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14. ABSTRACT The goal of project is to conduct research and development towards the realization of a "next generation" Advanced Modular Manikin (AMM) designed as an open-standard modular manikin platform. The AMM team is building a core simulator platform that is designed for the flexible integration of peripheral simulators, the assemblage of which represent a broad spectrum of human conditions for military medical and trauma training. The modular manikin will include central computing capabilities, wireless data transmission, fluidics, power management and medical simulation capabilities using open-source / open-standards to facilitate the connectivity of basic and customizable peripheral modules.					
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Table of Contents

1. Introduction.....	3
2. Keywords.....	4
3. Accomplishments	5
A. Development of AMM Standards.....	6
B. Scenario Development:.....	8
C. Anatomy Update and Physical Manikin Development	11
D. Electronics.....	17
E. Universal Connector.....	20
F. Software Development	23
G. Fluidics System	27
H. Module Integration	35
I. Verification and Validation Testing	36
J. BioGears Modification by ARA	43
K. Physiology Validation and Verification	45
L. American College of Surgeons (ACS) Validation Study	50
4. Impact	53
5. Changes/Problems/Risks.....	55
6. Products	57
7. Participants & Other Collaborating Organizations.....	57
8. Special Reporting Requirements	59
9. Appendices	59
i. Quad Chart.....	59

1. Introduction

As stated in the announcement for the Advanced Modular Manikin TM (AMMTM) and detailed in the solicitation W81XWH-13-R-0032 from JPC-1, the program seeks to:

“Advance the state of the art in medical simulation-based training. It is anticipated that the core AMM system will be state of the art, modular, and relatively autonomous. It will serve as a core platform that allows scaling from a simple, to a vastly more capable unit, using future commercial upgrades, “peripherals” that can be obtained from a variety of potential sources.

The intent is that the AMM be a platform upon which future technologies can reside through development of advanced peripherals through other efforts. It is envisioned that the advanced modular manikin be compatible with a wide array of peripherals and/or extensions leveraged with open-source / open-standard physical attachments, supply (electrical/fluid) connections and communications links. This broad AMM platform to be developed should have the ability to host capabilities that do not yet exist but that are anticipated to be developed within the next five to ten years. Creation of the AMM platform will allow for a usable manikin system that can incorporate future advances, from a variety of sources, easily into military medical training.”

Phase II of the program was funded to move the proof of concept demonstrated at the end of Phase I forward, so that any interested parties can use the published standards and the core platform to build new modules with, or to upgrade existing trainers to benefit from the technology developed under AMM. All of the work being done for AMM is being published under Creative Commons 4.0 as open source with open standards and will bear no licensing fees.

Phase II also finalized the move from a manikin-based concept to a truly interoperable, integrated system allowing virtual, physical and hybrid implementations, with a connection point to compare outcomes to actual patient care.

Phase II can be broken down into 3 distinct steps, each roughly one year long:

- Year 1 addressed high level design, architecture, defining major sub-systems, breadboarding various components and communication protocols.
- Year 2 focus moved from breadboards to integrated sub-systems and getting ready for alpha prototype, scenario development, BioGears refinements, initial industry outreach.
- Year 3 will address integrating new modules into the system, creating documentation and finalizing a developer’s kit, as well as a usability study to be done by the American College of Surgeons (ACS).

The program has assembled a team that brings together diverse talents for each of the critical technology areas needed to design, build, and test the next generation manikin system. The team members include University of Minnesota, University of Washington, Vcom3D, Army Research Laboratories STTC, and the American College of Surgeons Division of Education.

With military health care training requirements and civilian health care training expertise from the University of Washington, the University of Minnesota and the American College of Surgeons, we have developed injury and treatment scenarios for male and female patients that best demonstrates relevant enhancement of training and assessment capabilities and opportunities across a diversity of learners, roles and environments. Associated with each scenario, maladies/injuries derived from a list of perceived military medical training and ACS Division of Education training needs were mapped to AMM “segments”. To support this, solid work models were created from CT scans from anthropomorphic accurate representation of a typical serviceman and woman and are being used to create anatomically correct reference systems to be delivered as part of the AMM package.

AMM Team leadership

Principal Investigator: Robert M. Sweet, MD, FACS, University of Minnesota

Co-PI: Mojca R. Konia, MD, PhD, MACM, University of Minnesota

Subcontract: University of Washington CREST – PI: David Hananel

Subcontract: Vcom3D – PI: Ed Simms, PhD

Subcontract: American College of Surgeons – PI: Ajit Sachdeva, MD, FRCSC, FACS

Subcontract: Army Research Laboratory – PI: Jack Norfleet, PhD

2. Keywords

Modular, Manikin, Open Source

Glossary of important terms:

1. AMM™- Advanced Modular Manikin. Name of the project as well as the Trademark name of operating system/standards and platform that will be provided under the efforts of this contract as a deliverable to the U.S. Department of Defense.
2. Phase 1 AMM™- 4 Advanced Modular Manikin Prototype concepts designed under four competitive contracts that ended February 2016.
3. Phase 2 AMM™- After selection, University of Minnesota-led contract to develop the Advanced Modular Manikin standards and platform that ends in September 2019.
4. "CORE" - Central operating resources (computer, power, fluid, air)
5. "Module" or “Peripheral” – Interchangeably refers to a capability or system that can be connected to the platform.
6. “Smart Module”- A module that transmits data to and from the CORE system and responds to changes in conditions communicated across the system.
7. “Dumb Module” – A module that doesn’t transmit data to and from the CORE.
8. "Segment"- One of 6 parts of the human form that can connect. (Left arm, right arm, left leg, right leg, head and neck, torso).
9. "Databus"- Data backbone that allows all components to communicate.
10. "Physiology Engine"-Software module that receives and generates physiologic states.

11. "Fidelity" – "Likeness to the model we are intending to simulate". There are 4 main sub-classifications of fidelity for medical simulation: Anatomic fidelity, Physiologic fidelity, Tissue fidelity and Affective fidelity (Hananel, Sweet).
12. "Generalizability for Learning groups"- Ability of the system to accommodate the development and interoperability of modules that are educationally relevant for multiple learning groups.
13. "Generalizability for environments"- Ability of the system to accommodate the development and interoperability of modules across multiple healthcare environments.
14. "Roles"- Military medical facilities focused on escalating levels of specialized care/expertise. (0-4)
15. "Ruggedness"- Refers to the ability to withstand the wear and tear of the intended uses of the training system.
16. "Laboratory Bench testing"- Refers to testing of the mechanics/operability of the system that occurs under standard conditions created in the laboratory
17. "Educational Field testing"- Refers to testing of the system that occurs under the conditions encountered during the intended educational training.
18. "Clinical bench testing"- Refers to testing of the clinical interventions of the system that occurs under standard conditions created in the laboratory.
19. "Interconnectivity"- Ability of modules/peripherals to be able to physically connect through the CORE.
20. "Inter compatibility"- Ability of modules/peripherals to transmit standard, interpretable data across the CORE.
21. "Interoperability"- Products from multiple companies can work within the same system.
22. "Automated metrics"-Learning data that is automatically derived from the module.
23. "Mules"- Early Prototypes meant to troubleshoot and test interoperability.
24. "Alpha" – The system being used for the ACS-AEI run study.
25. "Beta" – The system being used for our final demonstration to JPC-1 at the end of the contract.

It should be noted that our concept of AMM is not limited to a physical manikin. It is a platform/operating system and set of standards that facilitates interoperability between hardware and software systems for the purpose of healthcare simulation training and assessment. It is open source and has the capability of including a mix of physical systems, virtual systems, medical devices and software engines, etc. Our system will demonstrate interoperability between and among examples of each of these entities.

3. Accomplishments

Specific Year 2 accomplishments are detailed below and include:

- a. Development of AMM Standards
- b. Scenario Development
- c. Anatomy Update and Physical Manikin Development
- d. Electronics
- e. Universal Connector

- f. Software Development
- g. Fluidics System
- h. Module Integration
- i. Verification and Validation Testing
- j. BioGears integration and modification to accommodate scenario requirements
- k. Physiology Validation and Verification
- l. American College of Surgeons Validation Study

A. Development of AMM Standards

The AMM standards cover three broad areas: Patient Definition, Connectors and Data Models. The relevant data is being pushed to the AMM Portal as work progresses.

Patients that are simulated are defined by two large data sets, the anatomic models and the physiologic models. The anatomic data sets are derived from MRI, optical scan and Life Cast models and are being published in formats that can be used on both modelling and engineering platforms. On the physiology side we currently are focused on the BioGears physiology engine. Therefore, patients are defined based on the data elements used and published by BioGears.

A major accomplishment this year was the universal connector development effort. A universal connector was critical to ensure interoperability. The universal connector has been developed and is currently being tested and fabricated for integration into the segments. Connection points for segments of the physical platform using the universal connector include arm-torso (A-T), leg-torso (L-T), and head-torso (H-T). In addition, a separate OT connector has been designed allowing for organ-torso (O-T) connections. Our two designs provide mechanical coupling, power, data, fluid and air connectivity between and amongst the segments in a single small-scale unit.

The third area for standards is the Data Models. The key Data Objects that are defined around each Educational Encounter (the key tracking unit) are as follows:

- Patient – Described by the anatomic and physiologic components, that initial set is layered with disease states and injuries as a basis of scenarios
- Learner – From an AMM perspective this data is limited to performance assessment data and to be able to maintain a uniformed format is currently limited to, performed correctly or an error occurred with a description of the error.
- System – This data object tracks the state of each plug-in component of the integrated system to support a distributed, modular, interoperable design and signal each plugged in components capabilities to the system and its state before and during an educational encounter.

Finally, we are creating a set of data tables that can be accessed by all and completes the building blocks for the “language” of AMM. They currently include:

- Physical and Physiological Findings – cues, labs and studies that can be seen, palpated or heard that allow providers to perform their initial patient assessment and triage

- Drugs – a table of drugs that the supported physiology engine can consume
- Diseases – a table of diseases defined to the system that can be used by the scenario
- Instruments – a table of instruments that are available to the system and can either produce or consume data that are clinically significant

AMM Portal

The AMM website is now live and can be found at

<http://www.advancedmodularmanikin.com/about.html>.

The site includes an Intake Form for potential industry partners to use and identify their area of interest and start a dialogue with the AMM team.

System Architecture

AMM Phase II Architecture is defined by the following components:

Base Reference Model

- Standard unified connectors
- Digital representation of anatomic structures
- Platform
- Software
- Computing Resources
- Resources Provided
- Fluidics
- Power
- Data Structures
- Physiology & Findings
- Learner performance data
- Simulator performance data
- Simulator State Data

System Data Model

In order to assure proper communication of the state of the patient between modules, a standard data dictionary was created. The development of the data models was continued in Year 2 with development and refinement of the AMM data objects, Educational Encounter and AMM Data Tables. The top level for this structure is shown in Figure 1. Only the top level is shown, since the lowest level contains 100's of entries defining the detail information being exchanged during operation.

