall be provided to assure basic safety of the remote control system.

Medical Electrical (ME) Equipment shall comply with relevant standards.

NOTE Remote control system is considered part of the ME system. The basic safety and essential performance aspects of 60601-1 apply. The protection against direct physical hazards under normal and single fault conditions is implied and includes tripping on the components of the system such as the cables and a cart if used.

Manufacturer shall disclose the residual risk.

7.2.2 Power

Disclosed information shall include whether the remote control system will operate while the medical device is not connected to mains power.

Means may be provided for backup power to the auxiliary HMI.

In the event of loss of mains power, the behavior of the auxiliary HMI shall be disclosed. However, loss of power to the remote control system shall not inadvertently affect the operation of the medical device with its primary HMI.

NOTE Without backup power, a loss of power will shut down the remote control system and may create a hazardous situation.

7.2.3 EMC

IEC 60601-1-2 is recommended but not required.

Rationale: The tests of IEC 60601-1-2 are time consuming and expensive and need very specialized equipment. Requiring these tests would delay availability such that new designs might not be available when needed. Disclosure that these tests have not been performed and that other equipment must be kept at a distance should be considered sufficient.

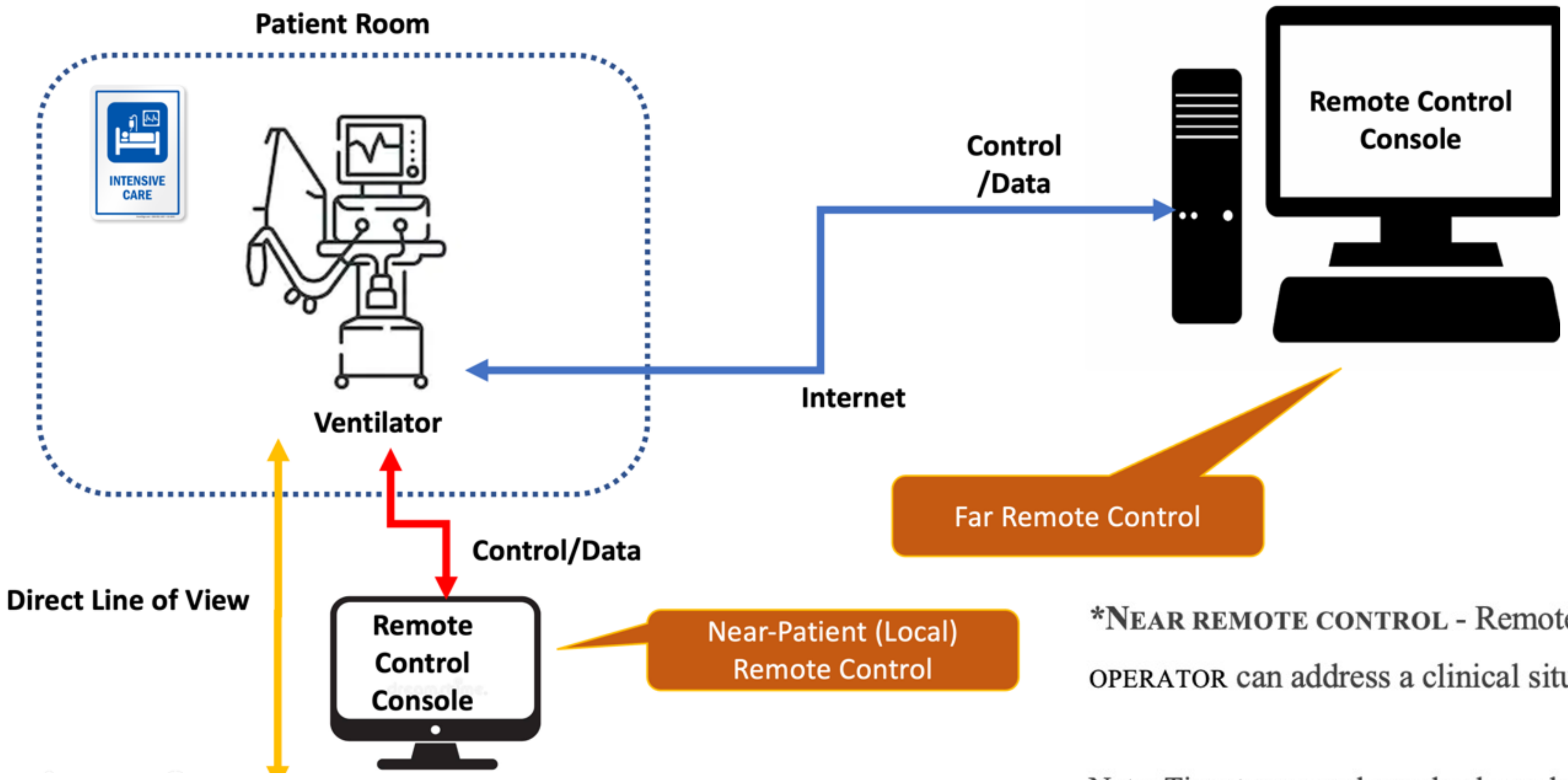
Note 1 The hardware used for the remote control system may be vulnerable to radio frequency and electro-magnetic pulses, static discharge, brownouts and voltage spikes. The impact can range from temporary disruption of command and control to permanent damage to circuit boards. Proper shielding, grounding, power conditioning, and/or surge suppression is recommended.

7.3 Locus of control, information focus

7.3.1 Locus of control

Means shall be provided to manage contention for control from multiple sources.

Near-Patient (Local) Remote Control vs. Far Remote Control



Definitions in process in AAMI standards committee (IOWG)

*NEAR REMOTE CONTROL - Remote control of ME EQUIPMENT from a location where the OPERATOR can address a clinical situation in a timely manner.

Note: Time to respond may be dependent on environment attributes such as physical proximity to the patient environment (ability to make adjustments to the patient/ ME EQUIPMENT UNDER CONTROL), time to take mitigation actions (e.g., time to don/doff), and the line of sight to patient environment.

*FAR REMOTE CONTROL -. Remote control of ME EQUIPMENT from a location where the OPERATOR cannot address a clinical situation in a timely manner.

AAMI Remote-Control Standard under development

American National Standard 5/4/2023

Remote control of medical devices: Lung Ventilators and Intravenous (IV) Infusion Pumps

Approved xx xxxxxx 20xx by
AAMI

Approved xx xxxxxxx 20xx by
American National Standards Institute, Inc.

Contents

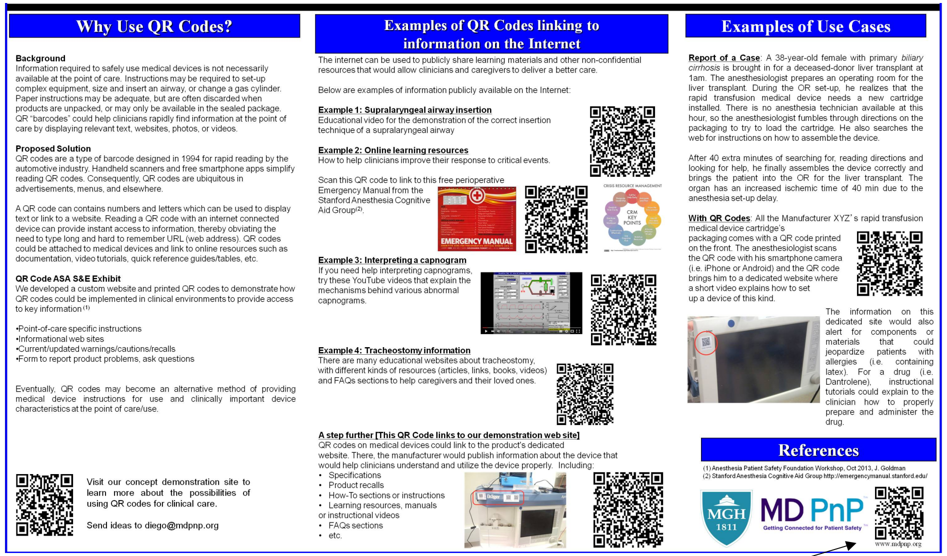
QR Code on screens and devices could help assure availability of point-of-care documentation in emergency conditions:

- APSF 2013 Workshop – QR Code public proposal
- ASA 2015 Annual Meeting Scientific Exhibit S29 “QR Codes for Medical Device Point-of-Care Product Information”
  - 3rd place award
  - Could link to detailed video instructions
- 2023 DRAGER Atlan example →

ASA 2015 Annual Meeting Scientific and Educational Exhibit S29 (Hall G)

QR Codes for Medical Device Point-of-Care Product Information

Julian M. Goldman, M.D.[1], Diego Alonso, M.S.[2], David Feinstein, M.D.[3], James H. Philip, M.D.[4],
William A. Paulsen, Ph.D.5, Mary M. Weick-Brady, M.S.N.[6]
[1]Anesthesia, Mass General Hospital, Boston, MA, USA, [2]Mass. General Hospital, Boston, MA, USA, [3]Anesthesia, Beth Israel Deaconess Medical Center, Boston, MA, USA, [4]Brigham and Women's Hospital, Boston, MA, USA, [5]Quinnipiac University, North Haven, CT, USA, [6]US FDA Center for Devices in Radiological Health, Silver Spring, MD, USA.



