JOHNS HOPKINS
APPLIED PHYSICS LABORATORY

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

01/25/2021

Outline

- Motivation and challenges
- MDIRA Description
- Being MDIRA-compliant
- MDIRA Reference Implementation
- MDIRA and robotics

Motivation

Military Operations

- U.S. air dominance and unobstructed communication are not assured
- Large number of casualties; shortage of skilled medical providers
- Smaller forces fight on an expanded battlefield and in multi-domain operations
- Potential for operations within dense urban terrain

Civilian Disaster Relief

- Limited access and support resources (e.g., hurricanes)
- Diverse geographic locations and variability of on-site staff qualifications
- Prolonged care may be needed before evacuation is possible

Growing need for interoperable medical capabilities, including autonomous systems, for prolonged care in austere environments

Challenges to Medical Device Interoperability

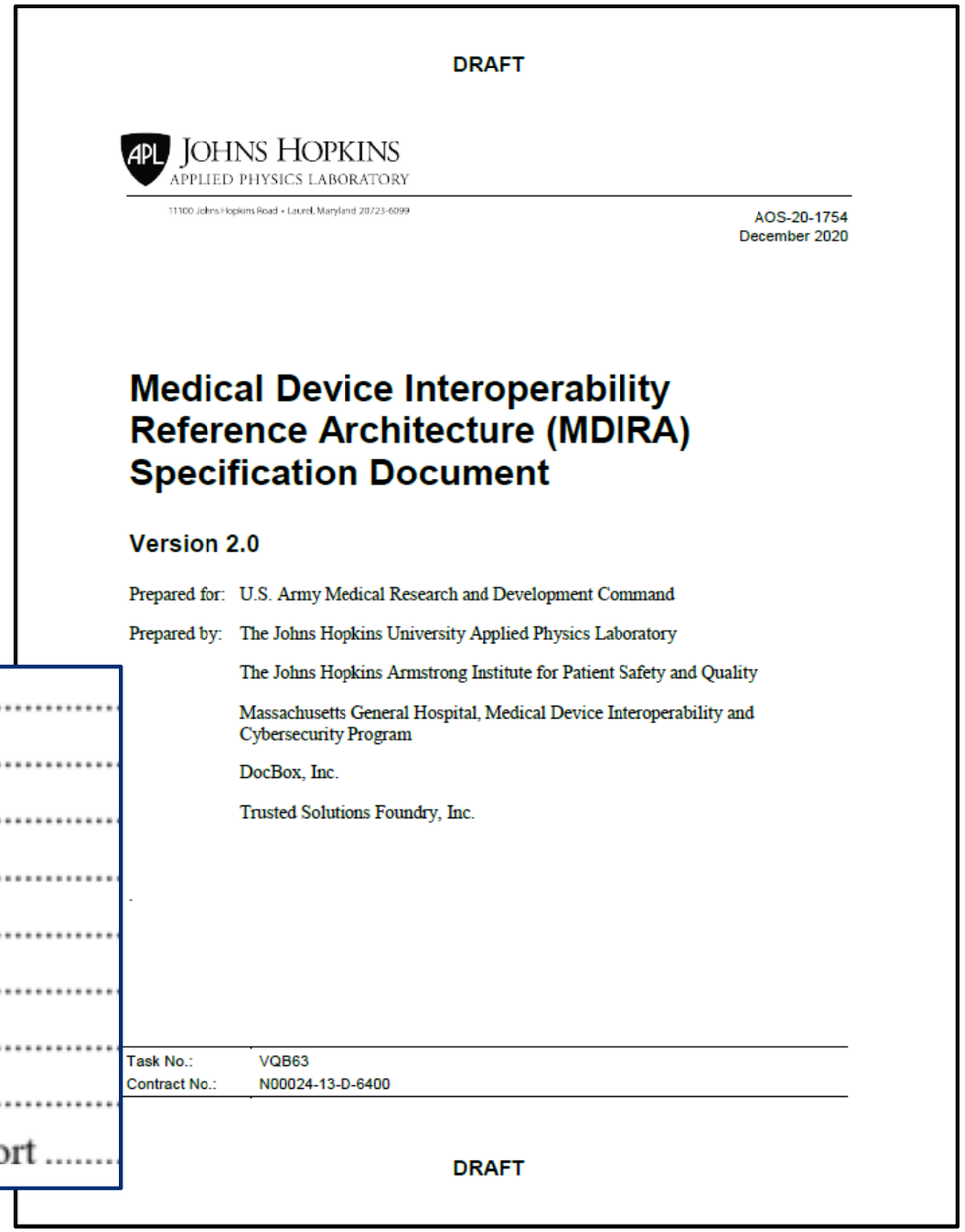
- Autonomous medical systems will consist of medical devices operating within an Integrated Clinical Environment (ICE)