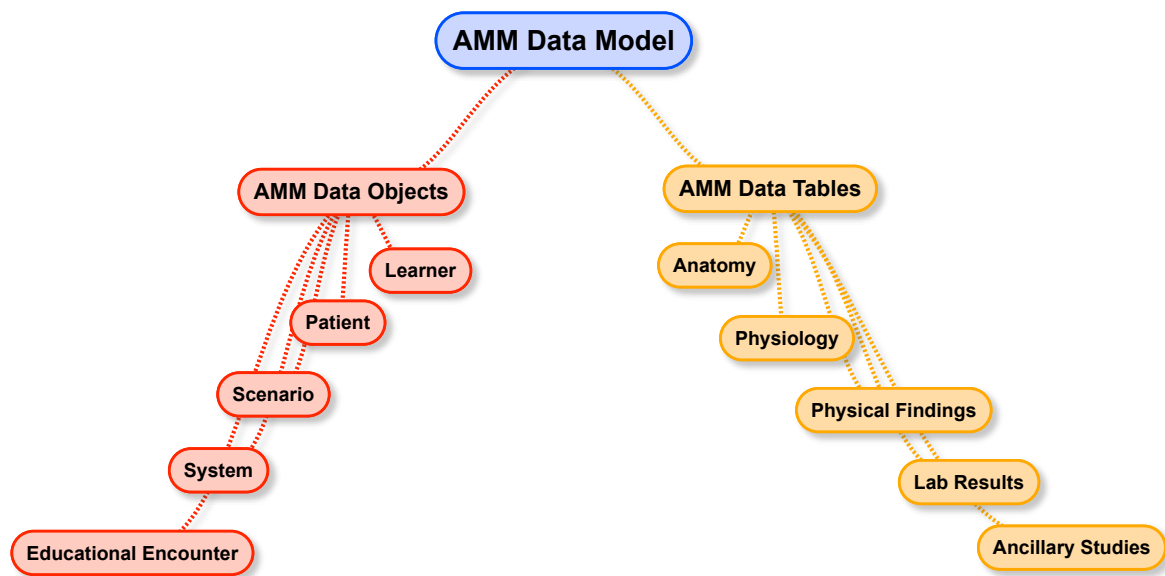


Figure 1: Top Level Data Structure

B. Scenario Development:

The scenario that will be used for the validation study by the American College of Surgeons has been developed by a multidisciplinary team of leaders in academic and military healthcare education. Particular attention was paid to making the scenario appropriate across several Roles of care, and levels of training with generalizability across military-relevant learning groups and environments. It was designed to feature the interoperability and usability of the system. That being said, there were limitations, as the choice of included modules designed by external vendors was dependent upon their company’s vision and belief in the future of such a system. The storyboard in Figure 2 below shows the scenario for “alpha” and demonstrates the communication inputs and outputs through the case.

The following is a synopsis of the scenario to be demonstrated contiguously across physical and virtual platforms.

- A male individual is riding in a Humvee Vehicle travelling at high speeds when an explosive is detonated below the vehicle. The individual inside is seat-belted as the vehicle rolls over several times. Rescue team arrives and extracts the individual from the rolled over vehicle. The individual is breathing and awake but appears to be in pain.
- An initial Inspection is done, and no noticeable injuries found.
- IV catheter is placed, fluids connected, and vitals are checked/monitored.
- *Patient is transported to a Forward Operating Base (FOB).*
- Physical Exam at FOB – abdomen becomes tender and mildly distended, patient continues to be in pain.

- Vital Signs/Physiology Engine Output– shock state – still has tachycardia. BP starts trending down to 90's systolic.
- FAST Exam – free fluid found in abdomen.
- Vital Signs/Physiology Engine Output – shock state – mild hypotension and continued tachycardia.
- Vital Signs/Physiology Engine Output – shock state – ongoing resuscitation by IV fluids. Mild tachycardia and systolic in the 90's or high 80's.
- *Patient is transported to the Operating Room.*
- Intubation output – forces from intubation readout.
- Intubation input – instrument force received.
- Laparotomy
- IVC bleeding.
- Spleen ruptured.
- Bladder ruptured.
- Spleen removed.
- IVC repaired.
- Bladder rupture repaired.

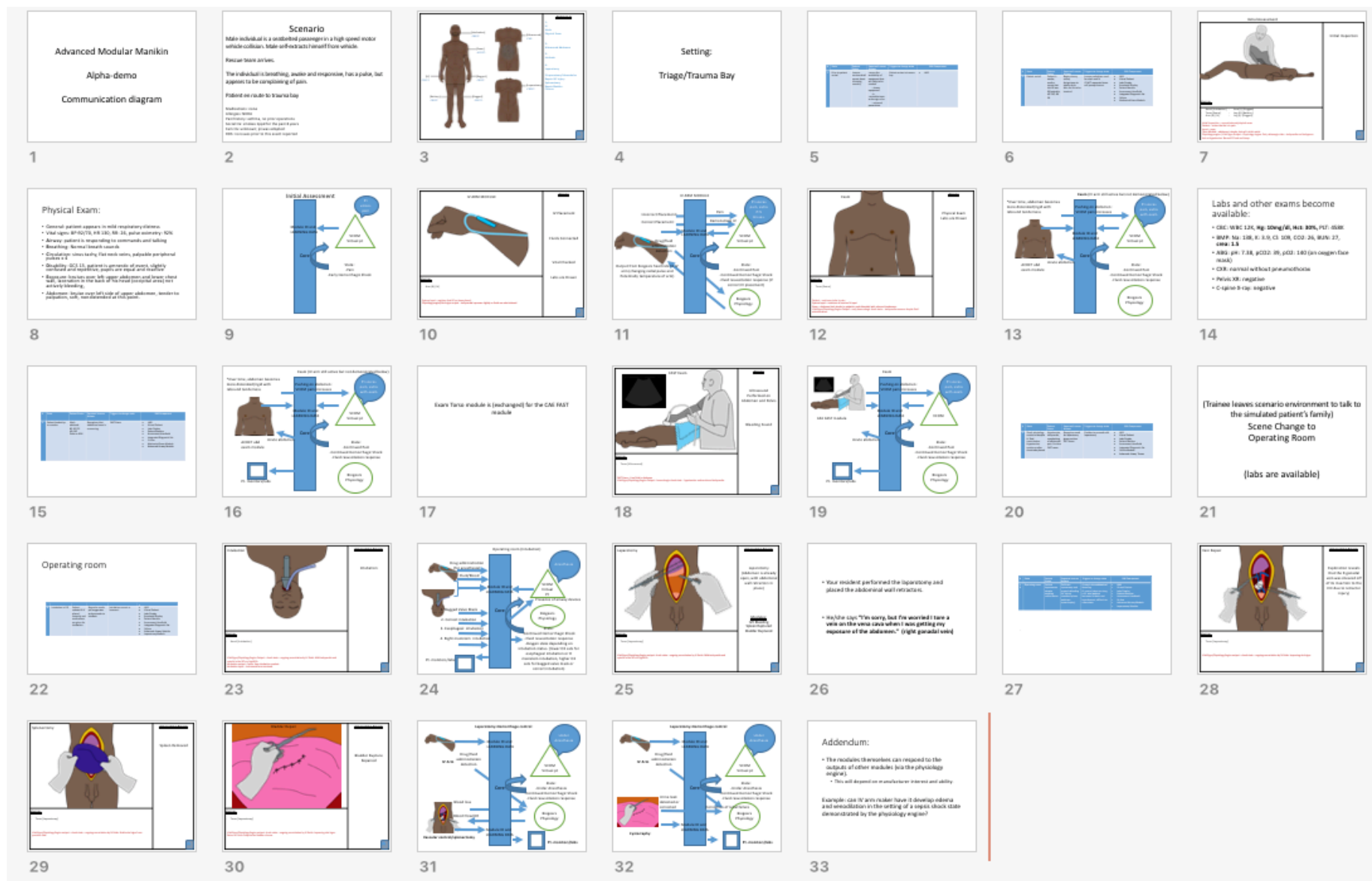


Figure 2: AMM Alpha-demo Communications Diagram. The arrows represent data element transmissions.

C. Anatomy Update and Physical Manikin Development

Year two focused on completion of the male anatomical 3D data set, the development of the female anatomical 3D data set, and their distribution in OBJ, STL, and IGES formats. Basic anatomy has been separated into groups. See Figures 3-10 below.

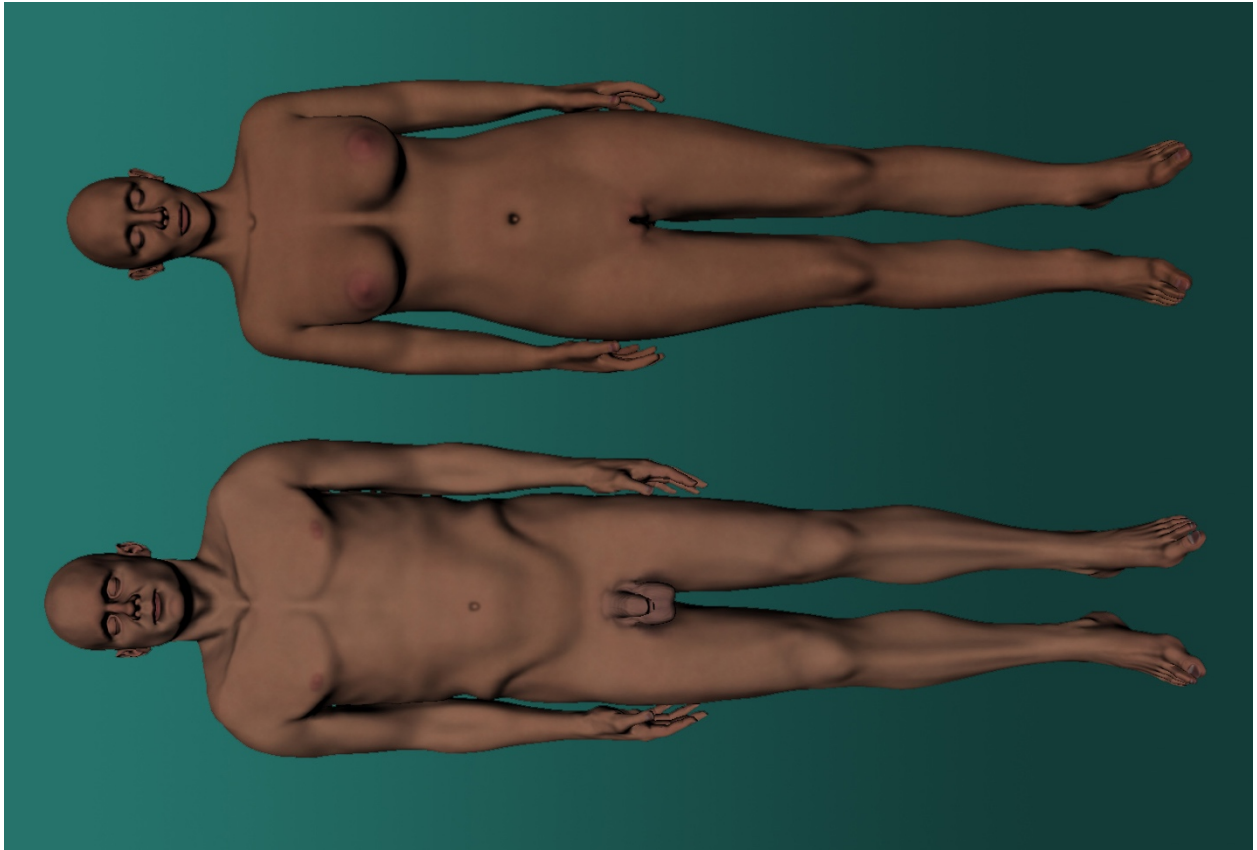


Figure 3. Epidermis (in parts); Cut Planes (module separations)