Why Use QR Codes?

Background
Information required to safely use medical devices is not necessarily available at the point of care. Instructions may be required to set-up complex equipment, size and insert an airway, or change a gas cylinder. Paper instructions may be adequate, but are often discarded when products are unpacked, or may only be available in the sealed package. QR “barcodes” could help clinicians rapidly find information at the point of care by displaying relevant text, websites, photos, or videos.

Proposed Solution
QR codes are a type of barcode designed in 1994 for rapid reading by the automotive industry. Handheld scanners and free smartphone apps simplify reading QR codes. Consequently, QR codes are ubiquitous in advertisements, menus, and elsewhere.

A QR code can contains numbers and letters which can be used to display text or link to a website. Reading a QR code with an internet connected device can provide instant access to information, thereby obviating the need to type long and hard to remember URL (web address). QR codes could be attached to medical devices and link to online resources such as documentation, video tutorials, quick reference guides/tables, etc.

QR Code ASA S&E Exhibit
We developed a custom website and printed QR codes to demonstrate how QR codes could be implemented in clinical environments to provide access to key information (1)

•Point-of-care specific instructions
•Informational web sites
•Current/updated warnings/cautions/recalls
•Form to report product problems, ask questions

Eventually, QR codes may become an alternative method of providing medical device instructions for use and clinically important device characteristics at the point of care/use.

Visit our concept demonstration site to learn more about the possibilities of using QR codes for clinical care.

Send ideas to diego@mdpnp.org

Examples of QR Codes linking to information on the Internet

The internet can be used to publicly share learning materials and other non-confidential resources that would allow clinicians and caregivers to deliver a better care.

Below are examples of information publicly available on the Internet:

Example 1: Supralaryngeal airway insertion
Educational video for the demonstration of the correct insertion technique of a supralaryngeal airway

Example 2: Online learning resources
How to help clinicians improve their response to critical events.

Scan this QR code to link to this free perioperative Emergency Manual from the Stanford Anesthesia Cognitive Aid Group(2).

EMERGENCY MANUAL

CRISIS RESOURCE MANAGEMENT
CRM KEY POINTS

Example 3: Interpreting a capnogram
If you need help interpreting capnograms, try these YouTube videos that explain the mechanisms behind various abnormal capnograms.

Example 4: Tracheostomy information
There are many educational websites about tracheostomy, with different kinds of resources (articles, links, books, videos) and FAQs sections to help caregivers and their loved ones.

A step further [This QR Code links to our demonstration web site]
QR codes on medical devices could link to the product's dedicated website. There, the manufacturer would publish information about the device that would help clinicians understand and utilize the device properly. Including:
- Specifications
- Product recalls
- How-To sections or instructions
- Learning resources, manuals or instructional videos
- FAQs sections
- etc.

Examples of Use Cases

Report of a Case: A 38-year-old female with primary *biliary cirrhosis* is brought in for a deceased-donor liver transplant at 1am. The anesthesiologist prepares an operating room for the liver transplant. During the OR set-up, he realizes that the rapid transfusion medical device needs a new cartridge installed. There is no anesthesia technician available at this hour, so the anesthesiologist fumbles through directions on the packaging to try to load the cartridge. He also searches the web for instructions on how to assemble the device.

After 40 extra minutes of searching for, reading directions and looking for help, he finally assembles the device correctly and brings the patient into the OR for the liver transplant. The organ has an increased ischemic time of 40 min due to the anesthesia set-up delay.

With QR Codes: All the Manufacturer XYZ’s rapid transfusion medical device cartridge’s packaging comes with a QR code printed on the front. The anesthesiologist scans the QR code with his smartphone camera (i.e. iPhone or Android) and the QR code brings him to a dedicated website where a short video explains how to set up a device of this kind.

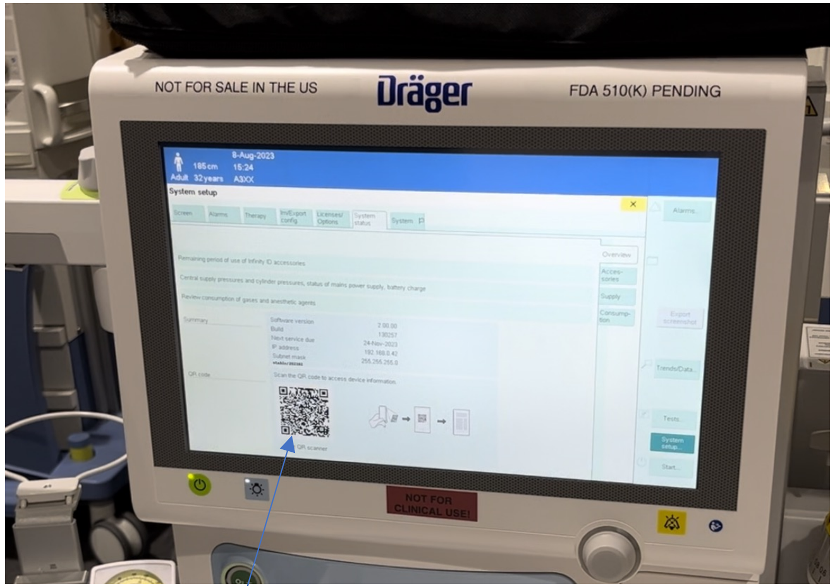
The information on this dedicated site would also alert for components or materials that could jeopardize patients with allergies (i.e. containing latex). For a drug (i.e. Dantrolene), instructional tutorials could explain to the clinician how to properly prepare and administer the drug.

References

(1) Anesthesia Patient Safety Foundation Workshop, Oct 2013, J. Goldman
(2) Stanford Anesthesia Cognitive Aid Group http://emergencymanual.stanford.edu/

MGH 1811
MD PnP
Getting Connected for Patient Safety
www.mdpnp.org

Learn more about our program at www.mdpnp.org (or scan the QR code in the bottom right corner!)



QR Code

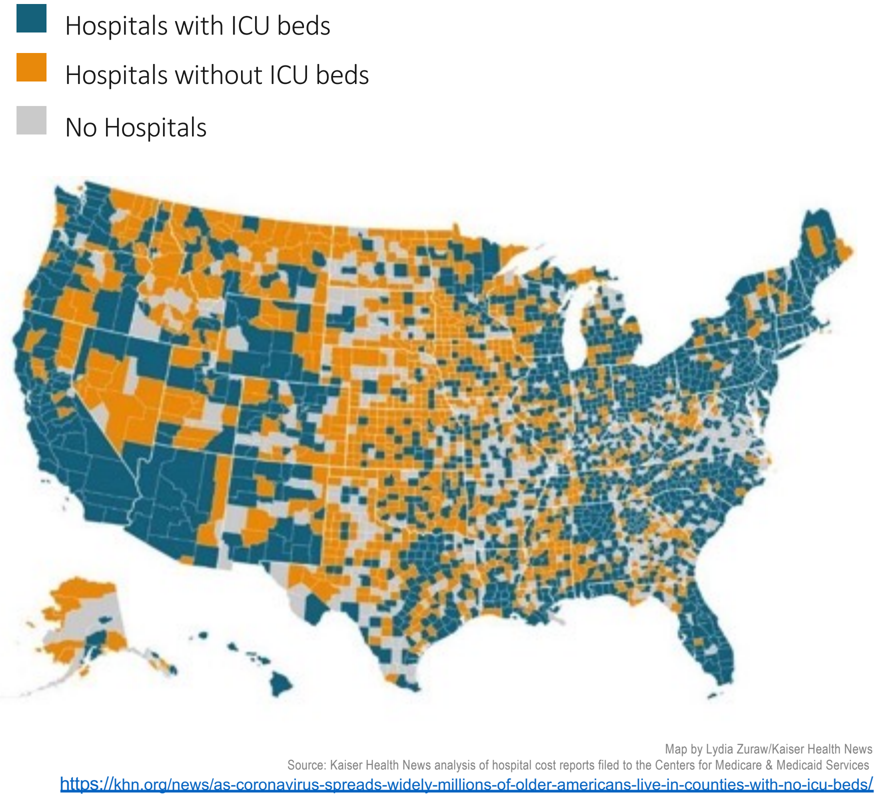
NATIONAL EMERGENCY TELE CRITICAL CARE NETWORK
NETCCN

Disasters stress healthcare system infrastructure, resources, and staff

Problem:

Locations without ICU beds do not have clinicians who know how to use ventilators – even if they become available. Necessary is a simple, consistent means to reliably and effectively support people who deliver critical care.

Barbashlan et al. NEJM Catalyst (2020)



Solution:
NETCCN solves this problem by linking remote critical care expertise to frontline clinicians using secure, HIPAA compliant applications on mobile devices.

