

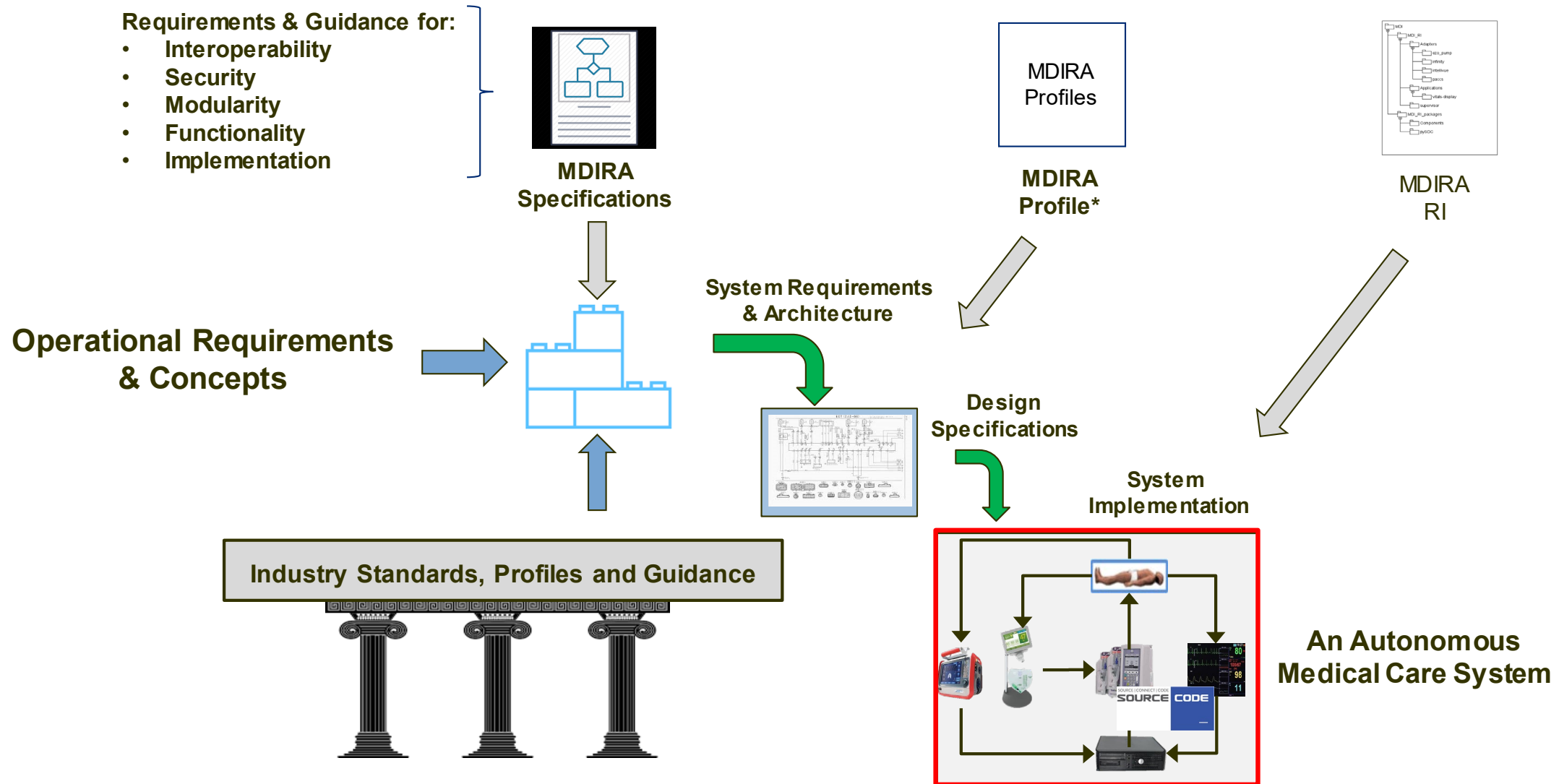
Update of the Medical Device Interoperability Reference Architecture (MDIRA) Project to IEEE Working Group Meeting