- Challenges with current autonomous medical systems or devices:
  - **Non-interoperable** – Individual, functionally-separate components
    - Better interoperability can improve care quality, improve patient safety, reduce personnel workload, enable autonomous care systems
  - **Limited openness** – Vendor custom interfaces
    - Open architecture (OA) designs can reduce technology upgrade costs, reduce 'vendor lock', support plug-and-play operational flexibility
  - **Inadequate security** – Limited security
    - Increasing national concern regarding information and cyber security

Objective: Develop a Medical Device Interoperability Reference Architecture (MDIRA) that guides development of interoperable, open, and secure medical systems, including autonomous capabilities

MDIRA Draft 2.0

Table of Contents Excerpts



DRAFT

JOHNS HOPKINS
APPLIED PHYSICS LABORATORY

11100 Johns Hopkins Road • Laurel, Maryland 20723-6099

AOS-20-1754
December 2020

Medical Device Interoperability Reference Architecture (MDIRA) Specification Document

Version 2.0

Prepared for: U.S. Army Medical Research and Development Command

Prepared by: The Johns Hopkins University Applied Physics Laboratory

The Johns Hopkins Armstrong Institute for Patient Safety and Quality

Massachusetts General Hospital, Medical Device Interoperability and Cybersecurity Program

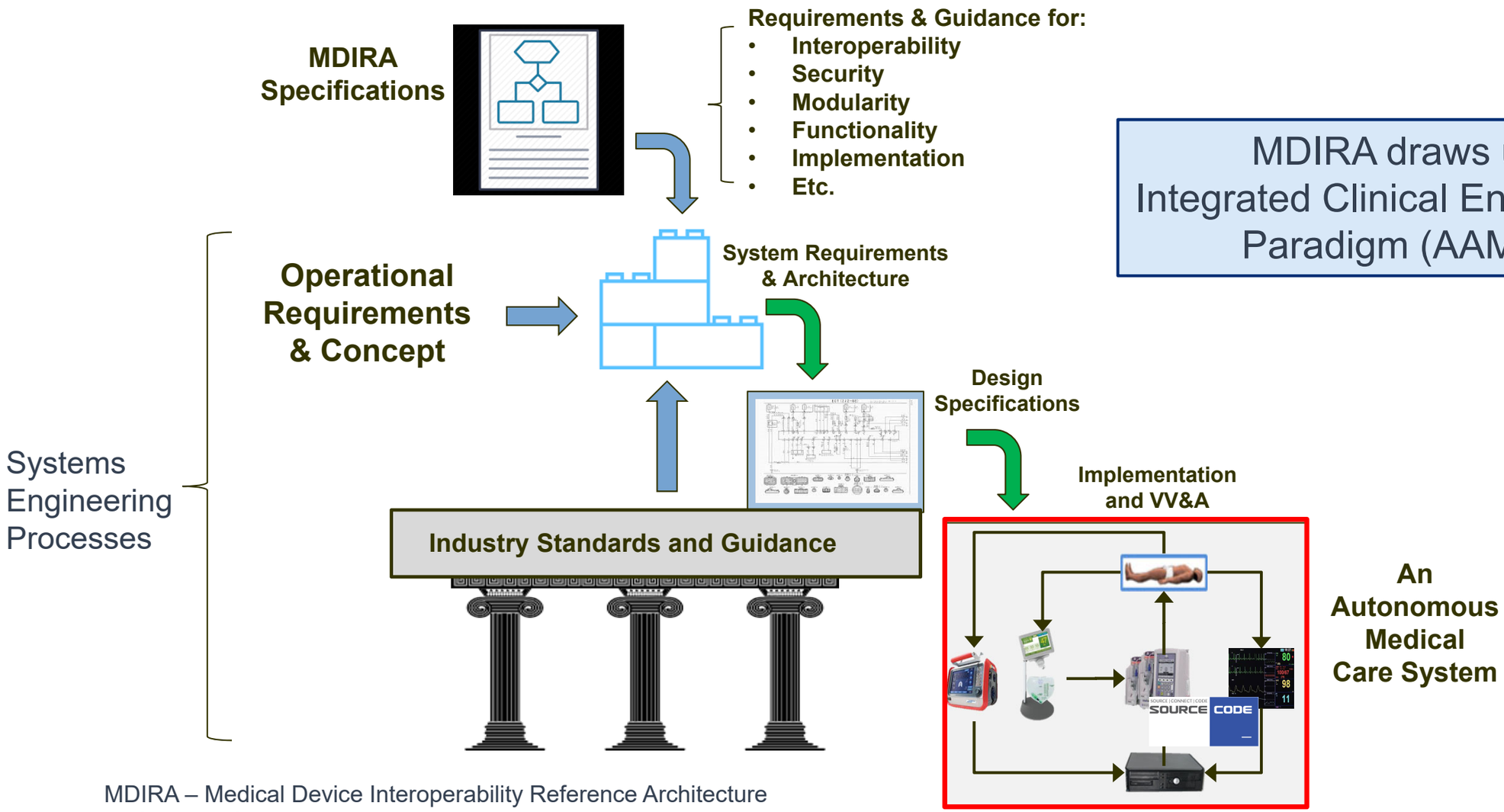
DocBox, Inc.

Trusted Solutions Foundry, Inc.

Task No.: VQB63
Contract No.: N00024-13-D-6400

DRAFT

MDIRA Role in System Development



MDIRA draws upon the Integrated Clinical Environment (ICE) Paradigm (AAMI 2700-1)

MDIRA – Medical Device Interoperability Reference Architecture
VV&A – Verification, Validation and Accreditation

What Does MDIRA Compliant Mean? (1 of 2)

- Have ICE Core Capabilities
  - Supervisor
    - Discover, authenticate, and register components
    - Integrate technical alerts
    - Monitor system health status
    - Authorizes requests to control
  - Data Logger
    - Log system forensics data
    - Log forensics data related to the patient's condition and care
- Use consensus information models and nomenclature standards that are supplemented as required