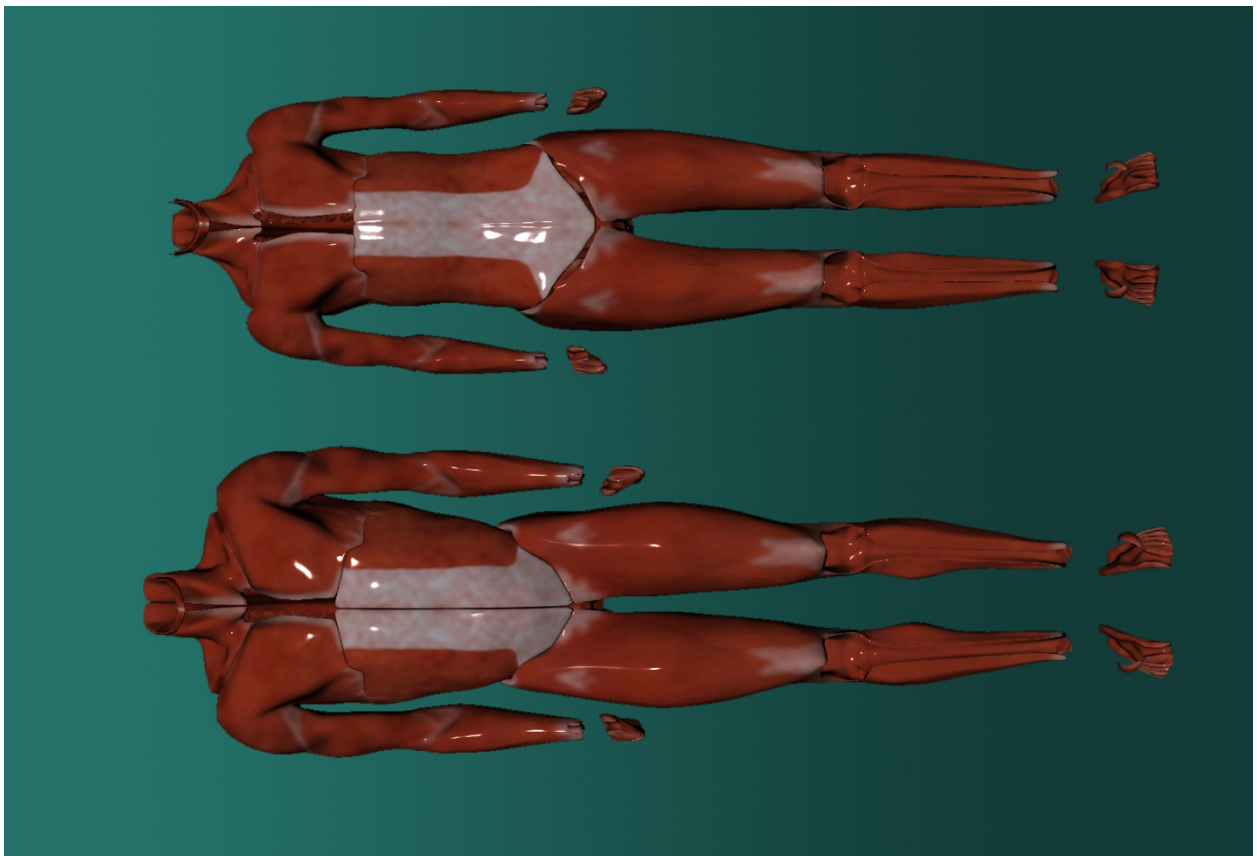


Figure 4. Muscle Groups

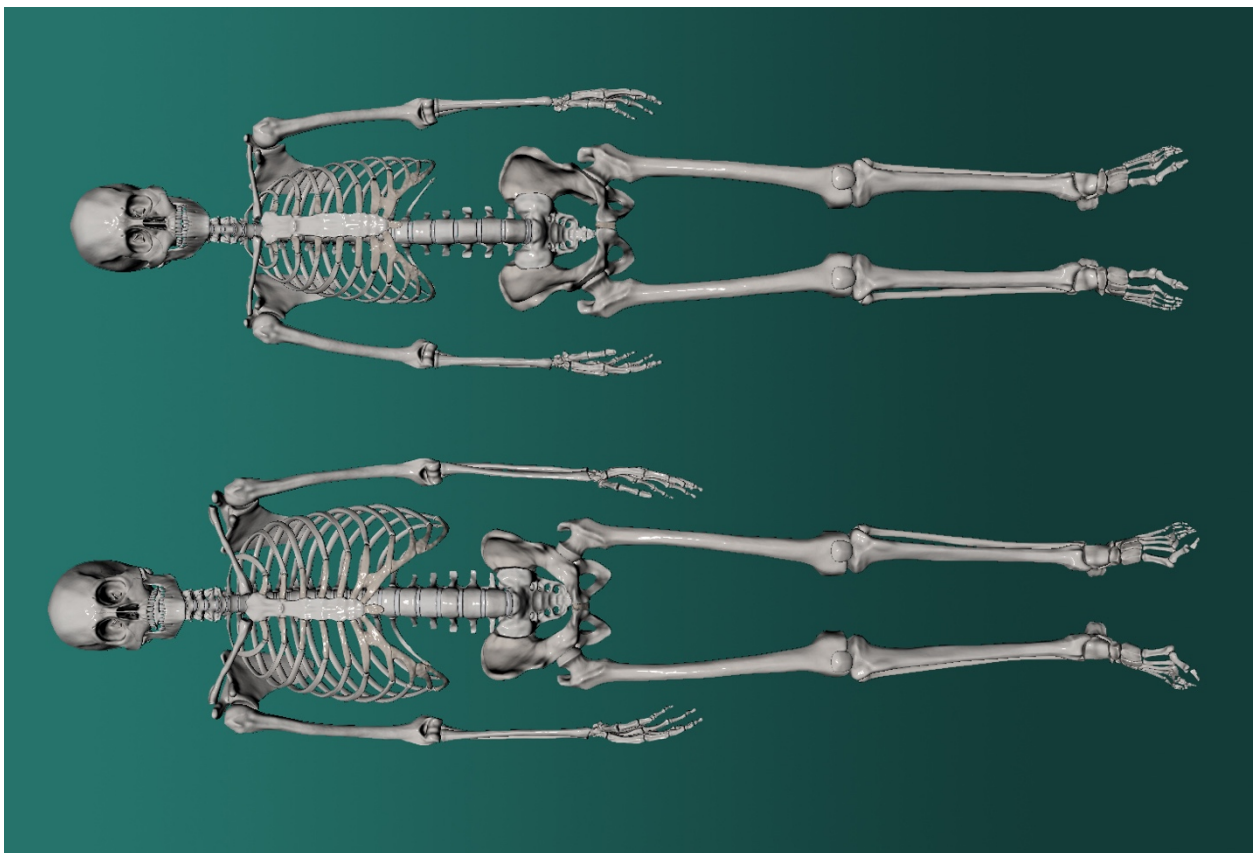


Figure 5. Full Skeleton

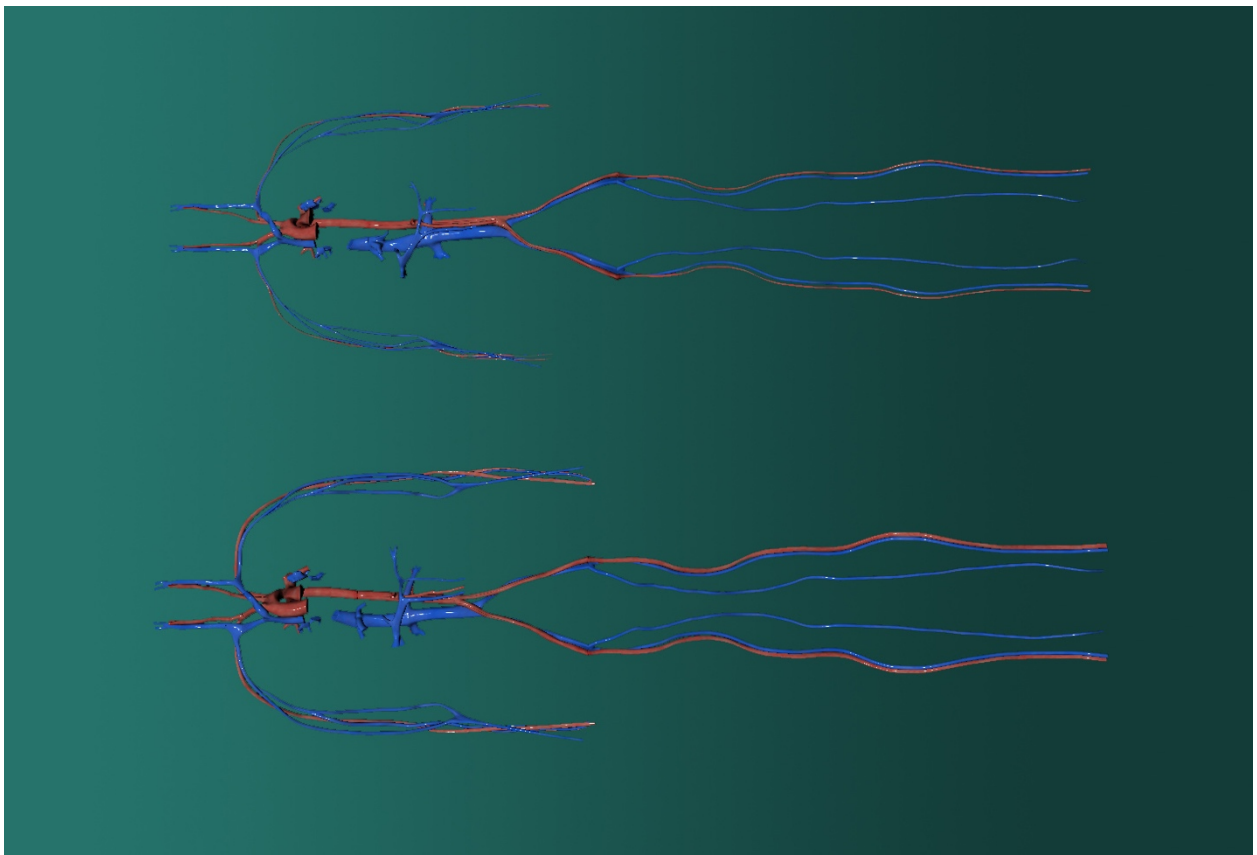


Figure 6. Large Vasculature

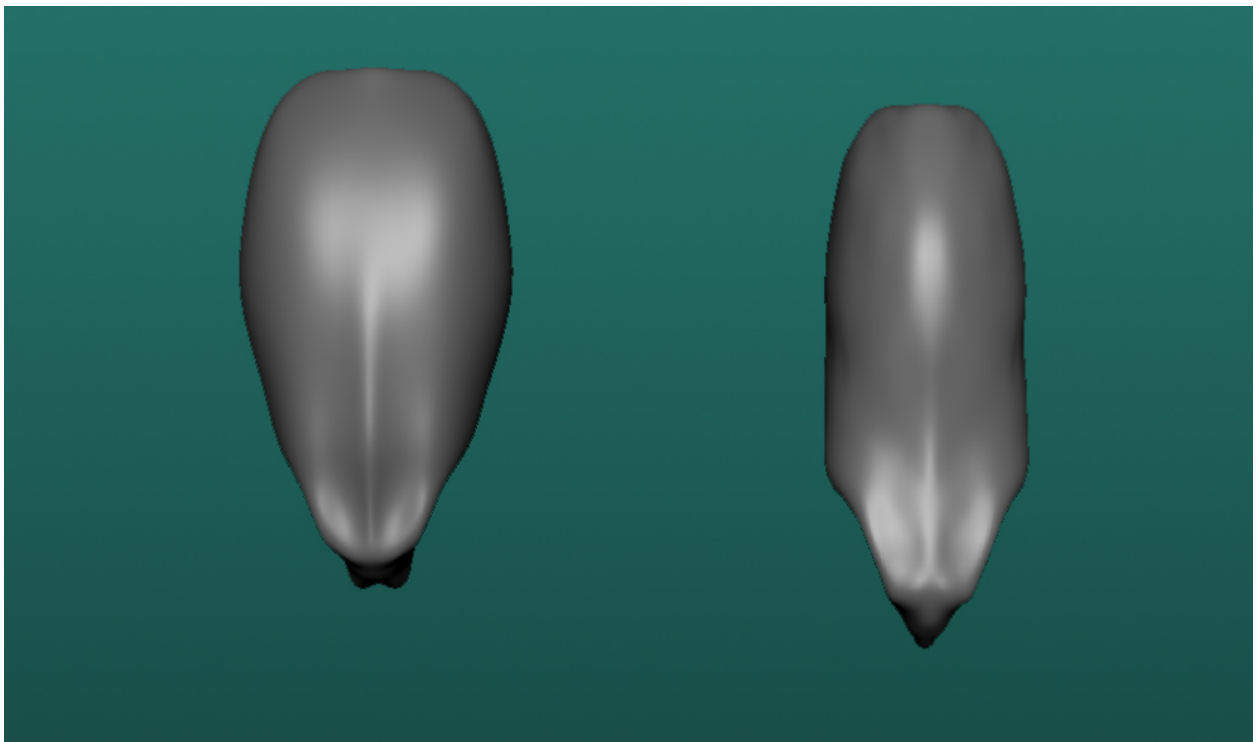


Figure 7. Body Cavity (negative organ space)