05/26/2021

Outline

- Brief intro to MDIRA
- Update MDIRA Draft 2.0
- Update on the MDIRA Reference Implementation (video)
- A MDIRA-conformant DDS-based OpenICE implementation
- Robotics update

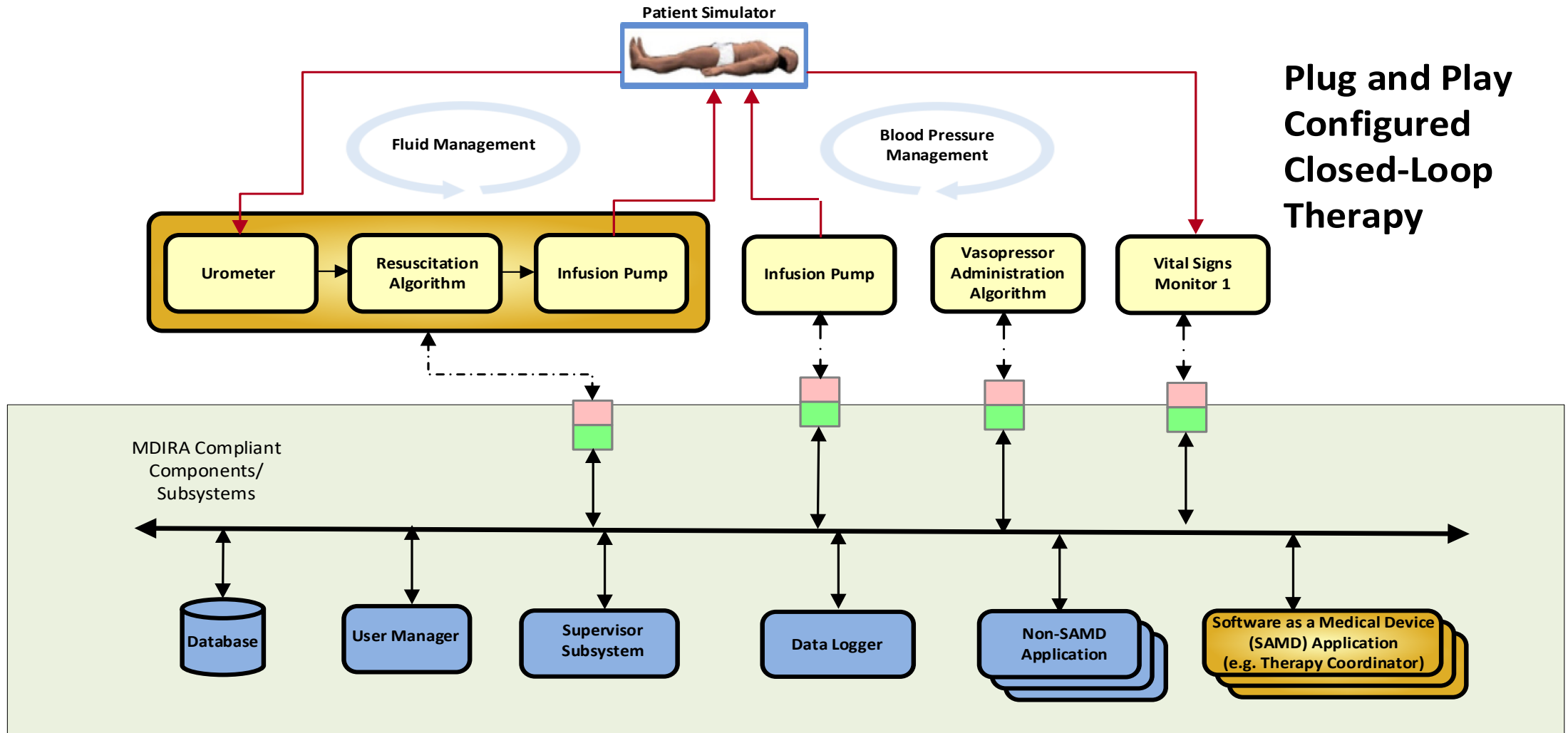
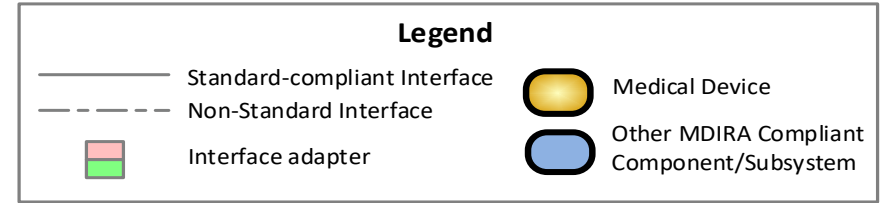
MDIRA Role in System Development