3 NETCCN teams have deployed in the Public Health Emergency (PHE) to 34 hospitals in 14 states or territories and provided care for almost 5000 patient days.

TiDE – "Technologies in Disaster Environments - enhances NETCCN capabilities.

ASPR ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE
Society of Critical Care Medicine The Intensive Care Professionals
TATRC
TiDE
NATIONAL EMERGENCY TELE-CRITICAL CARE NETWORK NETCCN

COL Jeremy C. Pamplin, Commander, jeremy.c.pamplin.mil@mail.mil,

First Demonstration Presented on December 17, 2021

December 17, 2021

An interim technology demonstration of

Remote Control of Ventilators and Infusion Pumps to Support Disaster Care

- Live simulations of clinical scenarios in which remote control of medical devices and interoperable data could improve patient care
- Connected sites in first technical demonstration:
  - Madigan Army Medical Center, JBLM, WA
  - Massachusetts General Hospital, MD PnP Lab, Cambridge, MA
  - Nihon Kohden OrangeMed, Santa Ana, CA
  - Thornhill Medical, Toronto, Canada

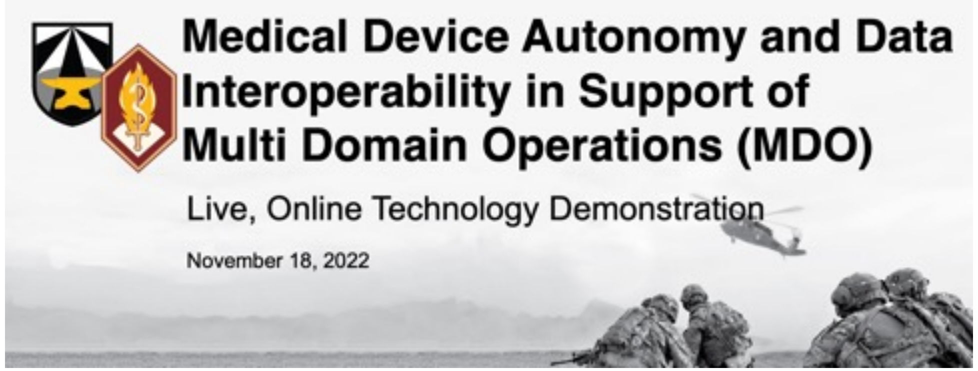
December 17, 2021

An interim technology demonstration of

Remote Control of Ventilators and Infusion Pumps to Support Disaster Care

1. Far remote control from MGH MD PnP Field Hospital* (Cambridge) to Nihon-Kohden Community Hospital (California) https://vimeo.com/665473382
2. Far remote control by MD @Madigan AMC during patient evacuation via ambulance (Toronto, Canada) https://vimeo.com/665476662
3. Remote control of ventilator and IV pump (Cambridge) to optimize care https://vimeo.com/665484469
4. Remote control from MD PnP Field Hospital observation area (Cambridge) https://vimeo.com/665487966
5. Situational awareness dashboard (from all sites to Waltham, MA) https://vimeo.com/665490502
6. Teleguidance (from Fort Mill, SC) of point-of care-ultrasound to MD PnP lab https://vimeo.com/665494677

*Note: These are fictitious hospital names and simulated patients. Geographic locations are accurate.
Some remote-control capabilities demonstrated today are under development and not yet intended for clinical use.



2nd live demonstration

1. Far remote-control of multiple medical devices for mass casualty event, Medical Field Hospital Role II @ Ft. Detrick from Seattle, WA
   https://youtu.be/bgaS9nSLwAg?t=1919
2. Far remote management of casualties during enroute care/med-evacuation by UAV from Seattle, WA
   https://youtu.be/bgaS9nSLwAg?t=2301
3. Data continuity and automated documentation from multiple vendor devices across continuum of care (Role II -> Medevac -> Hospital)
   https://youtu.be/bgaS9nSLwAg?t=2635
4. Integrated single UI data integration and control of multiple vendor IV pumps, ventilator, and patient monitor, simulated ICU, Boston
   https://youtu.be/bgaS9nSLwAg?t=2817
5. Remote control safety and performance pre-deployment assessment
   A. Competition for device control: Risk Management presentation: https://youtu.be/bgaS9nSLwAg?t=3450, and live IV pump control demonstration https://youtu.be/bgaS9nSLwAg?t=4004
   B. Network performance https://youtu.be/bgaS9nSLwAg?t=4298
   C. Cybersecurity https://youtu.be/bgaS9nSLwAg?t=4650

** Each description is followed by a YouTube video link directly to that section of the video*
https://www.youtube.com/watch?v=bgaS9nSLwAg. This section starts at 25:35

Far Remote Control

Demonstration #1

Remote control of NKV-550 Ventilator

California ← Cambridge

"LOCAL"
N-K Community Hospital
Santa Ana, CA

Monitoring Data →

← Control

"REMOTE"
MGH MD
Cambridge

NKV-550 Remote Application
running on DocBox ICE Apiary Platform

Scenario:

N-K Hospital: Patient is recovering. Placed on spontaneous ventilatory mode (PS).

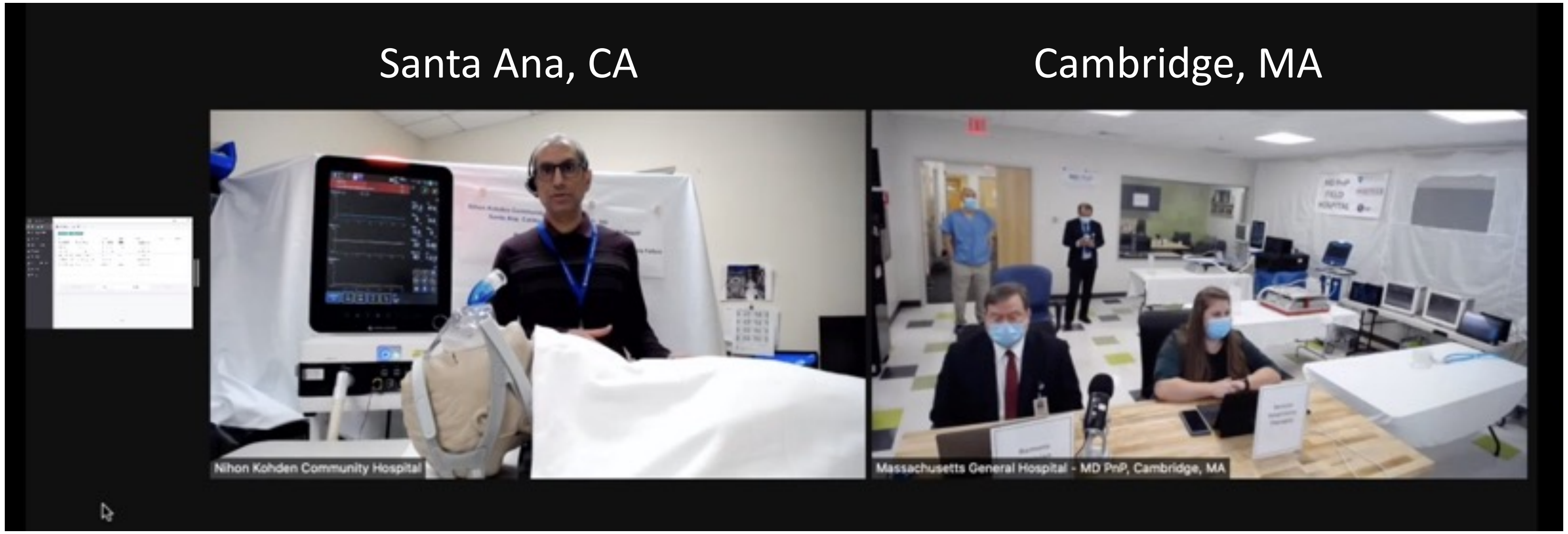
Event: Patient is administered pain medication (morphine), stops breathing (apnea), O_2 Sat Drops (82%)

N-K Hospital RN: Detects oxygen saturation is dropping and vent alarm. Calls for help

Remote MD: "I can see the problem and will adjust ventilator for you"

Remote MD: Changes ventilator mode to Volume Control mode.