Figure 8. Head Structures

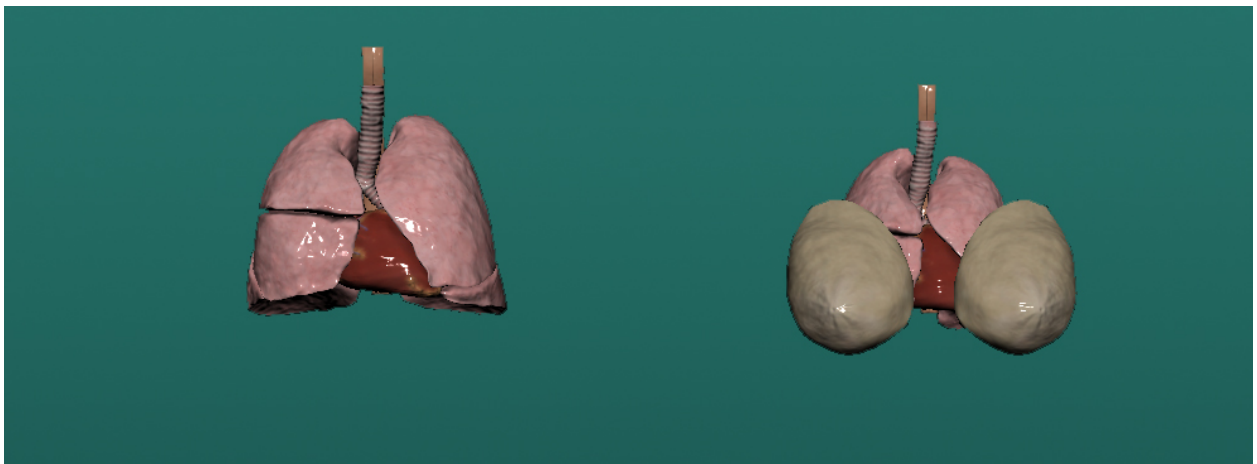


Figure 9. Thoracic Organs



Figure 10. Abdomen Organs; Male External Genitalia

Torso Shell

In order to visualize the model's anatomy in physical form, a digital file capturing the manikin's torso geometry and volume was used to control a milling machine to cut foam to the correct shape.



Figure 11a. Mold castings from model Figure 11b. Hollow thermo-formed manikin shell

The front and back foam components were used as molds to create thermo-formed shells. Figure 11a shows the shells that are pieced together to visualize the allowable space in which to place anatomy and mechanical components. Figure 11b shows a hollow shell representing the outer boundaries of the abdominal cavity. All organs can be placed within this form.

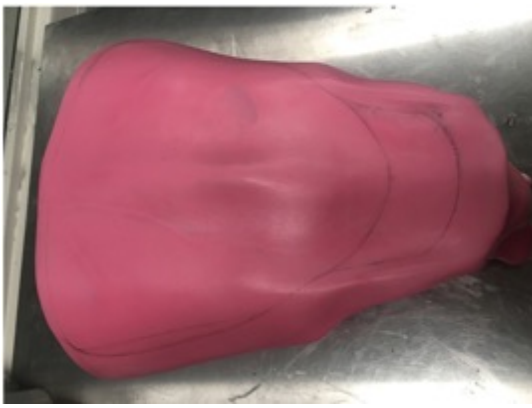


Figure 12a. Model of Abdomen



Figure 12b: Suspended in body volume

Shown in Figure 12a is a model of an abdomen. This same abdominal cavity is suspended within a torso shell to represent the spaces and boundaries available. Positioning is adjustable to allow determination of how to permanently affix this structure within the shell as shown in Figure 12b.

Figure 13 below shows how the lungs and pelvis anatomical structures are set into place. The clear plastic shell represents the anatomical boundaries and landmarks of our model. The clarity aids in visualizing spaces, boundaries, and complement allotments.



Figure 13. Anatomical Structures mounted in thermo-formed shell

Skin

Torso skin has been made with accurate thickness from the internal structures. See Figure 14. Two versions were populated with 3mm skin thickness for the thinnest possible option (displayed below), and with full variable thickness at all locations. The variable thickness shows optimized depth based on use of skin for surgical procedures, where tissue fidelity matters most.



Figure 14. Torso skins

D. Electronics

Subcontractor, Entropic Engineering has designed and manufactured the AMM Developer Kit (AMMDK) electronics and firmware libraries to enable rapid prototyping and development of new AMM-compatible modules.

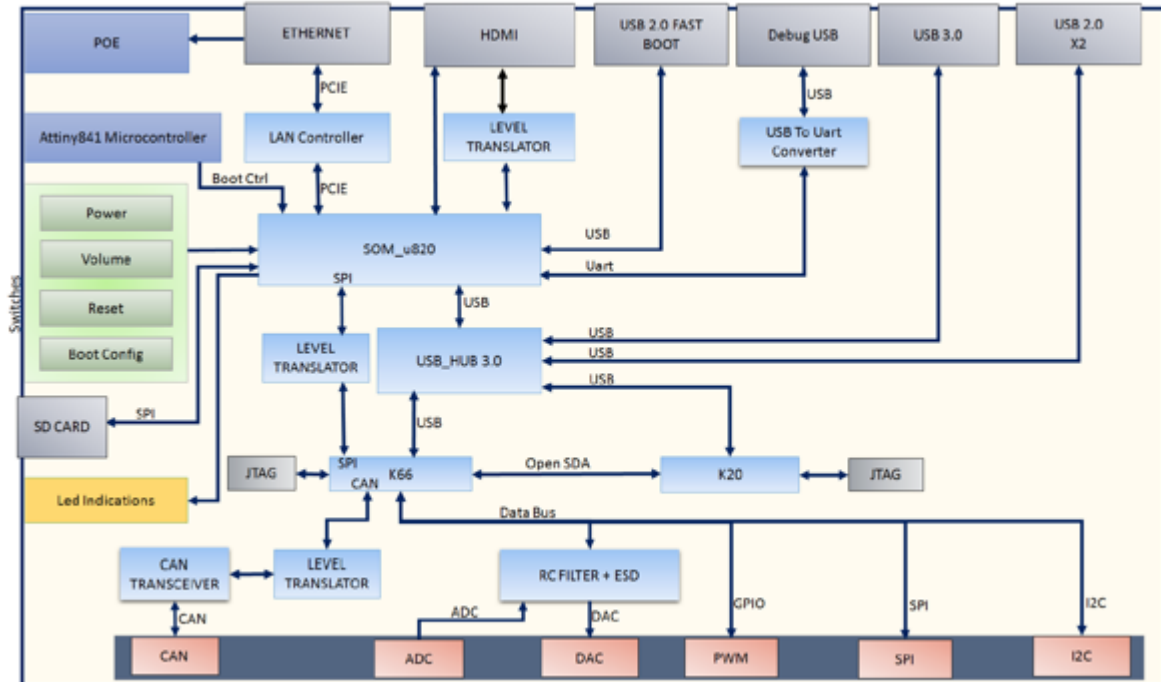


Figure 15. AMMDK Block Diagram

As shown in Figure 15, the AMMDK is built around the new “Qualcomm® Snapdragon™ 820E high performance embedded platform”, which is designed to provide powerful, energy-efficient, multi-core processing for the next generation of embedded computing applications, with manufacturer support until at least 2025. The AMMDK ties the extremely capable Snapdragon 820E to the Kinetis® K66 microcontroller built on the Arm® Cortex®-M4F core to enable connectivity to nearly any hardware peripheral with support for common electrical protocols such as I²C, SPI, CAN, UART, USB, and Ethernet, along with standard GPIO. In order to ease the complex burden of embedded software development, the AMMDK also features a Kinetis® K20 microcontroller configured solely to provide real-time debugging of the K66 micro. Finally, the AMMDK features external HDMI & USB ports to enable module developers to use the AMMDK as a development workstation.

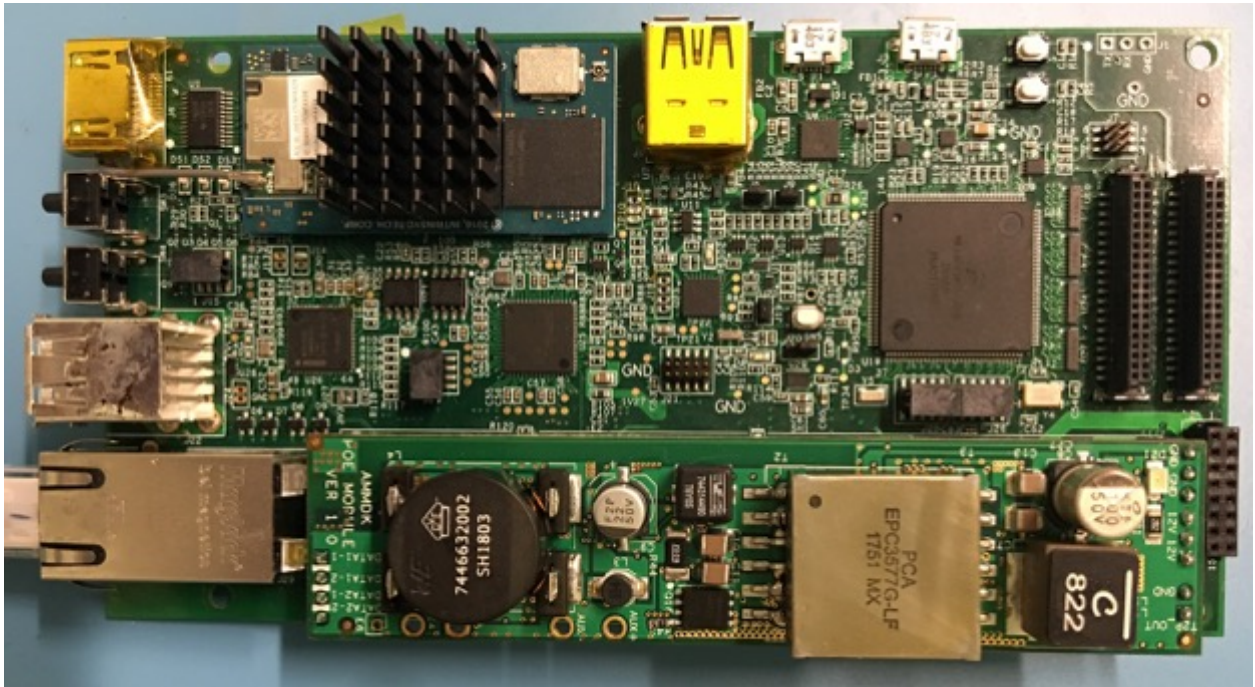


Figure 16. AMMDK Electronics Hardware

The completed AMMDK hardware, shown in Figure 16, will enable module makers to develop cutting-edge new simulators with advanced features such as VR, computer vision, and neural networks while also being able to connect to nearly any sensor or actuator and provide precise, real-time control as needed. The AMMDK also provides many wireless capabilities, including Bluetooth, Bluetooth Low Energy, Wi-Fi, and GPS, along with six-axis motion sensing, and the AMMDK can be powered either from a standard 12V barrel jack, or can be supplied with power and data connectivity via a single cable with Power over Ethernet (PoE).