*Profile - Specification showing in detail how to apply existing standards by restricting or constraining requirements in the referenced standards

Definition from "Medical Device Interoperability," AAMI, 30 March 2012(https://s3.amazonaws.com/rdcms-aami/files/production/public/FileDownloads/Summits/Interoperability/MDI_1203.pdf)

Reference Implementation: Focus: Multiple Autonomous Therapies



Update MDIRA Draft 2.0

- Draft v2.0 delivered to sponsor on 31 Dec 2020
- Implementing changes, including
 - New Conformity Assessment section
 - The supervisor concept has evolved to support flexibility in implementation
 - Adjudication of feedback from SME's
- Availability on MDIRA website by mid-June

MDIRA Specification

- **Completed:**

- Version 1.0 delivered and available on MDIRA site
- Implemented MDIRA requirements in RI
- Identified gaps in existing standards
- Version 2.0 update drafted based on lessons learned from RI and sent to collaborators for review and feedback

- **In Progress:**

- Complete adjudication of Version 2.0 comments and post updated specification on MDIRA site
- First-time practical application of MDIRA in Virtual Hospital project

- **Future:**

- Address gaps in standards
- Develop MDIRA profiles to provide guidance on application of standards and MDIRA specification

5.1	System Requirements
5.1.1	Interoperability
5.1.2	Openness
5.1.3	Minimize Risk of Patient Harm
5.1.4	System Management Capabilities
5.1.5	Patient Care Manager
5.1.6	Standardized External Interfaces
5.1.7	External Interfaces
5.1.8	Initialization
5.1.9	Data Management
5.1.10	Time Synchronization
5.1.11	Component Authentication
5.1.12	Change Component Settings
5.1.13	User Attribution
5.1.14	Security
5.1.15	Detect, and Minimize Impacts of, Data Degradation
5.1.16	Data Nomenclature and Semantics
5.1.17	Information Models

Table of Contents Excerpts

5.2	Supervisor Requirements
5.2.1	Power-on Self-Test (POST)
5.2.2	Synchronize Clock
5.2.3	Shutdown
5.2.4	Discovery and Registration
5.2.5	Authorization
5.2.6	Patient to Component Association
5.2.7	System Monitoring and Fault Handling
5.2.8	Provide Patient Care Management Support

5.2.5.2 Authorize Control Requests

(MR-038.1) The Supervisor **SHALL** verify that the combination of controller and controlled components are safe and compatible for the intended purpose according to protocols established through the risk management process (see Section 5.1.3).

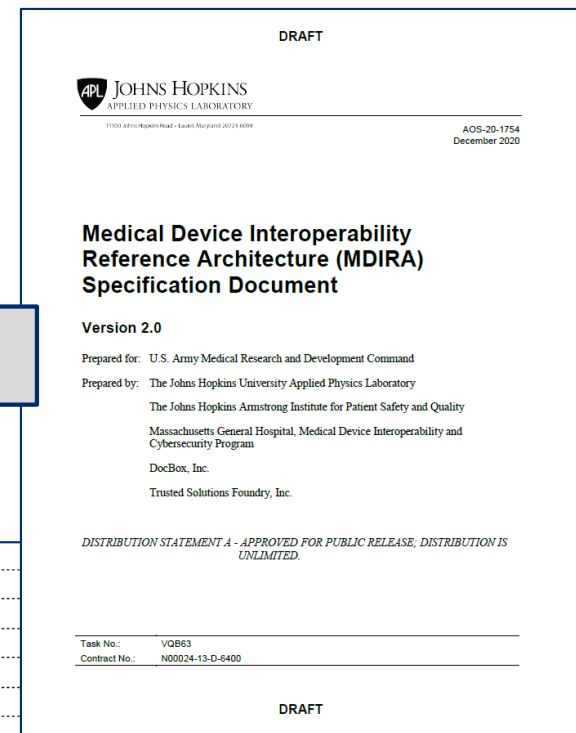
Control examples include an alarm management application that changes alert condition thresholds in a patient vital sign monitor, and a therapy control application that regulates medication flow rate from an infusion pump.