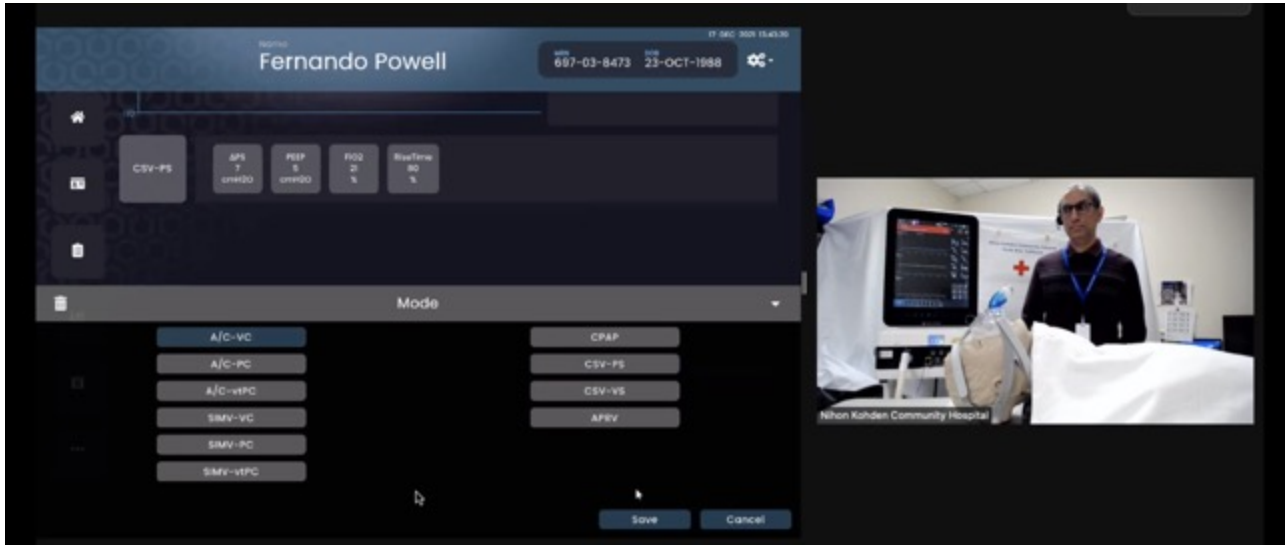
Demonstration #1



Simulated Patient

Remote clinicians

Remote ventilator controller



Screenshots from demonstration video 12/17/21

Far Remote Control

Remote control of NKV-550 Ventilator

California ← Cambridge

"LOCAL"
N-K Community Hospital
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Monitoring Data →

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Simulation #1

Dec 17, 2021

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Remote MD: Changes ventilator mode to Volume Control mode.

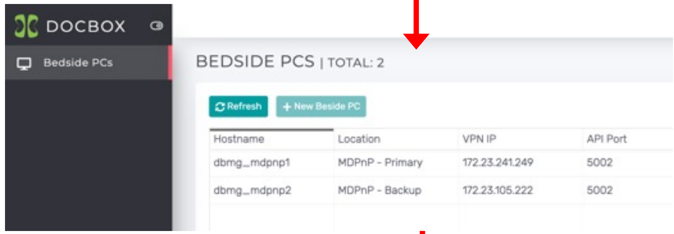
+115 MA CP JG

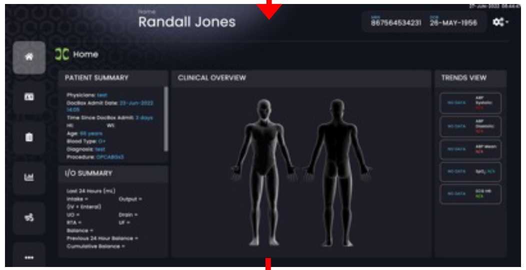
Goldman, Julian M., M.D.

Remote Control Ventilator Demonstration Using Commercial Medical IoT / ICE Platform

Devices in demonstration:

- Nihon Kohden NKV 550 ventilator
- DocBox – MIoT ICE platform

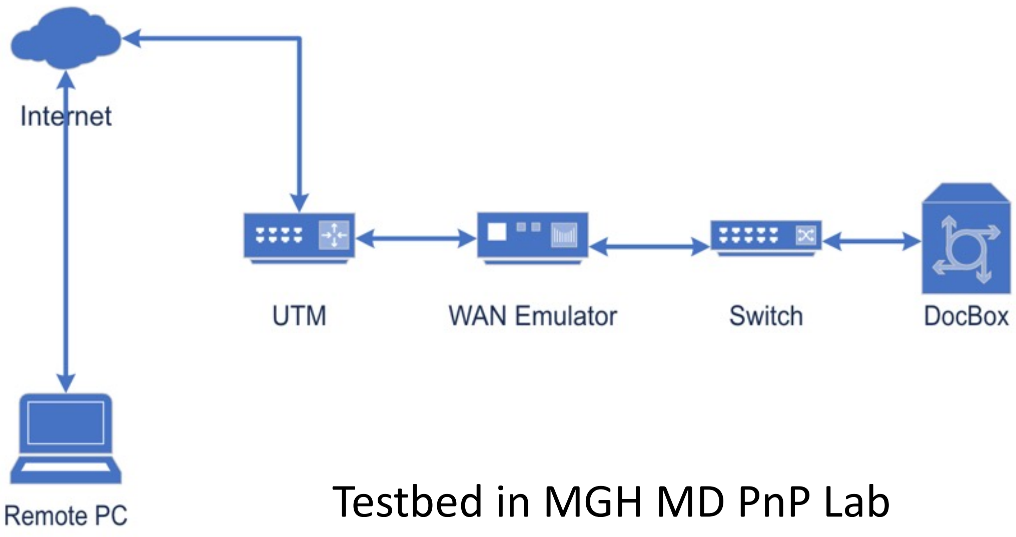




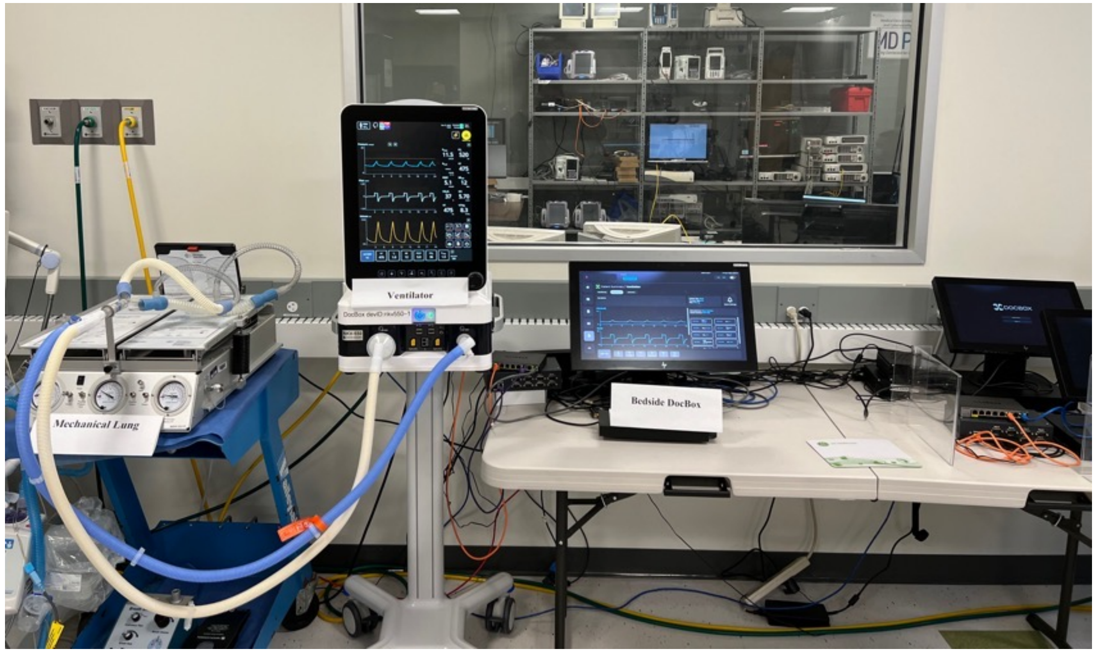
Remote control safety and performance pre-deployment assessment: Network performance implications

Remote control of Nihon Kohden NKV-550 Ventilator via DocBox ICE platform with insertion of controlled network traffic delay

- Bedside control
- Far-remote control



Testbed in MGH MD PnP Lab

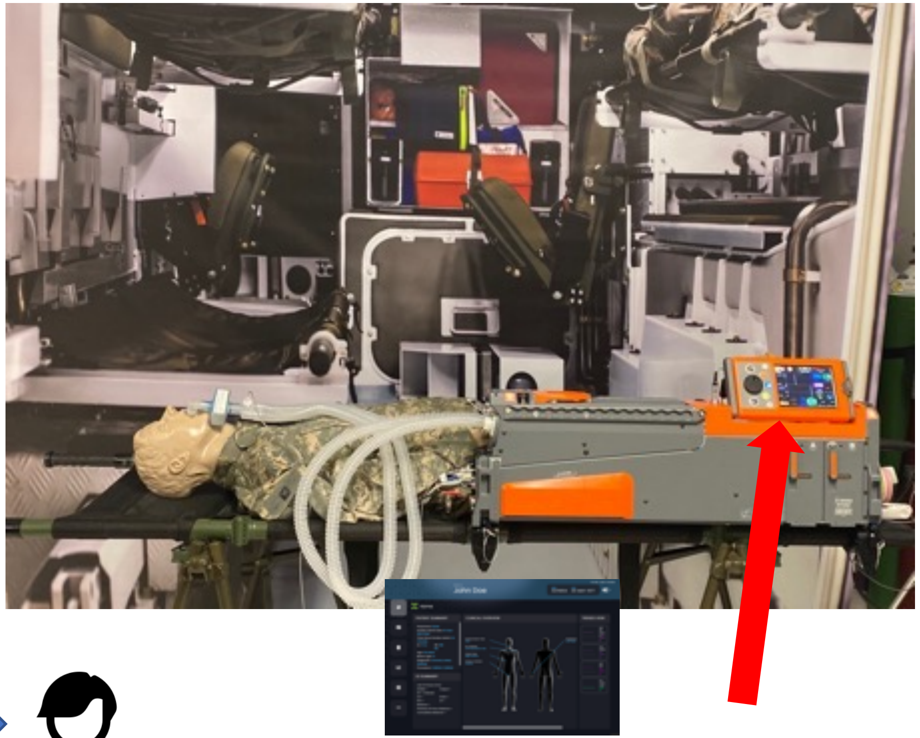


Far Remote Control During Evacuation of Patient
Remote control of Thornhill MOVES SLC (ventilator, monitor, O_2 concentrator)