Not All-Inclusive

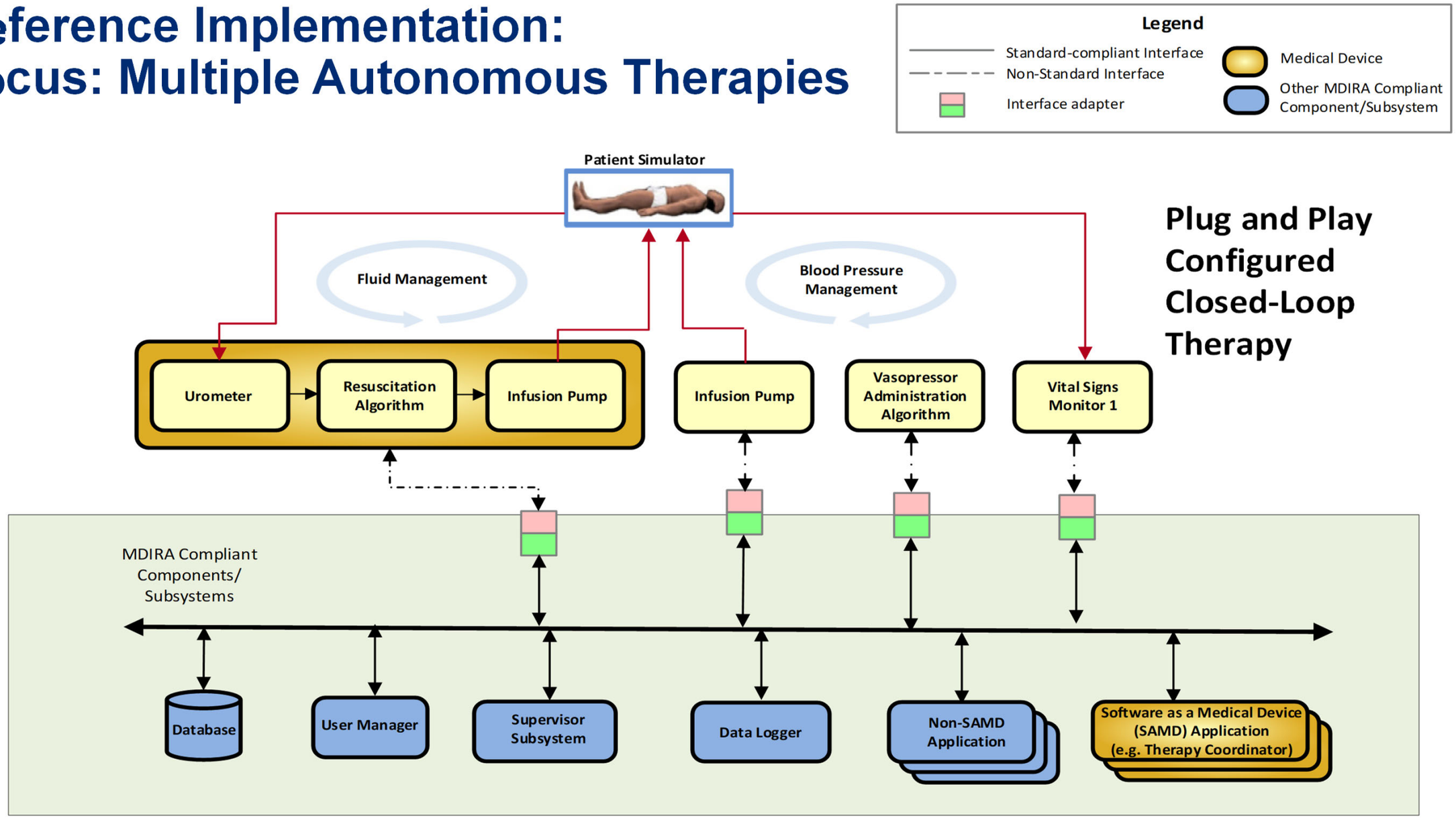
What Does MDIRA Compliant Mean? (2 of 2)

- Components
  - Connect and be ‘discoverable’ on a network of other components
  - Represent its ‘type’ and service capabilities
  - Provide health and status information
  - Provide capability to receive and respond to control/settings information from authorized components
  - Support system security features
  - Use community-consensus information models and nomenclatures supplemented as required

Not All-Inclusive

- External Interfaces
  - Use community consensus communications, information model and communications standards. Notional examples:
    - A FHIR-based interface to an EHR system
    - A standard interface to an autonomous evacuation vehicle