(MR-038.2) The Super **SHALL** prevent control conflicts, i.e., two or more components inappropriately attempting to concurrently change the same operational setting, in the same component, according to protocols established through the risk management process (see Section 5.1.3)

(MR-038.3) The Supervisor **SHALL** authorize, subject to MR-038.1 and MR-038.2, component requests to control other components (i.e. change their operational settings).

Requirements Excerpt

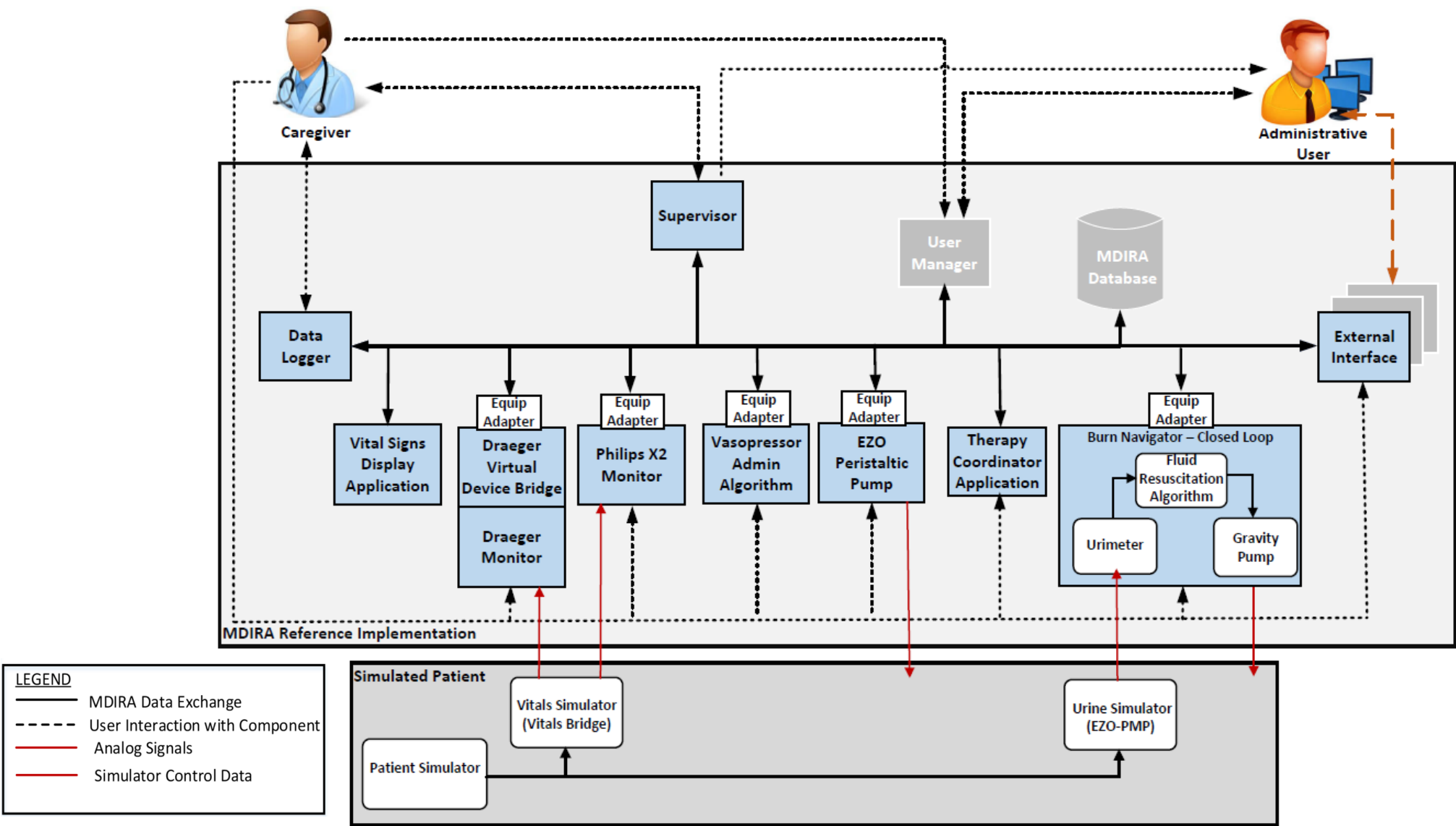
<https://secwww.jhuapl.edu/mdira/>



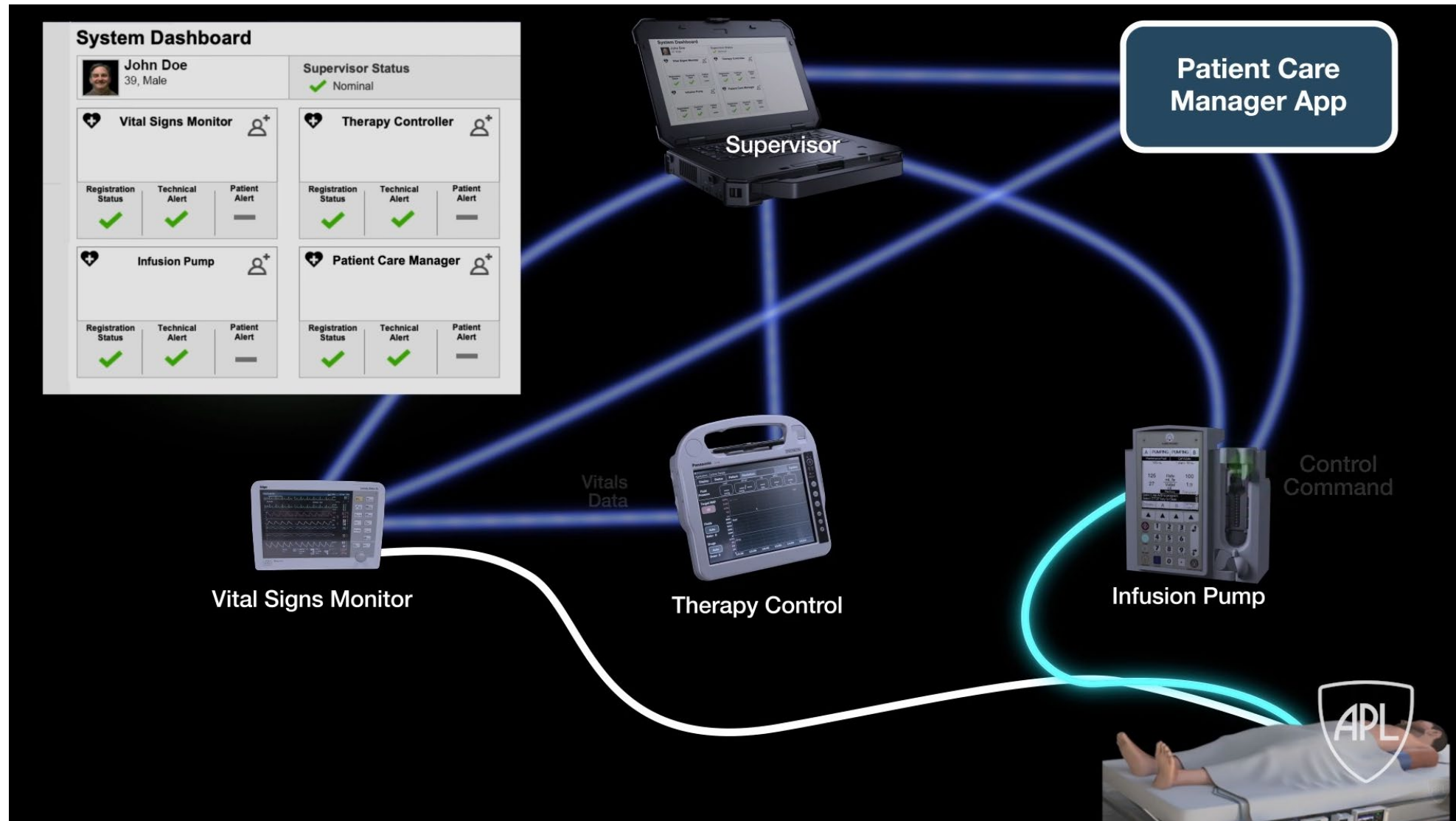
The Purpose of the MDIRA Reference Implementations