Madigan AMC, Seattle

Madigan AMC -> Toronto

Toronto



Omnicure

Communication

Omnicure

MD

NETCCN Tele-critical Platform)

Control

EMT Toronto

Thornhill MOVES SLC
DocBox Apiary Platform

Scenario

Toronto EMT at Thornhill Patient Transport. MD in Seattle

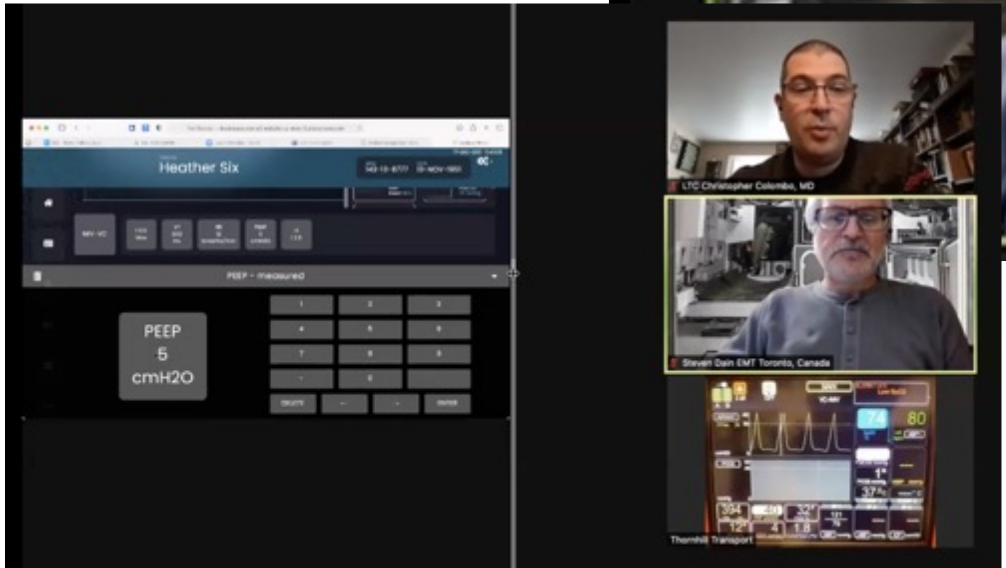
Toronto EMT: uses Omnicure NETCCN app to find remote MD

Toronto EMT: "Ready to transport. Pt is on vent. O_2 sat is low. Help"

Remote MD: Increase Ventilator O_2 concentration to MAX. Not effective

Remote MD: Increases Ventilator PEEP setting. Sat increases.

Demonstration #2

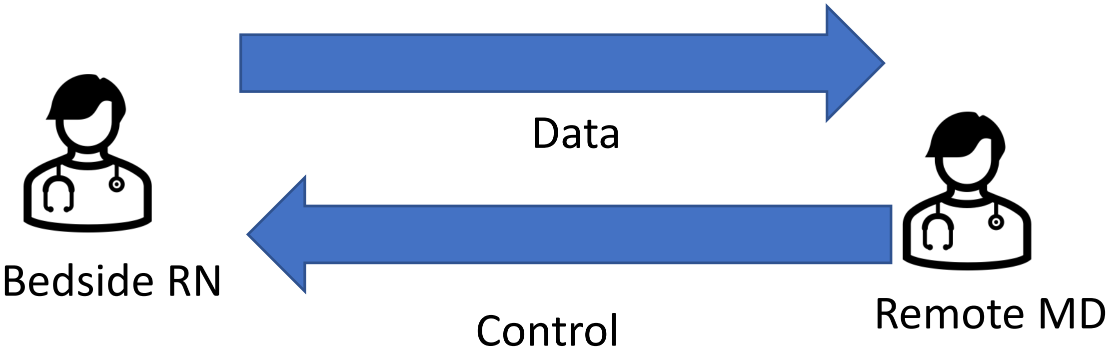


Thornhill ventilator and monitor

Screenshots from demonstration video 12/17/21

Remote Control of an IV Infusion Pump and Ventilator

MD PnP ICU, Cambridge, MA



Infusion Pump Remote Control and Data OpenICE Research Platform

PB 980 Remote control software Medtronic

Sapphire Infusion Pump

Medtronic PB980 Ventilator

Philips MX800 Bedside Patient Monitor

Scenario

Bedside RN: O_2 saturation is low. Calls for help.

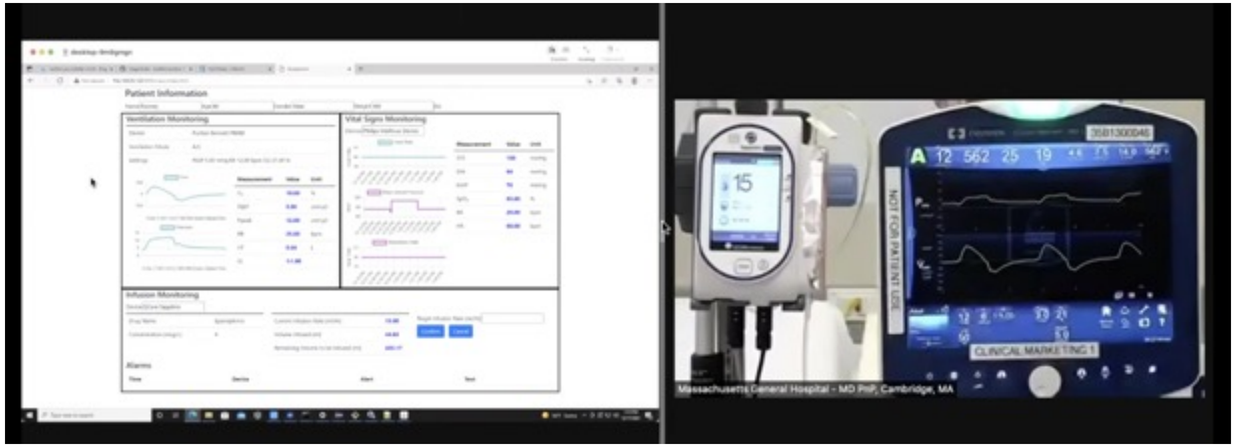
Remote MD: Increases PEEP, but BP falls

Remote MD: Increase norepinephrine infusion rate

(Also controlled NeuroWave Accupump)

Note – “The Medtronic concept devices used in this demonstration are for non-clinical purposes by Massachusetts General Hospital Medical Device Interoperability Lab.”