In order for the AMMDK hardware ‘motherboard’ to connect to specific peripheral devices such as sensors and actuators, an application-specific ‘daughterboard’ needs to be connected to provide the required signal conditioning, level shifting, and physical connections to the peripherals. This ‘Application Board’ connects to the AMMDK by way of the three pin-header connectors located on the right edge of the board in Figure 16 and is able to stack on top of the AMMDK, much like a ‘shield’ for hobbyist electronics systems.

For the modules CREST is producing for the reference alpha and beta manikins, Entropic Engineering designed and manufactured a ‘CREST Application Board’ to meet the needs of

the CREST modules. Figure 17 shows how the CREST Application Board fits on top of the AMMDK board to save valuable space by reducing the needed electronics footprint. As shown in Figure 18, the AMMDK ‘stack’ of boards combines much disparate functionality into a single, compact unit, requiring only a single ethernet cable for connectivity and power.

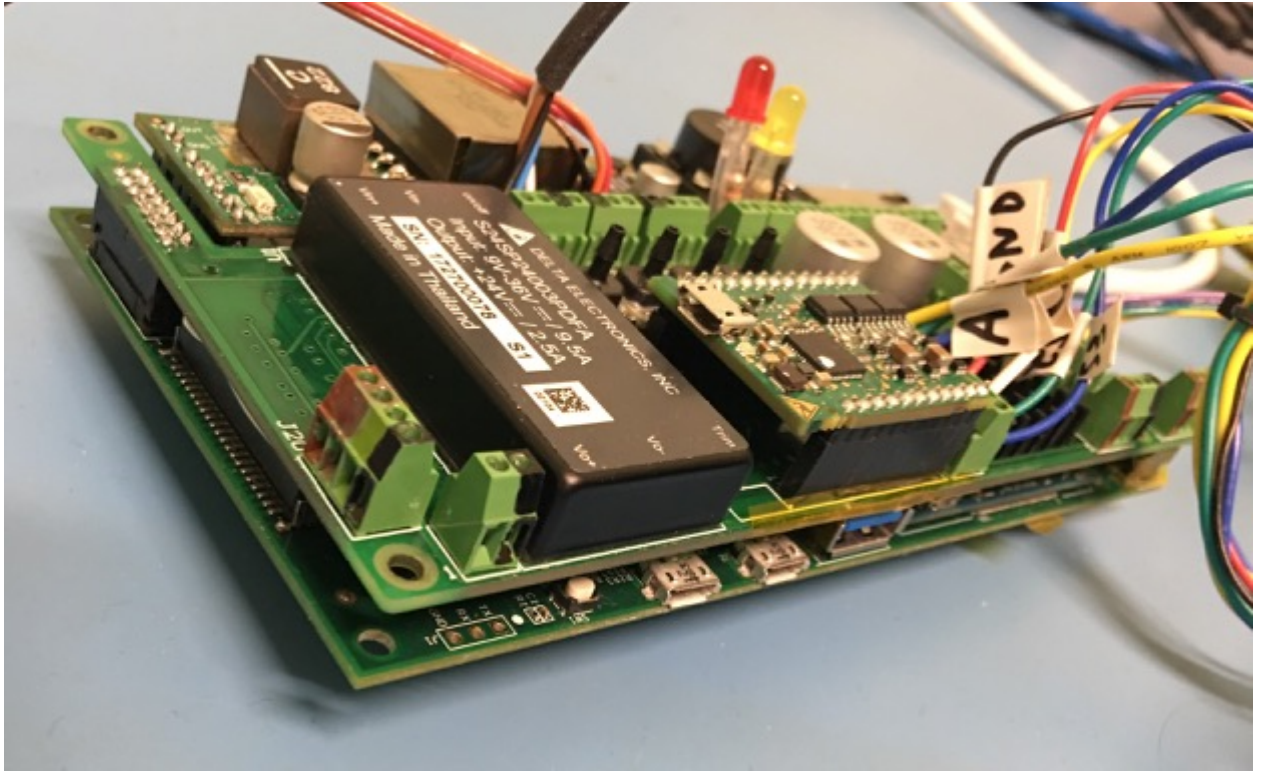


Figure 17. CREST Application Board stacked on top of AMMDK Board

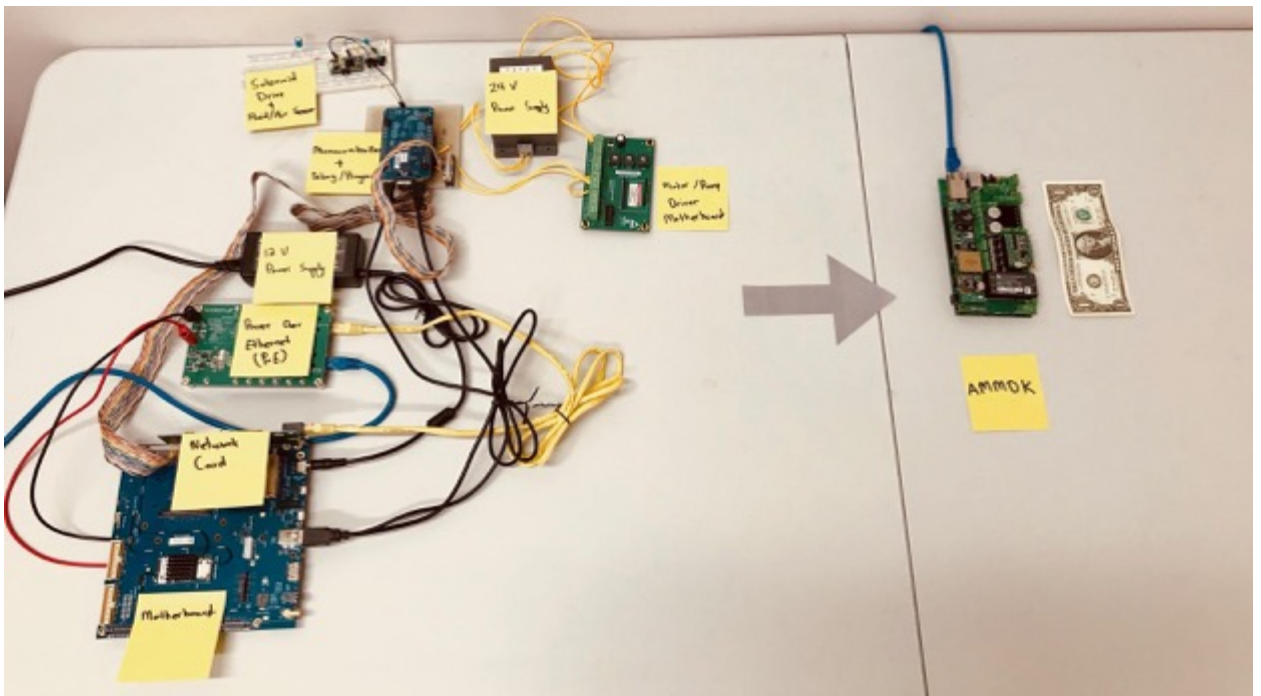


Figure 18. Prototype Hardware vs. AMMDK + CREST Application Board

E. Universal Connector

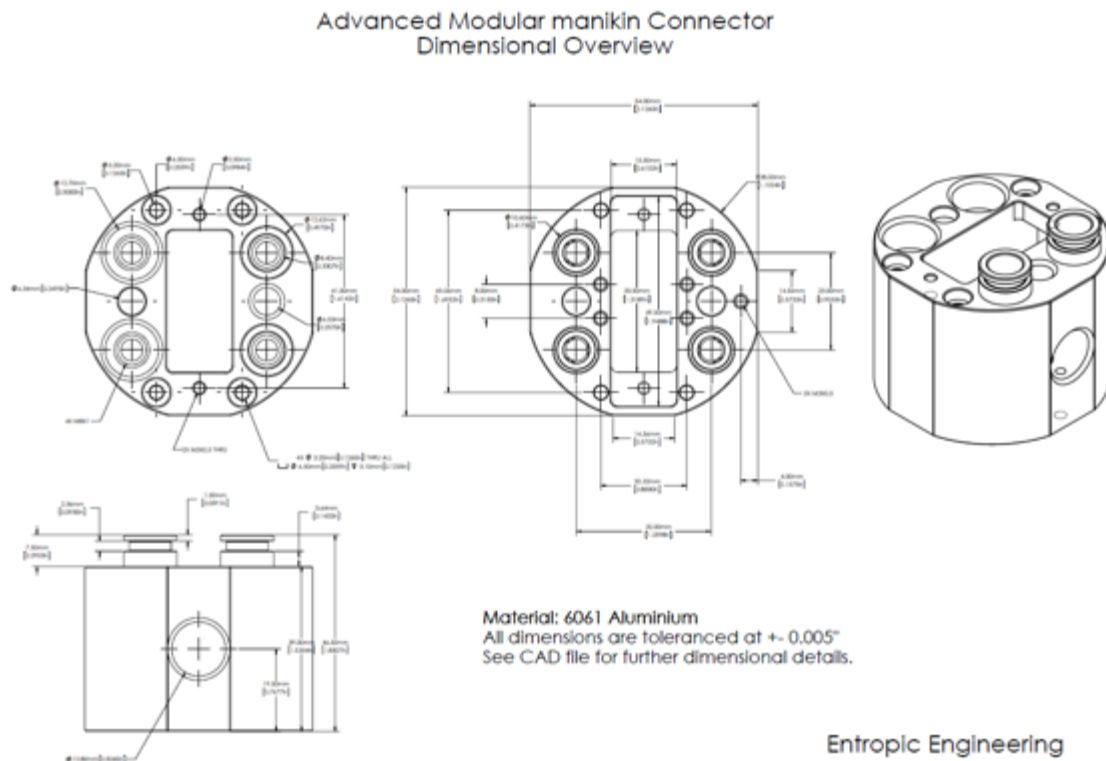


Figure 19. Custom Hybrid Electrical & Fluid Connector



Figure 20. AMM Universal Connector

The University of Washington and Entropic Engineering teams have designed and fabricated a universal connector for AMM physical modules, as shown in the schematic in Figure 19 and photo in Figure 20. The end result is a compact, functional connector which provides four fluid pathways along with an electrical connector that provides Ethernet connectivity (including Power over Ethernet [PoE]) and a high-power pathway to enable manikin operation with batteries stored in limbs. The connector is locked and released by a simple pin and latch mechanism, with the latch being inside a spring-loaded button. Both the electrical connector (from TE) and the Schrader valves are inexpensive commodity components.

The connector mates to the rest of the manikin by means of four bolt holes, with the intent that every module manufacturer will determine and fabricate whatever fixture best fits their needs. An example ‘sleeve’ which could be used to integrate the connector into an arm module is depicted in Figure 21 (along with an earlier connector design).