- Develop a prototype of a MDIRA-compliant system that supports future insertion of functions of increasing sophistication
- Demonstrate enabling security, trusted-control, reliability and safety functions
- Demonstrate several autonomous system use cases of interest for combat casualty care
- Provide opportunity for industry collaboration
- Support development and maturation of MDIRA
 - Prove out essential concepts
 - Identify gaps in underlying interoperability standards

Update on APL MDIRA Reference Implementation



MDIRA Reference Implementation Video



MDIRA Reference Implementation using DDS

(work performed at MGH/MDPnP)

Security

- Upgrade to RTI's Connex DDS Secure
- User login and timeout
- Medical device authentication
- Fine-grained access control
- App compromise detection

Data Logging

- Leverage RTI's DDS Recording Service for data logging
- Archive in external MySQL database
- Automatic data schema generation

Data Quality Monitoring

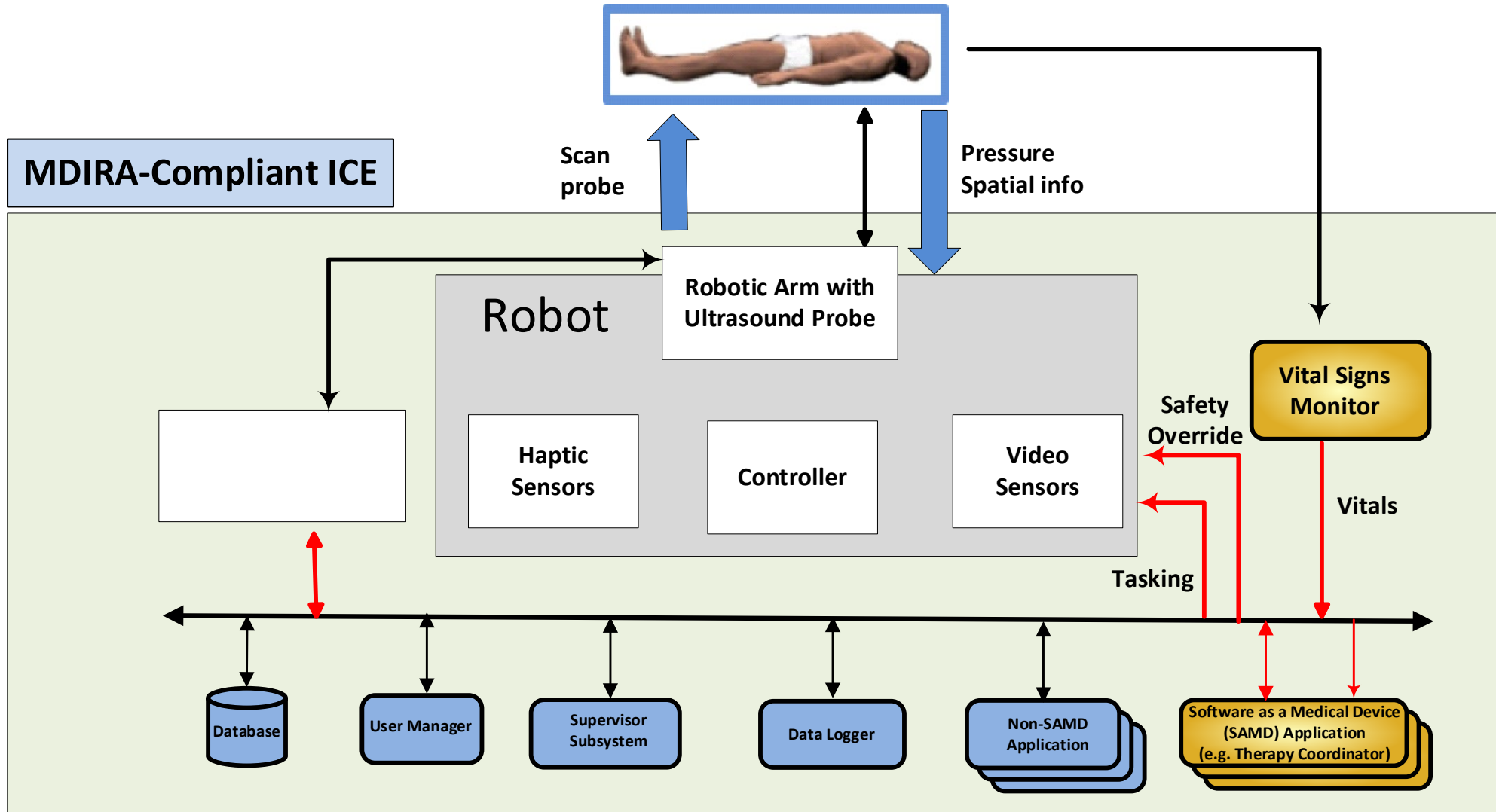
- Offer as a system service
- Standard-driven data quality model
- Simultaneous monitoring of data quality for different devices and data types.