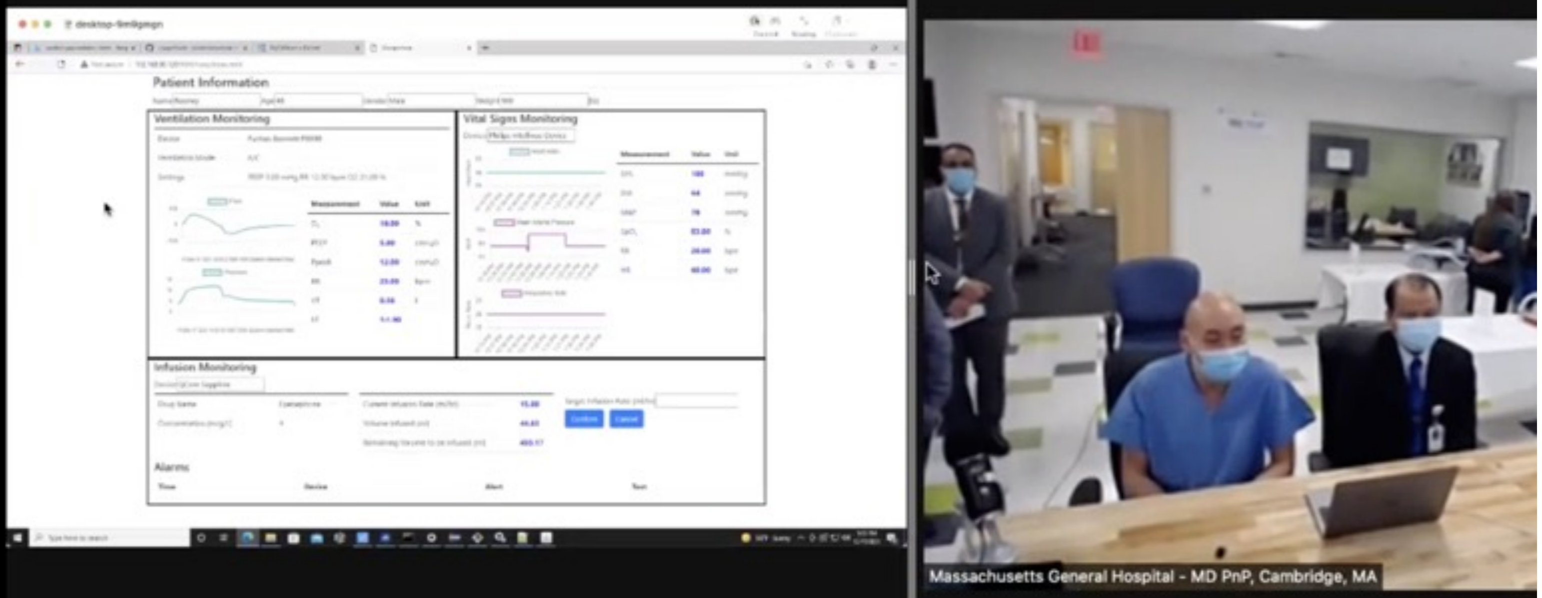
Simulated Patient in Cambridge, MA



Remote ventilator and IV pump control

Screenshots from demonstration video 12/17/21

Virtual Critical Care, Cambridge



Remote-control to manage, support, and evacuate mass casualties @ Ft. Detrick

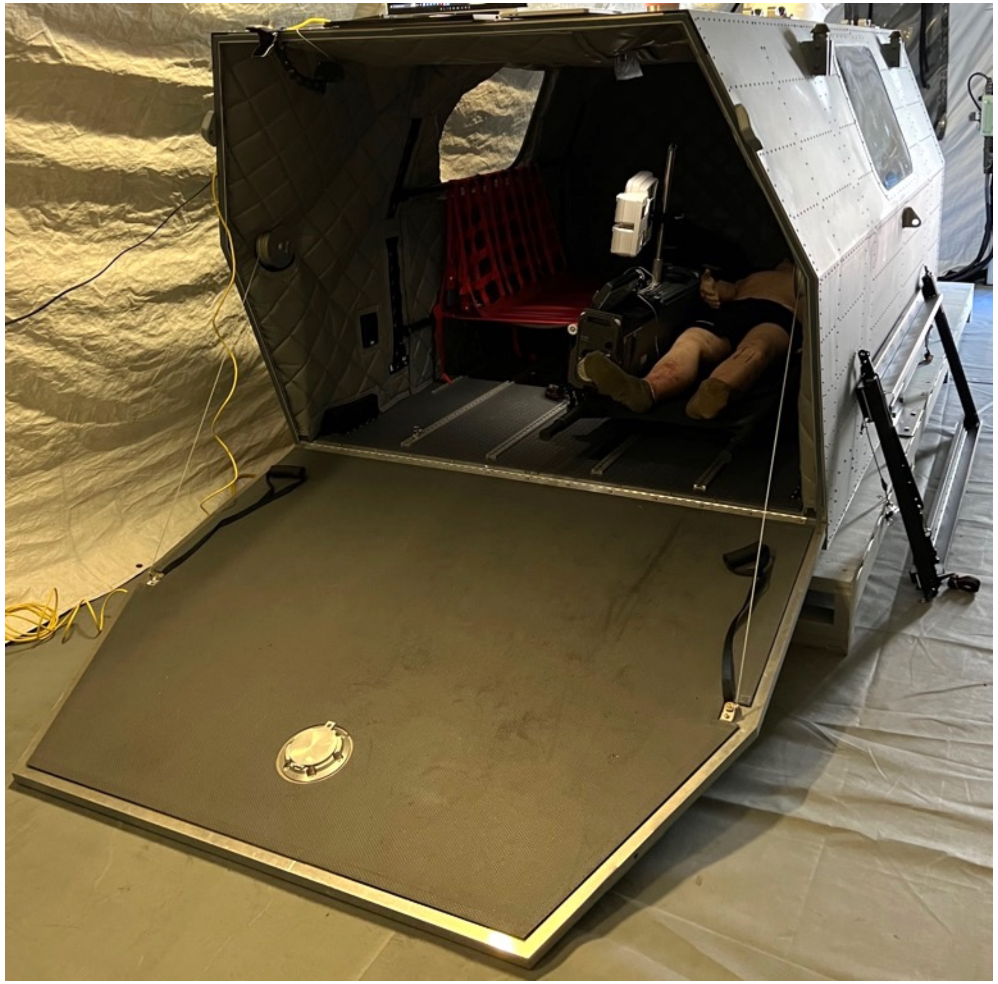
A. Far remote-control of multiple medical devices for mass casualty event, Medical Field Hospital @ Ft. Detrick, from Tacoma, WA
B. Far remote management of casualties during enroute care/med-evacuation by UAV from Seattle, WA

Point of Injury

Medics Arrive and Perform TCCC

Move Casualty from POI to Field Hospital

TATRC Simulated Field Hospital



M4 UAV Medical Evacuation Pod
Ft. Detrick, MD

1: Far remote-control of multiple medical devices for mass casualty event, Medical Field Hospital Role II @ Ft. Detrick from Seattle, WA

Far Remote Control and Monitoring (NKV-550 Ventilator and Philips vital signs monitor)

Casualty @ TATRC (Ft Detrick, MD) ← MD in Tacoma, WA

REMOTE MD

Monitoring Data

MD Communication with Medic
MD Control of ventilator

Monitoring through DocBox Apiary System and Communication with NETCCN Platform

Scenario:

- 4 Patients brought into field hospital with 1 Medic. Two casualties (C1 and C2) are critical. Casualty 1 needs evac.
- Casualties placed on NKV-550 ventilators and AccuPump IV pump.
- Medic: Calls for help with casualties.
- Remote MD monitors patients, assists with adjusting ventilator to resolve clinical issue.
- Medic prepares Casualty 1 for transport

1: Far remote-control of multiple medical devices for mass casualty event, Medical Field Hospital Role II @ Ft. Detrick from Tacoma, WA

Casualty #1 in Medical Field Hospital Role

NeuroWave IV Pump

NKV 550 Ventilator

Philips Monitor

2: Far remote management of casualties during enroute care/med-evacuation by UAV from Tacoma, WA

Remote Monitoring and Control of Thornhill MOVES SLC ventilator/monitor and NeuroWave AccuPump Dual-channel IV pump

MEDEVAC Transport ← MD @ Tacoma, WA

Monitoring Data

Control of Devices

REMOTE MD

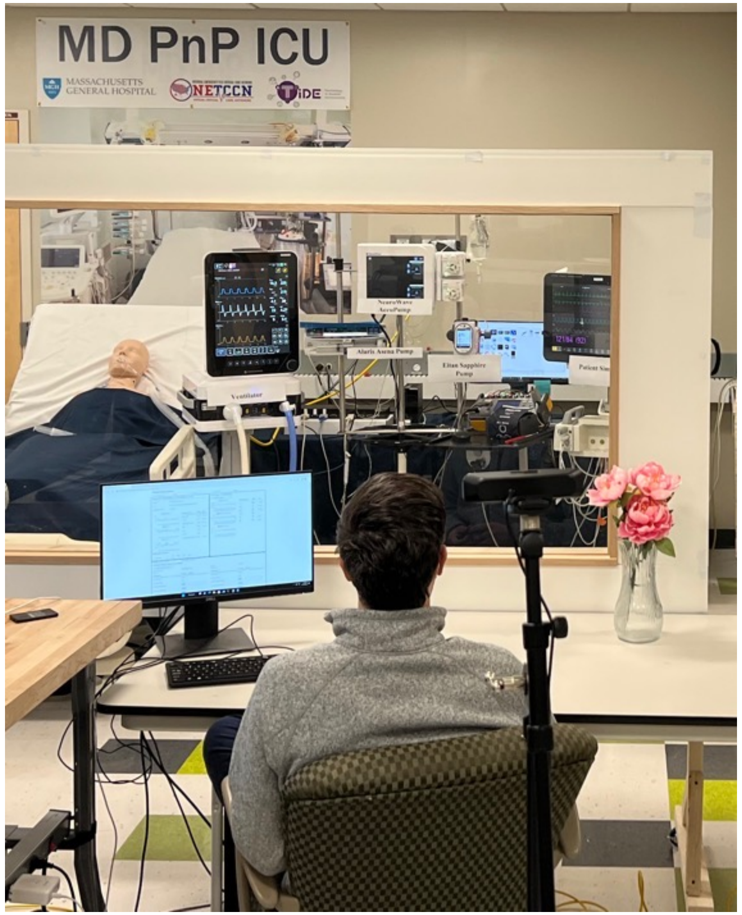
Ventilation and Fluid Infusion running connected via DocBox Apiary System