Reference Implementation: Focus: Multiple Autonomous Therapies

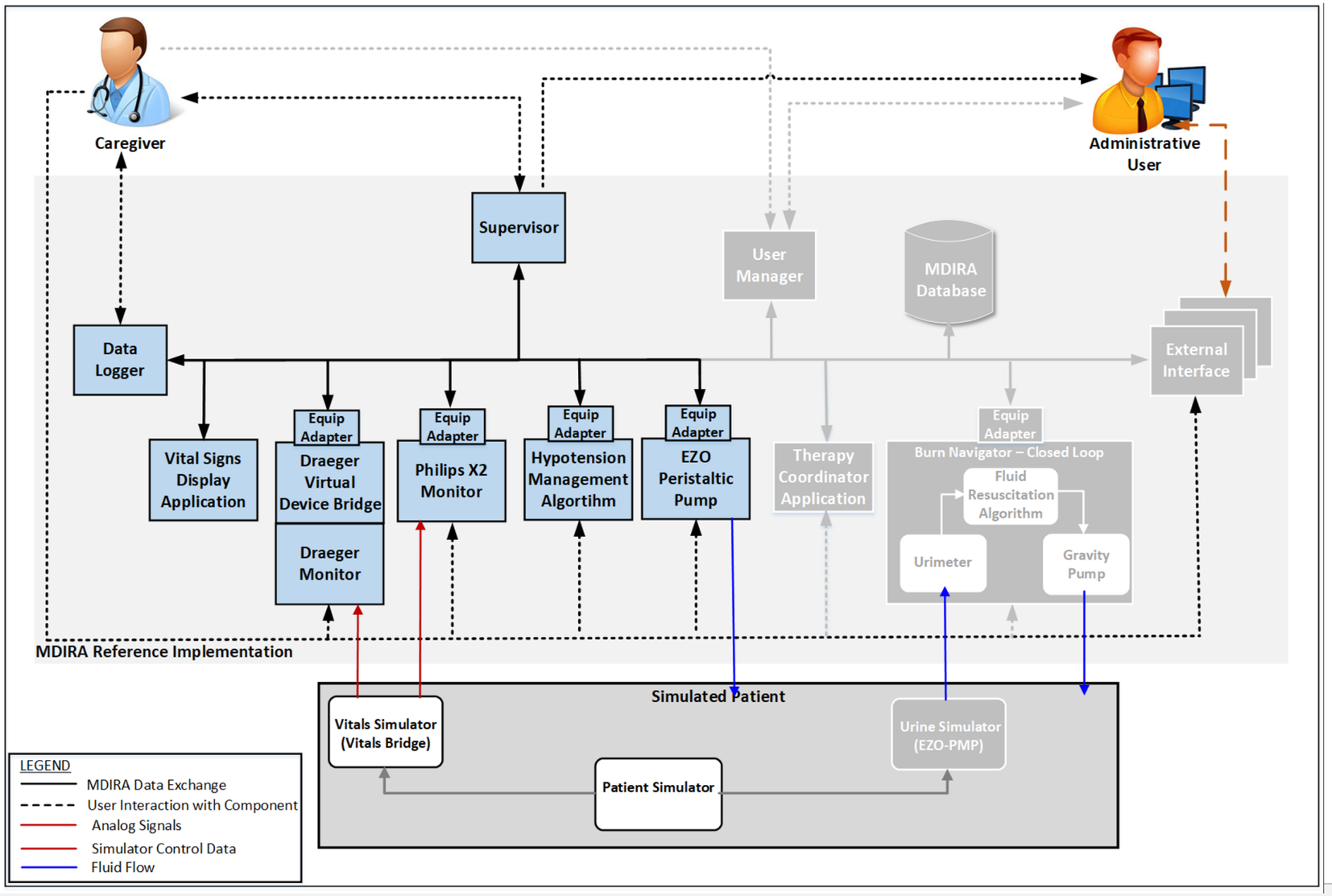


What is the Purpose of the MDIRA Reference Implementations?

- Develop ‘the bones’ 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 a catalyst for industry collaboration
- Support development and maturation of MDIRA
  - Prove out essential concepts
  - Identify gaps in underlying interoperability standards