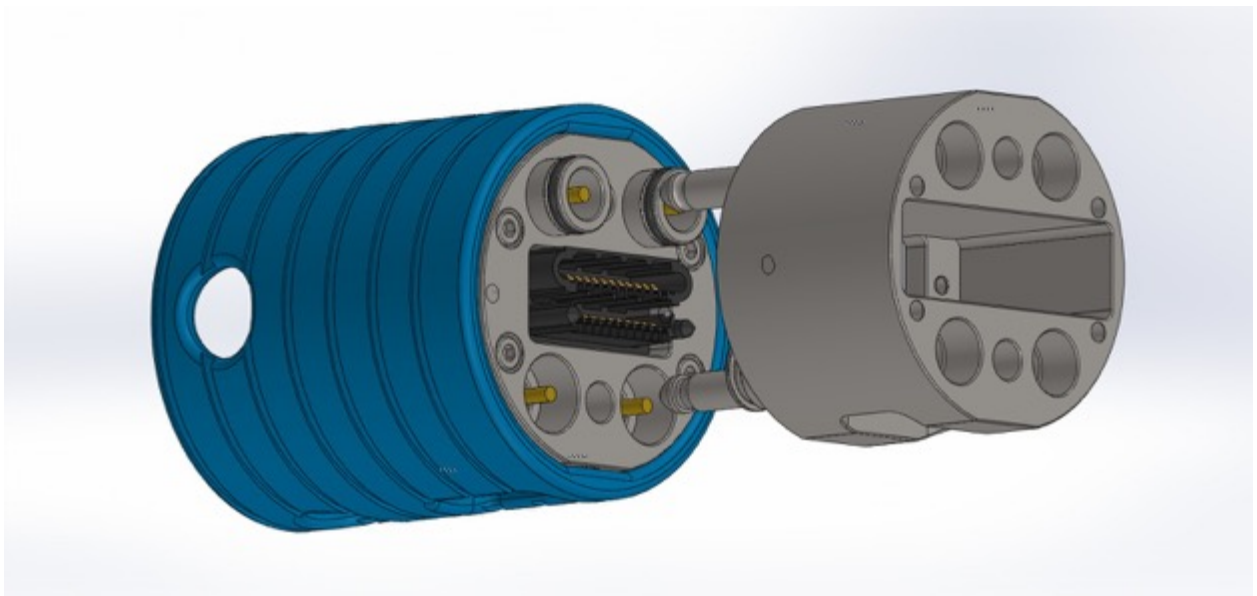


Figure 21. Example ‘sleeve’ for integrating Universal Connector into an arm module.

When connected, the protrusions insert into the sockets, causing opposing valves to open each other completely. The O-rings on the protrusions engage before the Schrader valves initially make contact, helping to ensure minimal leakage. This design also provides for a small gap between the connectors, as seen in Figure 22, providing resilience against minor damage and debris on the surface of the connector face.



Figure 22. Closed Universal Connector

Because the holding force is carried by the interface between the pin & button, both are made of hardened steel and manufactured separately from the body of the connector, as highlighted by the color difference of the button in Figure 22. This separation of functions also allows for tuning of the maximum holding force by modifying only the geometry of button or pin, and

also provides for enhanced serviceability of the connector. Additionally, the Schrader valves simply screw into the main connector body and can also be easily replaced if damaged. The desired design constraints that were met allows the same connector to be used for male and female manikins, as well as, neck and all limbs. Finally, as shown in Figure 19, both halves of the connector are identical, reducing part count and overall manufacturing cost.

F. Software Development

Vcom3D has continued development on the CORE computing modules, including the simulation manager and physiology engine module. Primary advances include expanding the AMM data model to add messages required for module status reporting, module configuration, and scenario configuration/execution. We are developing a software Module Manager to aggregate status and marshal the configuration of components for an educational encounter. The Module Manager is a critical part of the CORE computing system. Ancillary documentation has been created to define the responsibilities of a Module Manager as well as a glossary for common AMM-related terms to reduce implementation confusion. The Figure 23 below illustrates the primary functions of the Module Manager and its interaction with each Module as a scenario is loaded and then run.

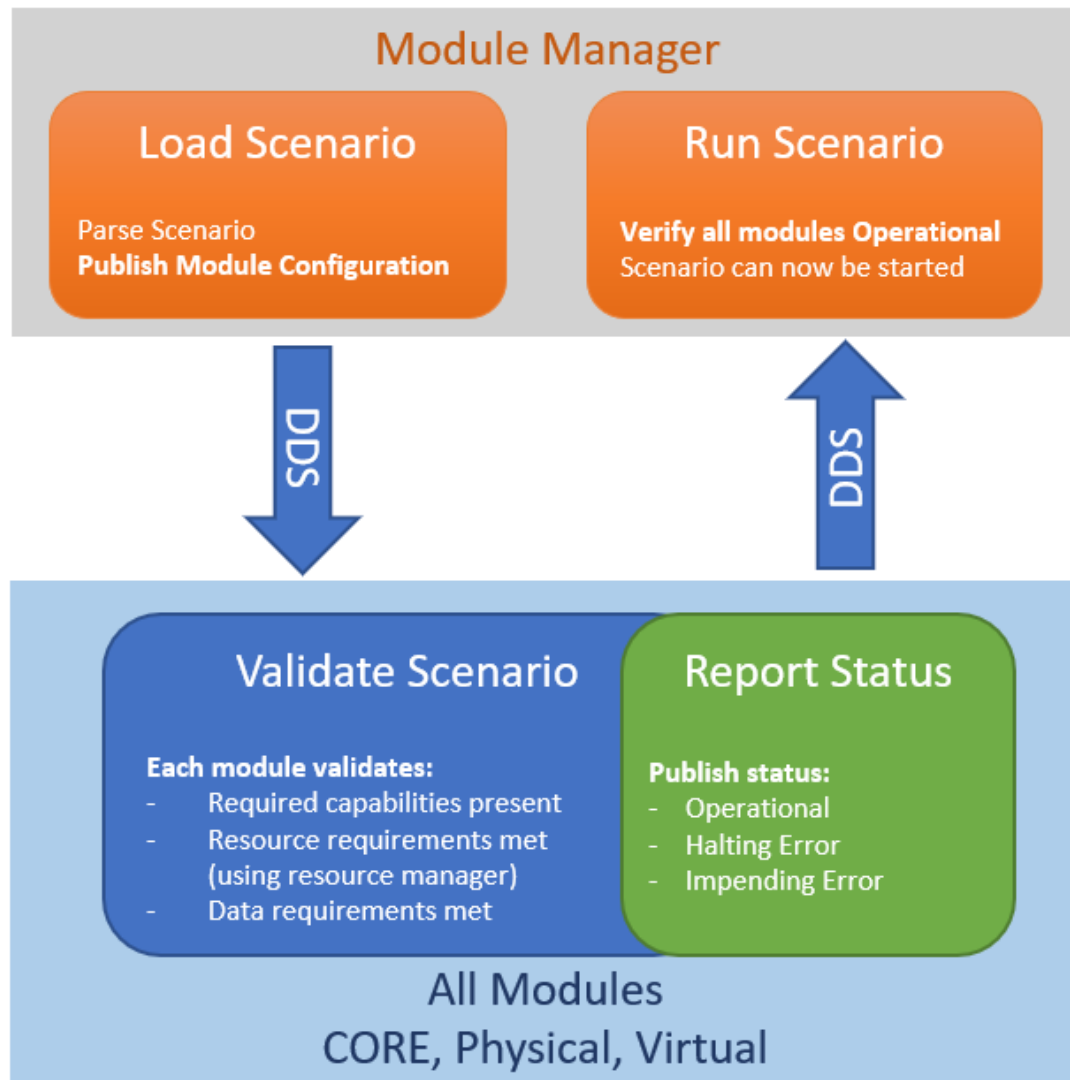


Figure 23. Module Manager Operational Overview

Enhancements have been made to the generic Data Distribution Services (DDS) code utilized by all AMM modules – this shared code allows modules to be rapidly integrated into the AMM system by providing standardized configuration handling and status reporting, thereby reducing the amount of software development required for new hardware and software modules.

Improvements have been made to the REST Adapter module and we have defined a preliminary ‘web application flow’, allowing for easier AMM web-connected application development. This allows us to more rapidly prototype and build AMM user interfaces for demonstration and testing.

Figure 24 illustrates the overall AMM core stack, highlighting the REST Adapter. The REST Adapter allows for curated access to the DDS bus using standard HTTP requests, allowing developers to build web applications and interfaces that can interact with AMM. Also shown as part of the core stack are the TCP bridge (used for network-connected modules, such as virtual equipment) and a generic serial bridge (used to connect to Arduino-type hardware), both of which are available in our AMM Github repository.

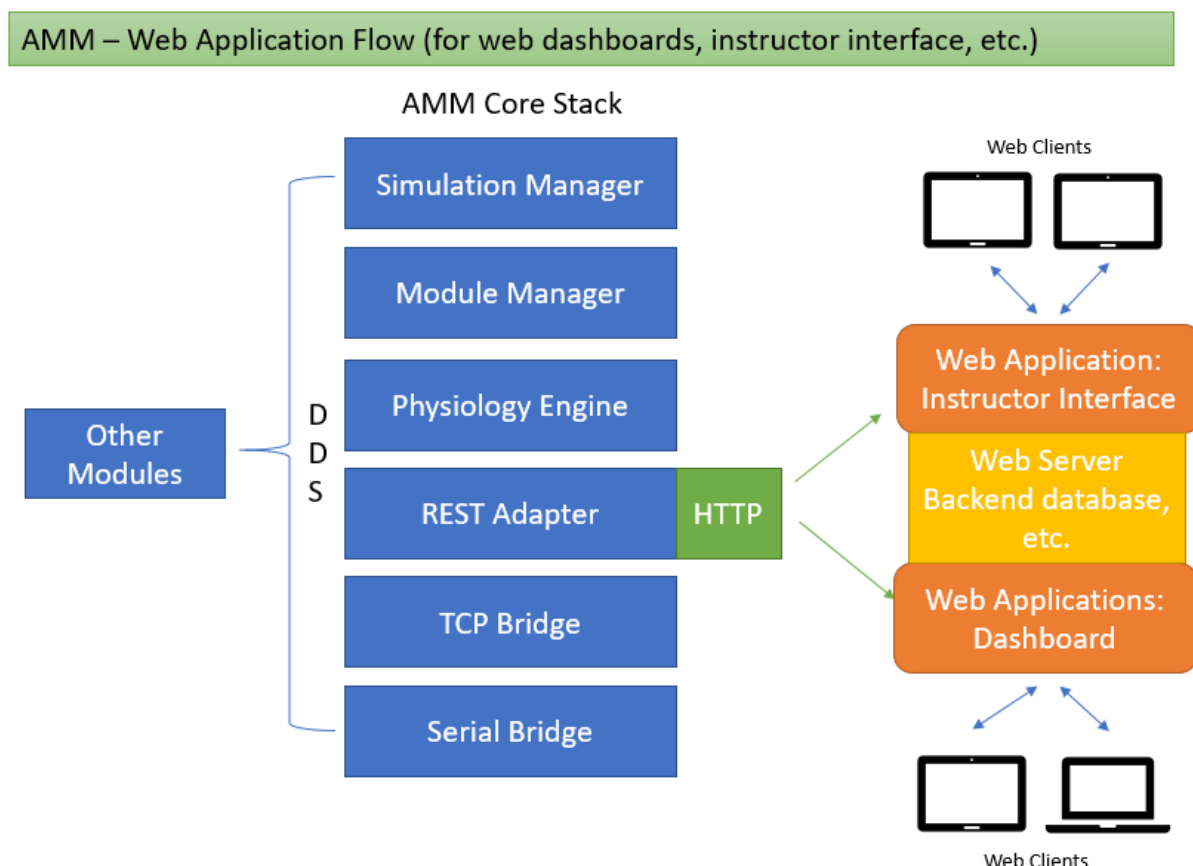


Figure 24. Web Application Flow for UI Development

Vcom3D continues to use and expand the Snapdragon 410C-based prototype System-on-Module (SoM) that the company has unitized in its AMM-conformant projects. One of these units was prepared and sent to UMN for accelerating the physiology engine scenario development and validation, and we have provided technical support to the UMN validation team to help with their work.