System Safety Fallback Mechanism

- Coordinate the system to orderly enter a fail-safe state
- Support app and device to negotiate fallback behavior

MDIRA Relationship to Robotics

A Notional MDIRA ICE/Robot Configuration



MDIRA Autonomy Activities

- **Completed:**

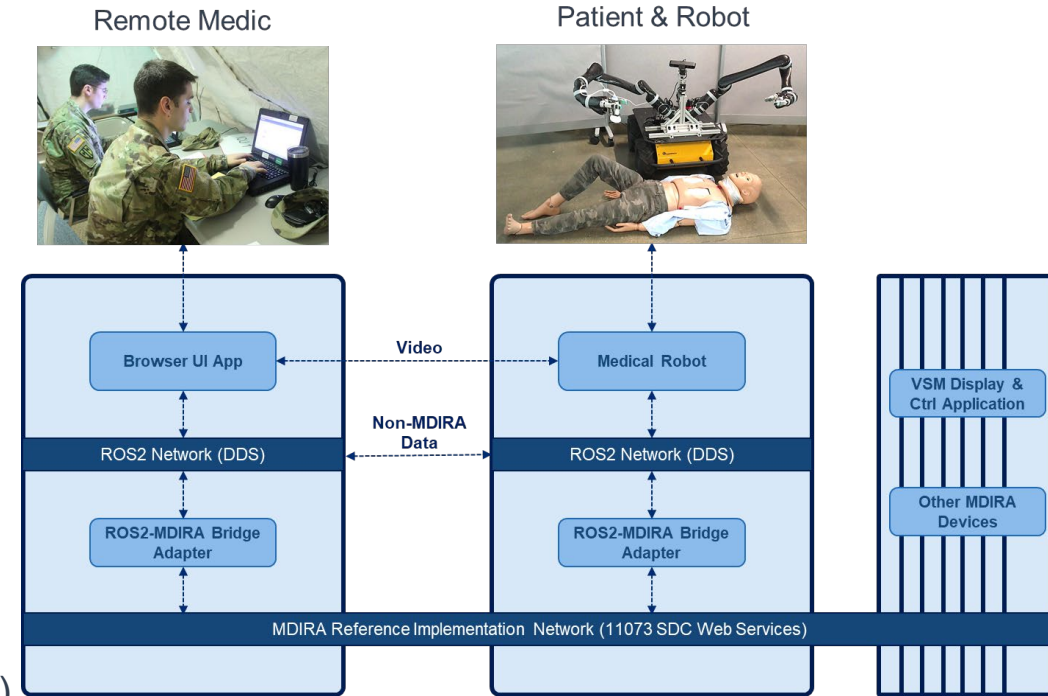
- Research Platform Development
 - Ultrasound probe collar to help robot hold probe
 - Phantoms that approximate healthy lung (B-lines) and tension pneumothorax (pleural line and A-lines)
 - Robot behaviors capable of scanning phantoms
 - User interface that provides high-level control of robot and video streams from ultrasound probe and robot mast camera
- Medic-Robot Teaming with variable levels of autonomy
 - Assistive Autonomy (medic customizes probe position and orientation)
 - Collaborative Autonomy (medic fine-tunes scan)
 - Supervised Autonomy (one-button scan, medic views results)
- MDIRA-Autonomy Integration
 - Integrated user interface and robot with MDIRA RI via MDIRA-ROS2 adapters, MDIRA discovery of user interface and robot