Update on MDIRA Reference Implementation

Delivered to sponsor Dec 31, 2021



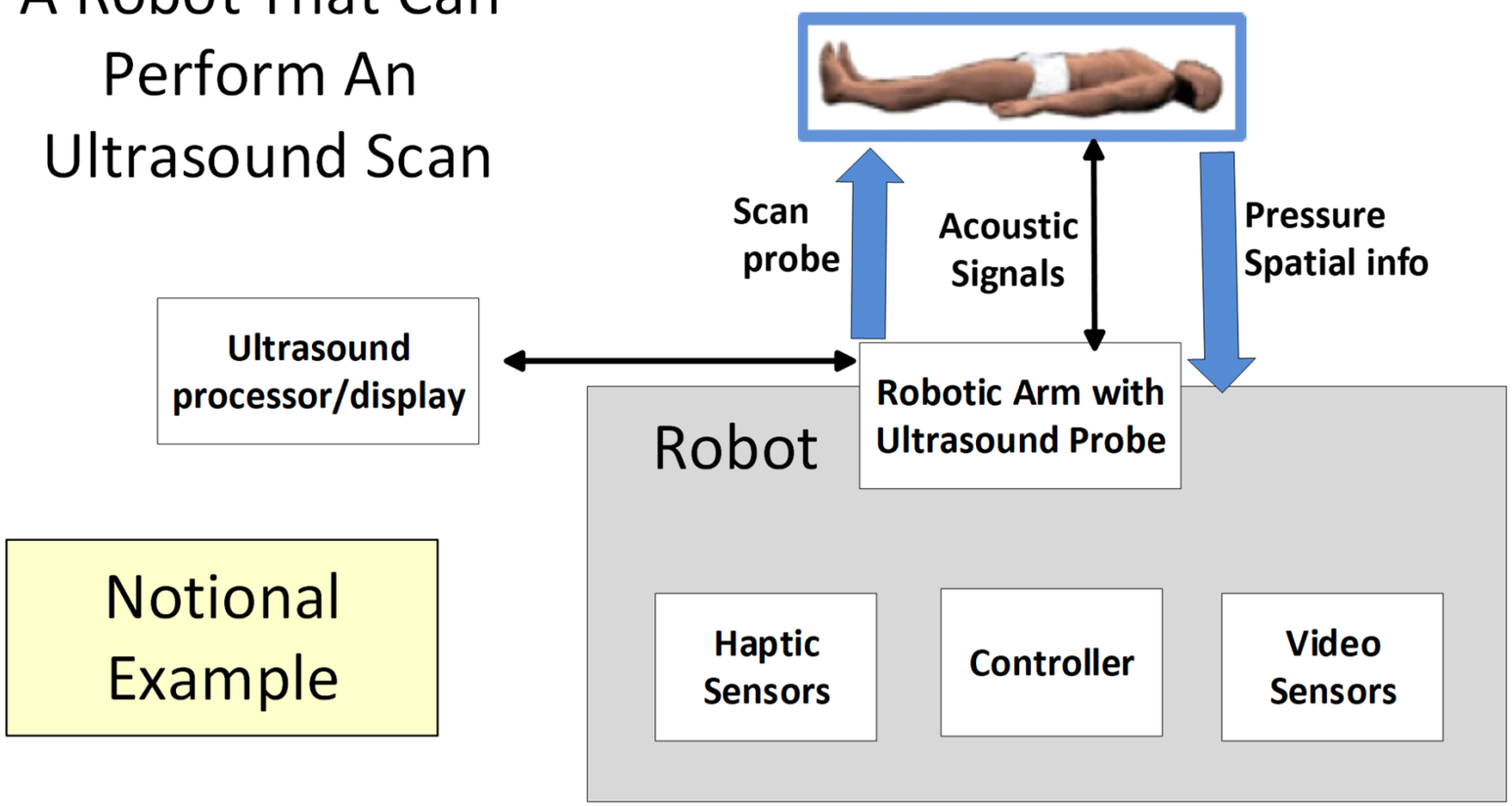
MDIRA Collaboration

- 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

Future Scope: MDIRA Relationship to Robotics (1 of 2)

Consider:

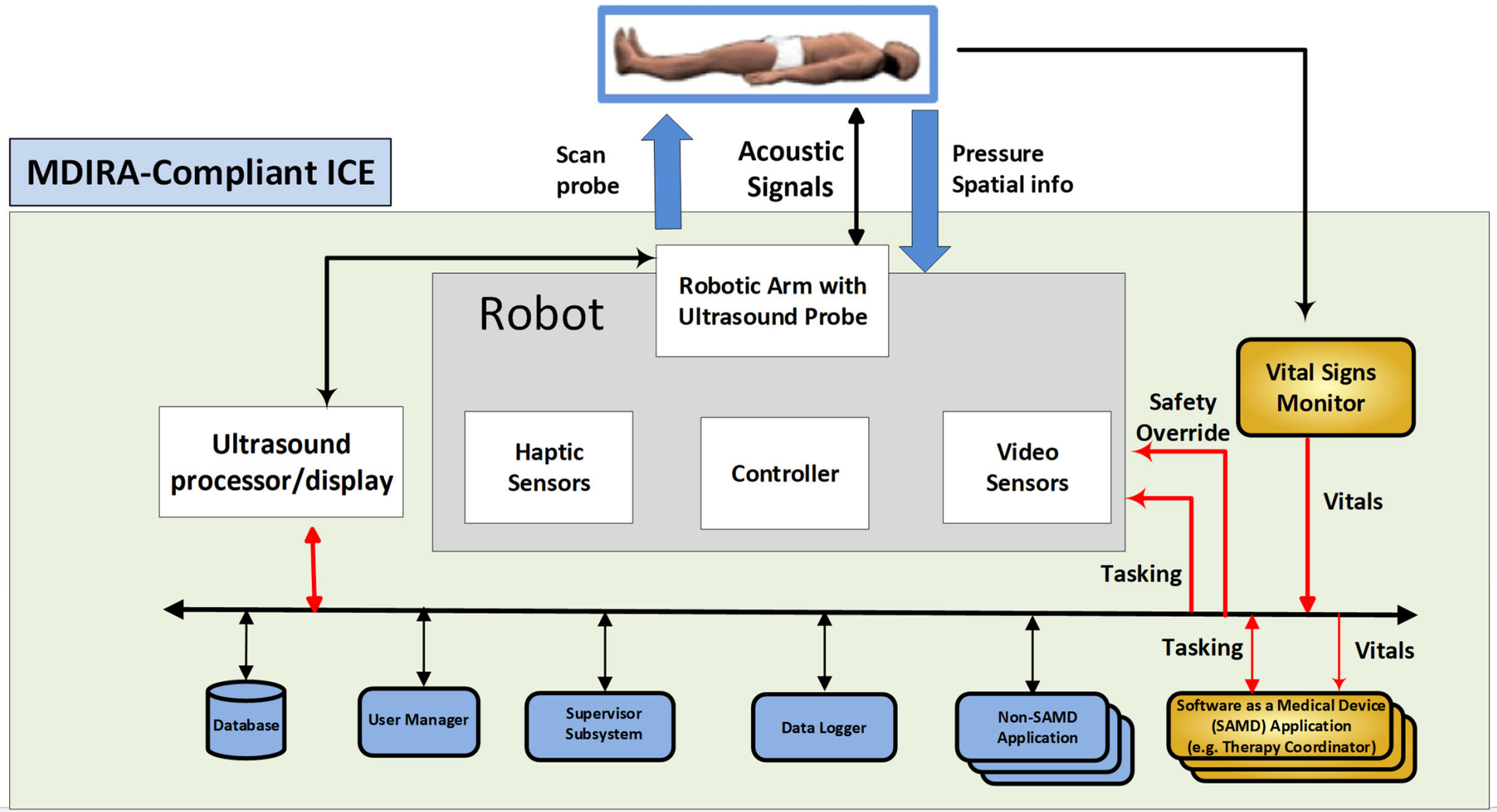
A Robot That Can Perform An Ultrasound Scan



Notional Example

Future Scope: MDIRA Relationship to Robotics (2 of 2)

A Notional MDIRA ICE/Robot Configuration



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.
  - Initial version of an SDC based RI has been developed by APL. The intent is to make this available in an open source repository in the future.
  - A second DDS based RI is in development. It's based on OpenICE and expected release 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
  - 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/

JOHNS HOPKINS

APPLIED PHYSICS LABORATORY