Scenario:
Casualty on MOVES SLC Ventilator and NeuroWave AccuPump being evacuated.
Medic required remote medical assistance
Medic reports: Patient is hypotensive, oxygenation is good.
Remote MD sees live data from from the MOVES monitor and ventilator, and IV pump
Remote MD decreases sedative rate and reduced ventilator PEEP setting

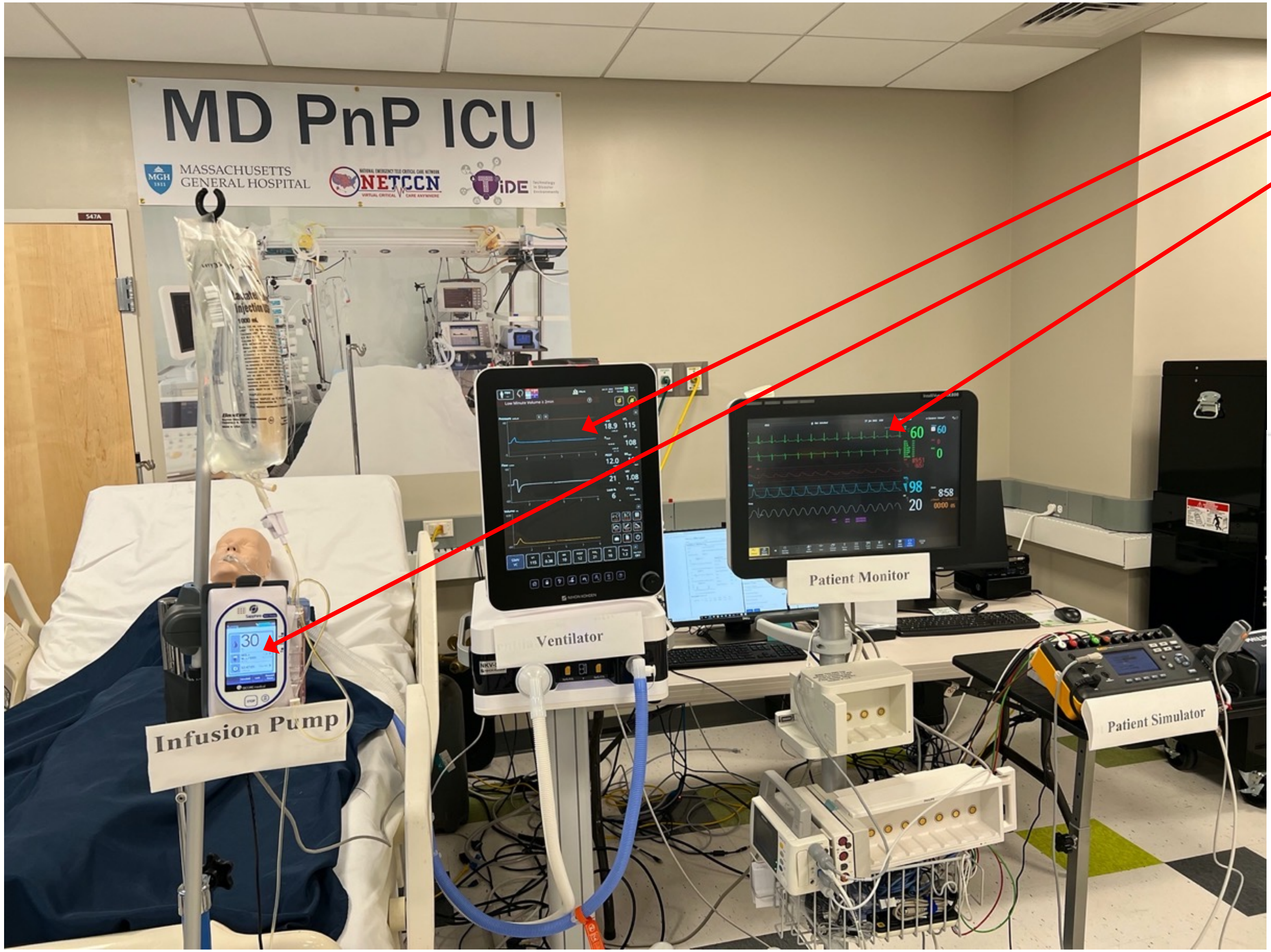
#4 Integrated single UI with data integration and control of multiple vendor IV pumps, ventilator, and patient monitor, simulated ICU, Boston

Remote-control from outside of patient's room:

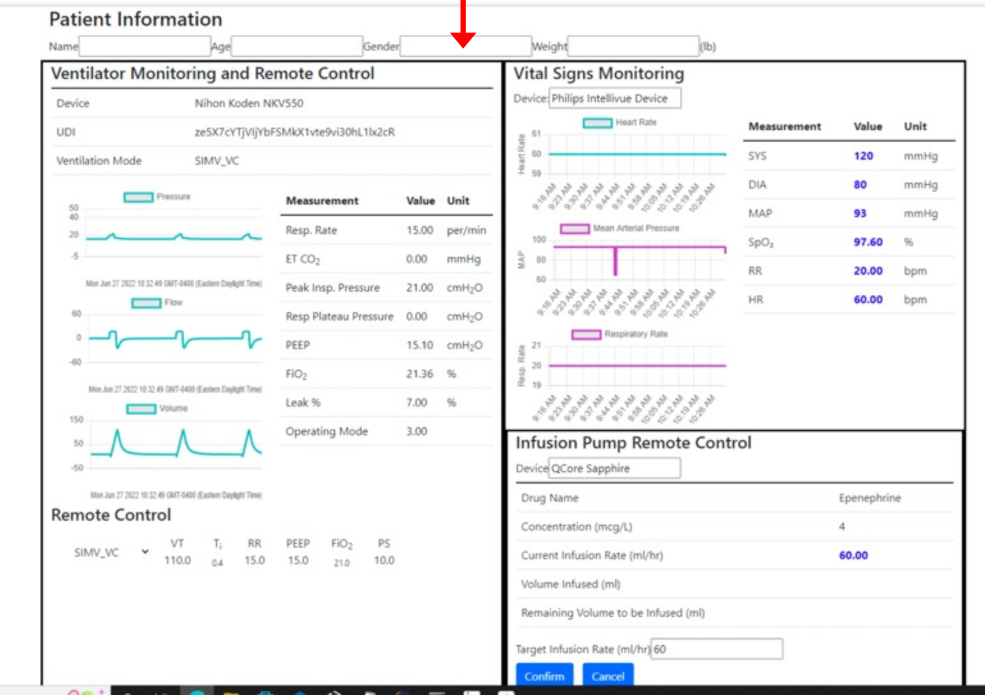
- Single integrated UI to control multiple brands of IV pumps, ventilator, and view vital signs
- Using OpenICE research ICE platform (Integrated Clinical Environment) in MD PnP Lab @ MGH



Tele critical care technology:



- Ventilator
- IV Pump
- Vital Signs Monitor
- Prototype application for **Integrated** data display and control of pump and ventilator



Remote Control Verification & Validation at the System Level

Leveraged the MD PnP lab emulation environment to:

- Conduct end-to-end system testing in simulated clinical environments
- Evaluate effectiveness of risk controls using simulated clinical scenarios
- Assess networking requirements for safe remote control using advanced network manipulation technologies

“Proving” Safety: Safety Assurance Cases

- SAC is a tool to support safety and regulatory submission
- Used in safety critical industries (rail, nuclear)
- FDA drove use for IV infusion pumps to address numerous safety issues
  - Page 9, Infusion Pumps Total Product Life Cycle, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/infusion-pumps-total-product-life-cycle
- Applied to remote control under DoD research portfolio

What is an Assurance Case?

- An assurance case (AC) is *a reasoned, auditable argument created to support the contention that a system of interest will satisfy the* [*insert specific safety requirement here*] (UK Ministry of Defense Standard 00-42)
- An AC is consisted of claim, argument, and evidence nodes, auxiliary supporting information (e.g., context and assumption), and the relation among these nodes. A "safety" AC focuses specifically on **safety**.
- Commercial AC tools are available (e.g., Adelard and GessNet) to support the development, maintenance, review, and auditing of AC, in tabular or graphic formats, or both.