- **In Progress:**

- Integration of user interface and robot via MDIRA-ROS2 message channels

- **To Do:**

- Explore impact of robot mobility and computer vision on autonomy, teaming and MDIRA functionality



MDIRA Collaboration

- Johns Hopkins University Applied Physics Laboratory (JHU/APL) - (Lead)
- Johns Hopkins Armstrong Institute for Patient Safety and Quality
- Massachusetts General Hospital (MGH), MDPnP
- DocBox, Inc.
- Trusted Solutions Foundry, Inc.
- Arcos, Inc.
- Dräger, Inc.
- Phillips, Inc.
- ICU Medical
- Zoll
- Capsule
- Others in process

Summary

- MDIRA Specification 2.0 is to be released in the next several weeks
 - Better clarified what is in and is not within MDIRA scope
 - Continue to advocate use of community-consensus communications, information model and nomenclature standards
- Reference Implementations provide practical experience and knowledge that solidifies the technical approaches and provides credibility to MDIRA.
 - APL version of an SDC based RI continues to be updated with planned release in June.
 - The intent is to make this available in an open source repository.
 - A second DDS based RI is complete. It's based on OpenICE and will be made available by mid-year.
- MDIRA supports the development of advanced point of care systems that may include autonomous medical treatments, medical robotics, AI, and telemedicine technologies
 - These advanced technologies will be considered in increasing rigor as MDIRA and these technologies mature
- Considerable work remains - much beyond the scope of the MDIRA project (current PoP ends in June)
 - Necessary supplements to standards and promoting industry adoption
 - Detailed use cases and concepts of operation involving advanced care technologies
 - Protocols for reliability and safety
 - Go to the MDIRA webpage for updates – <https://secwww.jhuapl.edu/mdira/>

MDIRA Website

<https://secwww.jhuapl.edu/mdira/>



MDIRA

Medical Device Interoperability
Reference Architecture

Home

Documents

Participation

Feedback

Johns Hopkins Applied Physics Lab

MDIRA

Medical Device Interoperability Reference Architecture

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The Defense Health Agency funded the U.S. Army Medical Research and Development Command to research technical architectures to support autonomous medical systems for prolonged care in austere environments and hospitals of the future.

The result is MDIRA, the Medical Device Interoperability Reference Architecture, a technical framework intended to guide stakeholder organizations and industry in developing interoperable, safe, and secure medical device systems that will deliver advanced and autonomous medical care. The MDIRA research team is engaging stakeholders from Government, industry, academia, and civilian healthcare who are on the cutting edge of integrated clinical environments, closed-loop care systems, medical device and cybersecurity standards, and regulatory clearance and approvals for patient safety.

The MDIRA Specification Document Version 1.0 provides requirements and implementation guidance for MDIRA-compliant systems focused on trauma and critical care in austere environments. MDIRA will evolve incrementally based on on-going research and collaboration.

 [Download Document](#)





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