The Interface Design Document (IDD) is being expanded to include changes to the AMM Data Model and the new Module Manager definitions. It will be completed and published during the next quarter. We will also continue developing the Module Manager and fully integrate the Core software with other AMM systems as part of the demonstration Mule. Vcom3D will continue supporting UMN physiological and scenario validation, continue improvements to the AMM web interfaces, and provide additional Snapdragon 410C-based prototype SOMs to help accelerate testing.

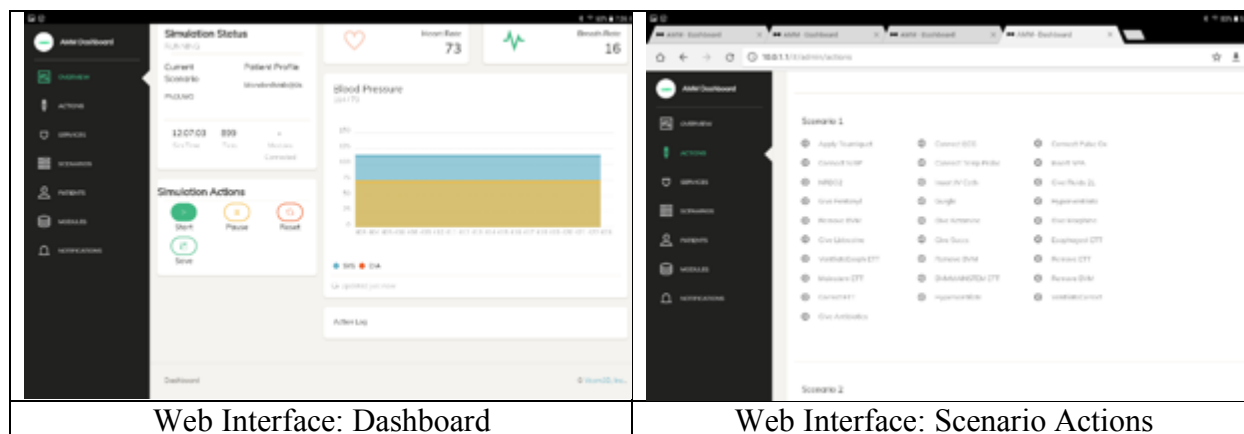


Figure 25. Web Interface

Scenario and User Interface Testing

The University of Minnesota and Vcom3D worked together to test the AMM core and available virtual models. The virtual modules implemented as web-based apps (see Figures 25 and 26), included:

- Instructor Tablet
- Virtual Patient
- Patient Monitor
- Triple IV Pump
- Lab Reports
- Ventilator

In addition, the following Core components were integrated:

- AMM Module Manager
- AMM Simulation Manager
- AMM Logger
- AMM REST Adapter
- AMM TCP Bridge
- AMM Serial Bridge
- AMM Logger

The Module Manager is a core software component that coordinates the participation, initialization, configuration, and termination of AMM modules during the educational encounter. All AMM compliant modules must perform an appropriate handshake procedure which includes information about the module, the capabilities it provides, and the configuration data needed to provide those capabilities. The Module Manager is also responsible for loading scenarios and publishing the configuration data specific to each

module to enable the capabilities required by the scenario. The Modules must validate their configuration and report the operational status of each of their enabled capabilities. The Module Manager will aggregate the operational statuses of all the modules to determine if all of the required capabilities of a scenario are available and operational. (Figure 2 above in the beginning of this report details this process).

The Simulation Manager is a core software module that drives the simulation by publishing simulation ticks at a frequency of 50 Hz.

The Logger is a core software module that monitors DDS message traffic for the purposes of analysis, debugging, and general health of the system.

The REST Adapter is a web service that converts REST requests to DDS messages in support of web browser-based modules like the Dashboard.

The TCP Bridge is a socket server that handles tcp communications with socket clients and converts them to DDS messages in support of modules which cannot natively implement DDS but can open network sockets such as the virtual patient and virtual equipment.

The Serial Bridge is a service that handles communications with hardware over a serial interface and converts them to DDS messages in support of physical components with microcontrollers.



Figure 26. View of tablets

In addition, the Chest Rise and IV Arm manikin modules were integrated.

The ACS Alpha scenario was used as a test-case to identify discrepancies, which are summarized in the attached spreadsheet.

Messages were successfully passed among the various modules via DDS. Thus, an IV catheter appeared on the virtual patient when the fluid sensor in the arm sensed flow, and the chest moved and heart beat at the respiration rate and heart rate computed by BioGears.

Some BioGears respiration and blood gas values did not respond appropriately, as identified in the attached spreadsheet. These issues are being reported to ARA, who are working with us to identify the source of the discrepancies.

Finally, some opportunities to improve the usability of the Instructor Tablet were identified. These mostly involve resizing and rearranging displays and controls.

G. Fluidics System

The fluidics supply system was integrated and assembled in a set of external enclosures for the internal integration/demo (aka Mule #1). The external configuration was chosen to facilitate development and trouble shooting. The demonstration scenario is a clinical procedure and the manikin will be draped. The target for final manikin is integration of the major fluidics components in a leg.

Functional requirements specifications for the AMM fluidics supply system are complete and were shared with Entropic Engineering for development of application software. During the integration event the fluidics system was connected to the new embedded controller stack (AMMDK). The stack contains a few key components for operation of the fluidics system. The motor controller module is integrated into the stack. Additionally, four pressure transducers are integrated into the embedded stack and only require a small gauge piece of tubing to connect to test ports in the fluidics system. Basic software functionality for the fluidics supply system was implemented and brought online during the integration event. A control loop to pressurize the system (two fluids and air) and control pressure to a setpoint was tested and is functional. Additionally, delivery of simulated blood to the IVC model was implemented and tested as well.

The fluidics supply system is designed to provide pressurized fluids, air and liquid waste removal to all segments of a physical manikin. The fluids supplied are simulated blood and clear fluid. The latter can be customized to simulate sweat, peritoneal fluid, urine, or tears etc. depending on application. Pressurized air is also made available to all segments.

Additional system design features:

- Double sided spill proof connectors at module interfaces (no leakage)
- Reservoir refill via spill proof quick connect
- Quiet operation pumps/valves/hoses/exhaust ≤ 45 dB
- Low system pressure for air and fluids 15 psi max
- Constant pressure fluid supply via flexible accumulator/reservoir
- Single intermediate power source: compressed air

The current benchtop system is limited to 7 psi system pressure for air and fluids based on available flexible reservoirs. A system pressure of 15 psi is targeted for the final system and component design/sourcing is planned. Reservoir capacity at the integration event was 1000ml for simulated blood and 500ml for clear fluids.

The fluidics supply system can be configured to house the major system components within the torso. Alternatively, the compressor may be placed in any other segment or externally. The main manifold, check valve manifold and reservoirs can be placed in any segment or externally. However, these components have to be collocated as a group. Two small manifolds that facilitates purging of internal lines will be placed in the torso. Figures 27 and 28 below show the component overview and schematic.

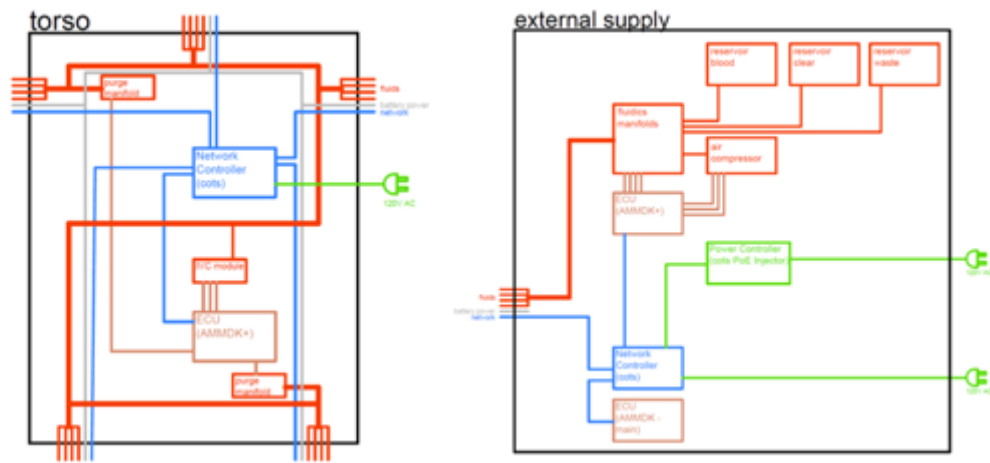


Figure 27. AMM system component overview at Mule 1 integration

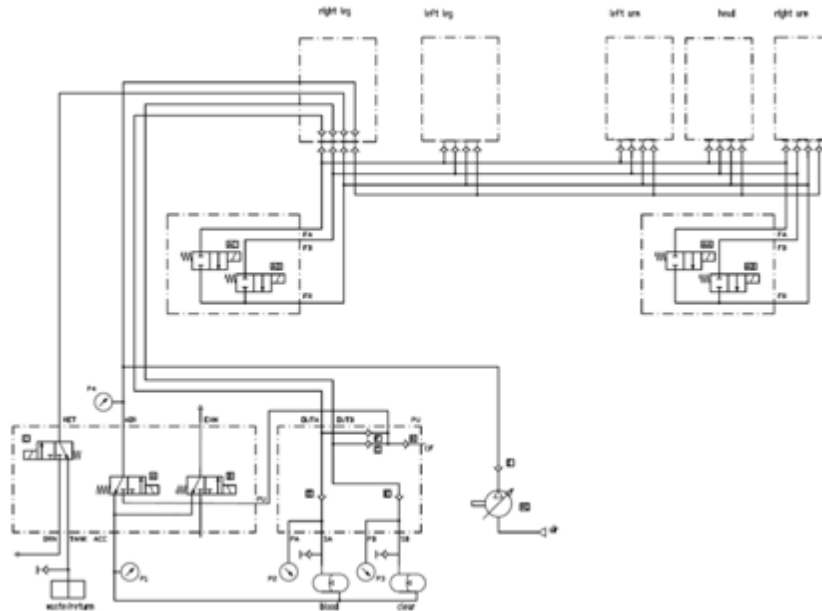


Figure 28. Fluidics supply system schematic showing external supply layout

The fluidic design for the IVC hemorrhage model has been proposed. See Figure 29. This model is part of the laparotomy module which is being developed by UW.

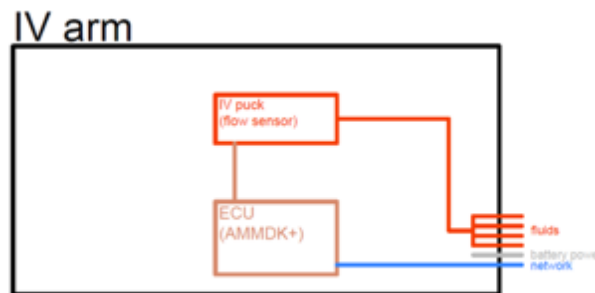


Figure 29. IVC hemorrhage module system schematic



Figure 30. IVC hemorrhage module under test at Mule 1 integration

For Mule 1 we used individual fluid connectors as a stand-in for the segment connectors as seen in Figure 30. Connector analogue is shown in Figure 31 and the fluid system specifications in Figure 32.