Generic AC Template for RCMD

- Limited to remote control aspects of device

- Identify key safety aspects of RCMD to demonstrate safety and support integration with remote control applications and systems from other vendors

- Apply industrial standards/best practices, and FDA regulatory framework/requirements wherever applicable

  - ➢ AAMI Medical Device Remote Control Draft Standards and AAMI TIR 38
  - ➢ FDA Cybersecurity Premarket Guidance
  - ➢ AAMI/UL 2800-1 safety standard for interoperable medical systems

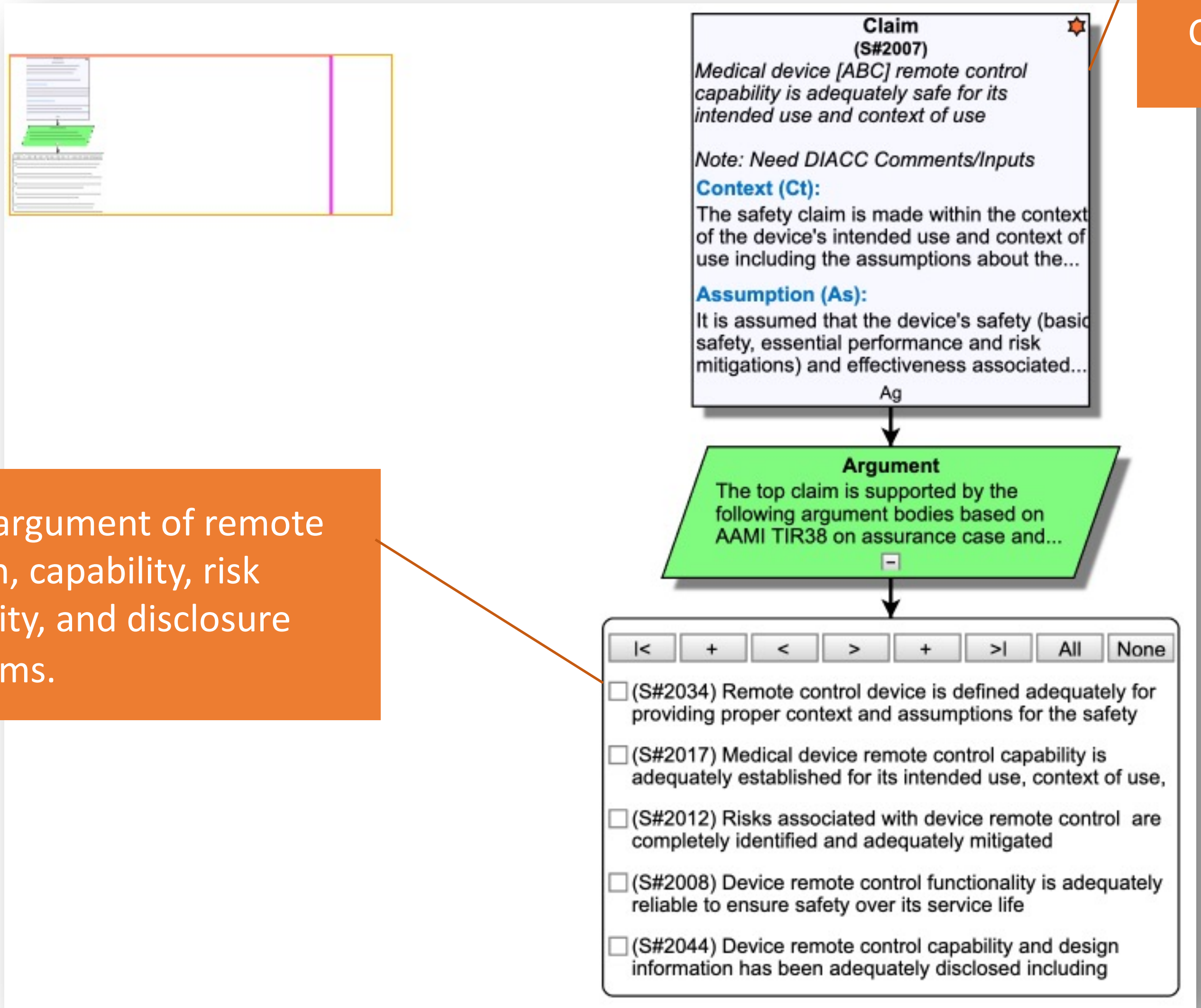
- Developed in Gessnet's TurboAC tool

AC Template of RCMD

- The generic AC template formulates safety assurance aspects for RCMD as a hierarchy of claims and sub-claims :
  - Clear definition of intended context of use for remote control
  - Implementation of remote-control capabilities
  - Adequate risk management
  - Demonstration of system reliability after the introduction of remote control
  - Sufficient disclosure to other vendors and system integrators

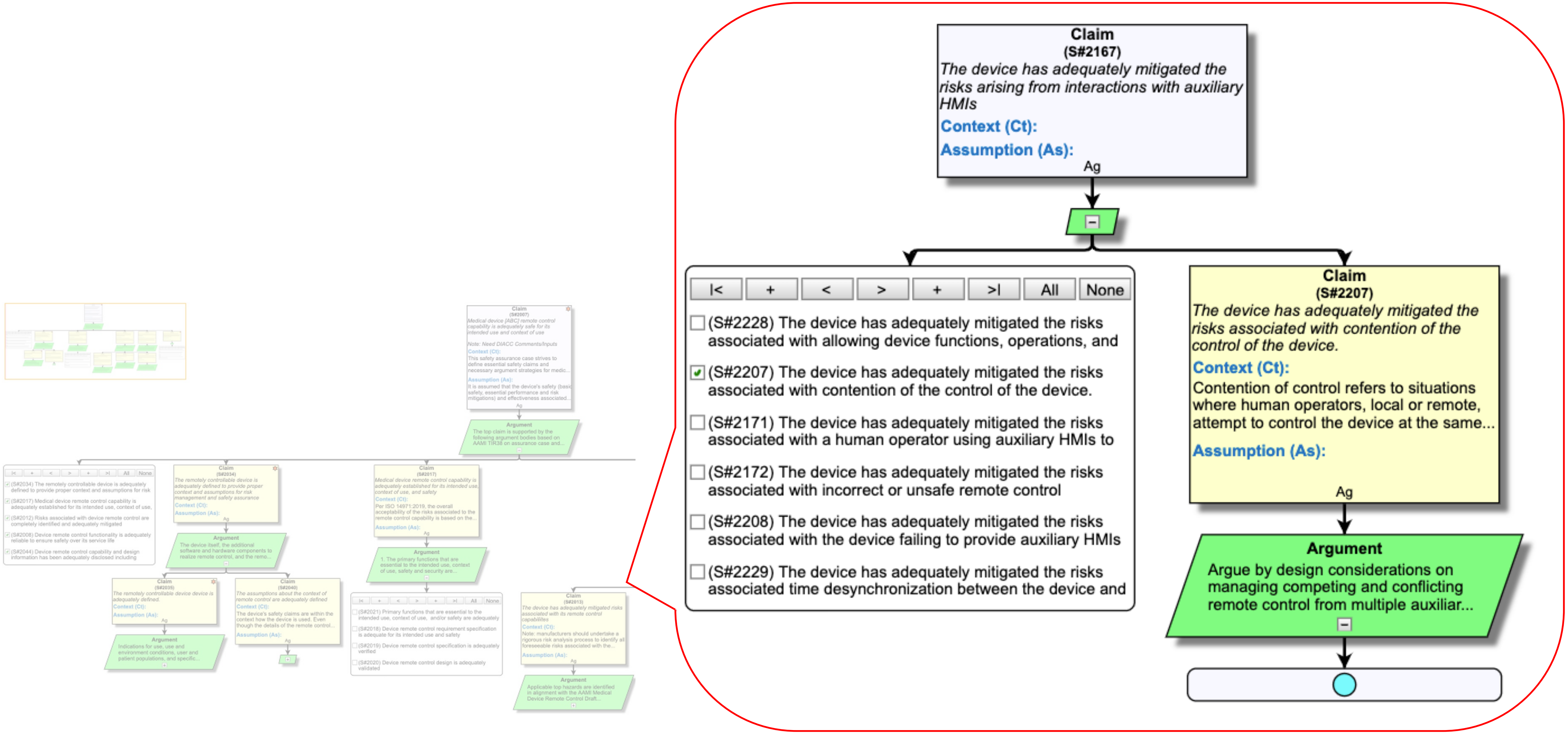
Top Level Claim

Top claim asserts the safety of the remote- control capabilities of the device.
Context and assumptions should be clearly defined.



Decompose the safety argument of remote control to definition, capability, risk management, reliability, and disclosure subclaims.

Assurance Case Snippet related to Contention/Competing for Control



Top Three Layers of the Generic Assurance Case for Remote Control

MASSACHUSETTS GENERAL HOSPITAL

MD PnP™ Getting connected for patient safety™

The MD PnP Program has an extensive network of senior collaborators and consultants in addition to the core team.

Team: Clinicians, computer scientists, and biomedical engineers

Julian M. Goldman, MD
Program Director

David Arney, PhD
Lead Engineer

Yi Zhang, PhD
Lead Research Engineer

More team members:
https://mdpnp.mgh.harvard.edu/about/

Mosa Al Zowelei, MS
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Bragadeesh Aroulmozhi, MS
BME + Developer

Thank you!

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