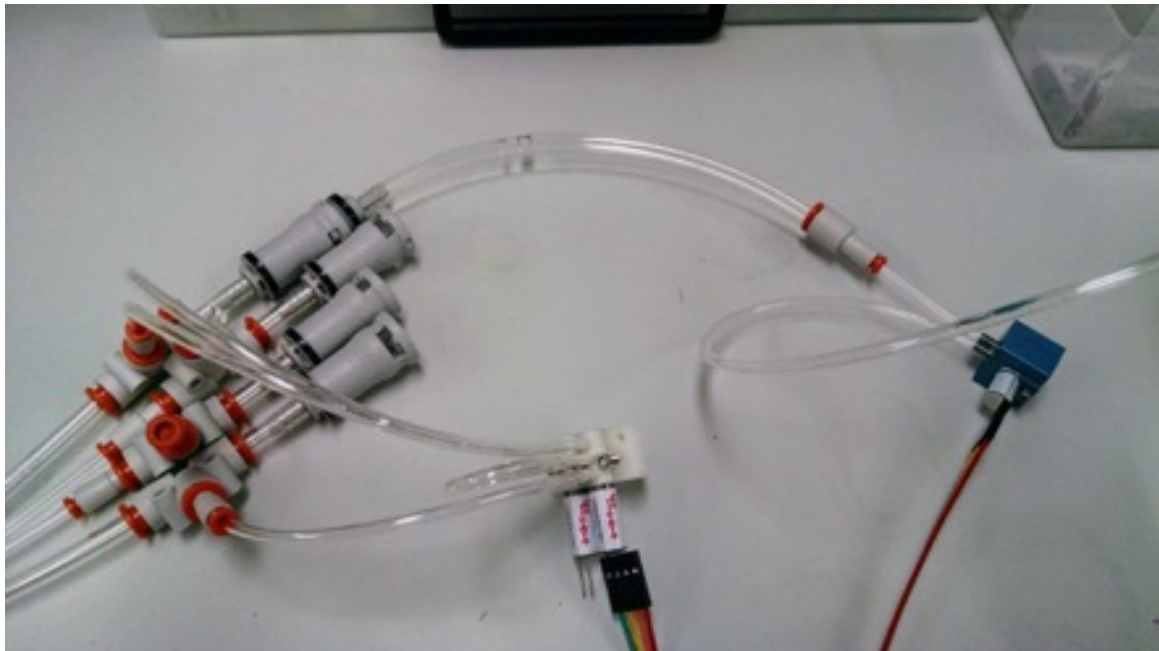


Figure 31. Connector analogue with ports for blood, clear, air and waste (left); purge manifold (center); hemorrhage valve (right)

	Fluid	Flow rate	Pressure	Reservoir capacity/other
1	blood simulant	1.5 l/min	1.03 bar	≤ 6 l
2	clear fluid (water)	250 ml/min	1.03 bar	≤ 1 l
3	waste/discharge (liquid)	500 ml/min	1.03 bar	≤ 2 l
4	compressed air	5 l/min	1.03 bar	

Figure 32. Fluid system specifications.

Manikin Structure

While year 1 of the AMM project was primarily dedicated to generating the anatomical datasets, ideation and concept work around physical form of an AMM compatible manikin, efforts in year 2 focused on developing a practical form to demonstrate the capabilities of AMM and serve as the trainer for an ACS study.

The manikin structure was laid out to provide a structural chassis, support segment connectors, a head connector and a rib cage and control system to simulate chest rise. Furthermore, to accommodate the goals of the ACS study scenario, development of a modular abdominal module was undertaken. This module made it possible to swap out key functional components in the abdominal space. The vision the team has for the manikin has been that of a LEGO™ set, that will allow for the rapid design of new modules based on a common set of mechanical and electrical components.

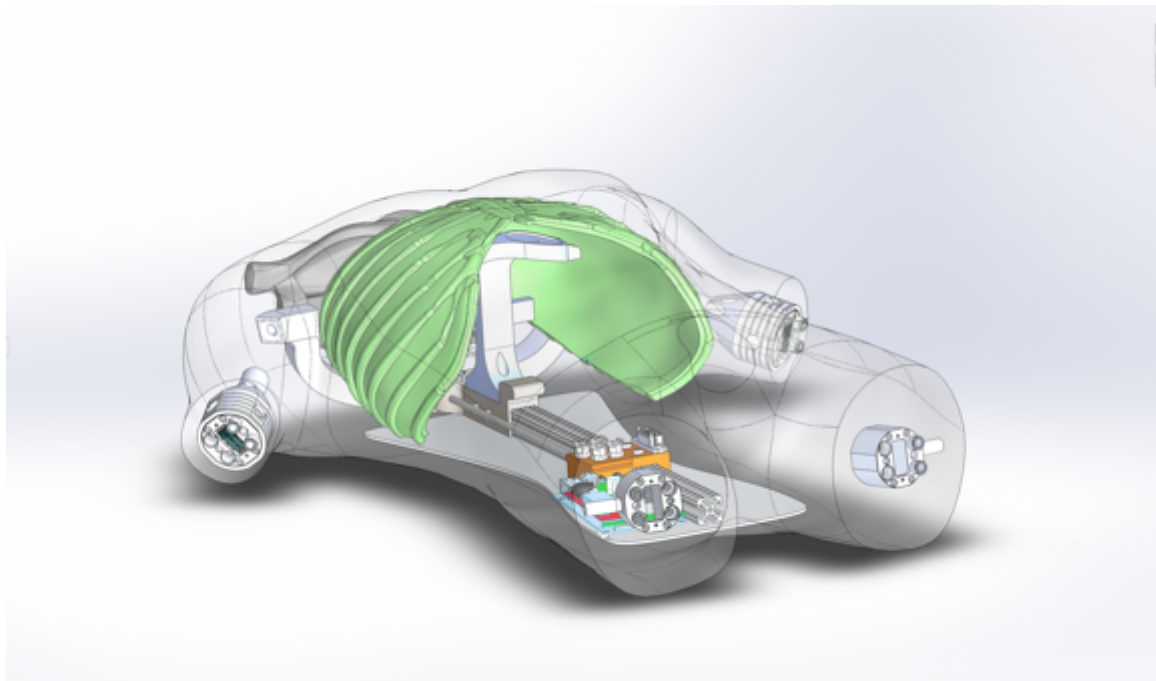


Figure 33. CAD rendering of structural manikin chassis for the torso

The basic internal structure for the manikin torso was developed and is in the process of refinement as shown in Figures 33 – 38. Structurally the torso is supported by t-slotted aluminum extrusion mounted to a base plate. The thorax will house the chest rise mechanism developed under the Advanced Airway Trainer project (Contract No. W911NF-17-C-0043). Key components are mounted to the aluminum extrusion to support relevant loads. To accommodate the abdominal module, space for all chest rise components is limited to the volume above the diaphragm. At this stage of development, the team plans to have the head integrated with the torso. The manikin head is planned to support endotracheal intubation.

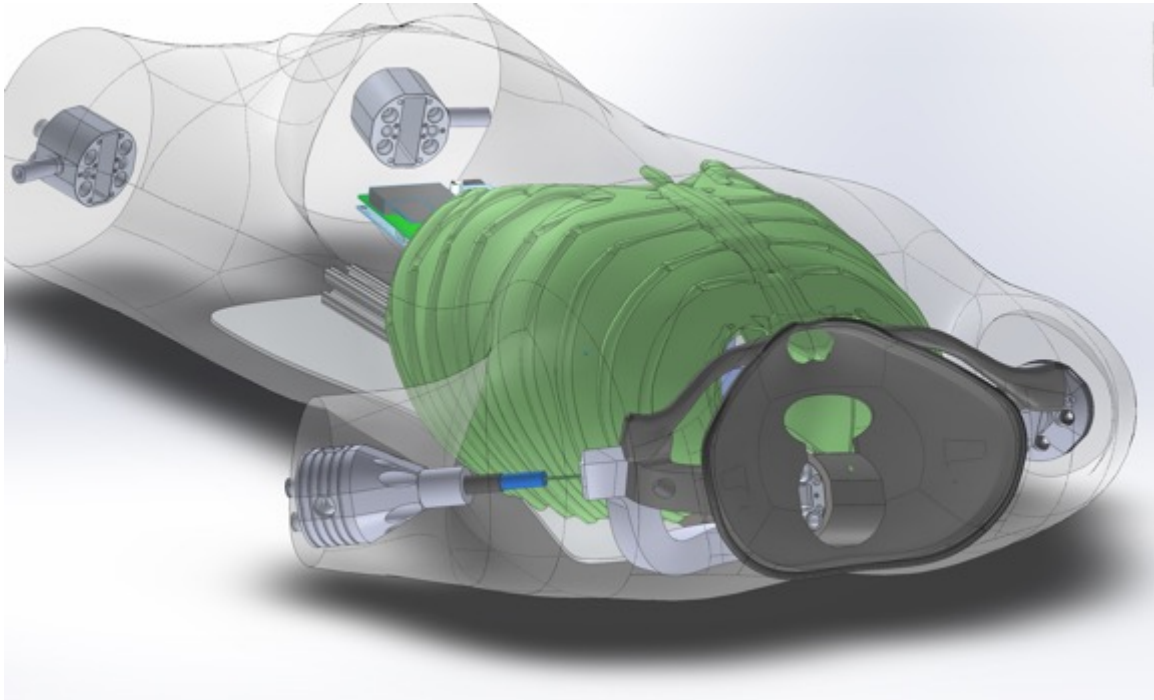


Figure 34. Structural manikin chassis with head interface plate, head connector, shoulder joints and rib cage plates

In order to make swapping out the abdominal module a user-friendly process, a connector arrangement in the area of the spine that provides fluids and electrical connections to the abdominal module has been developed. Unlike arm and leg modules the abdomen is not intended to be a complete AMM module. The decision was made to keep the embedded module controller in the torso outside the abdomen space, and route discrete sensor and actuator signals into the module and the electrical connector.

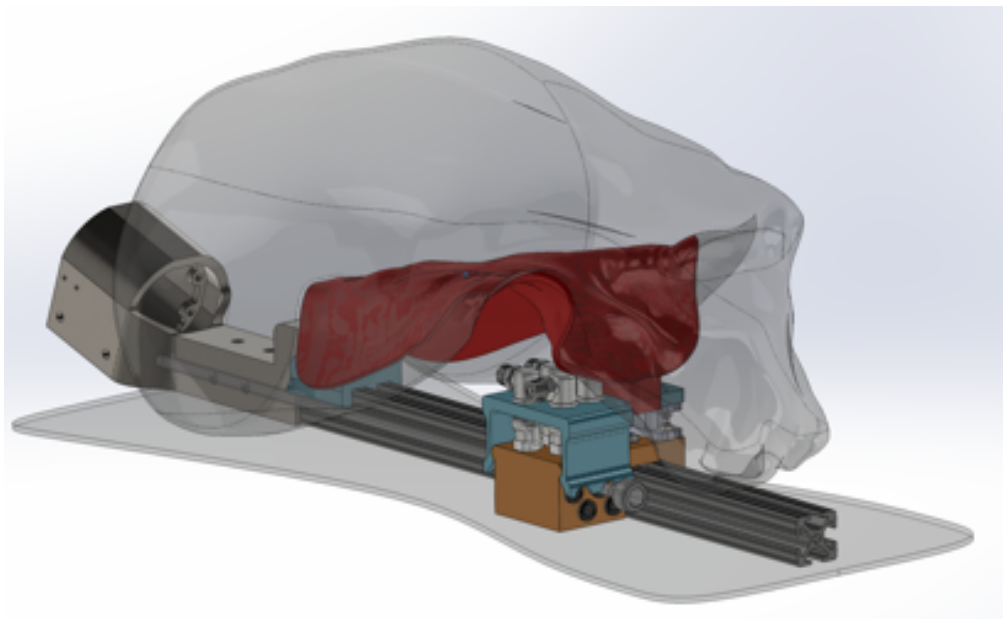


Figure 35. Spine connector and abdominal module

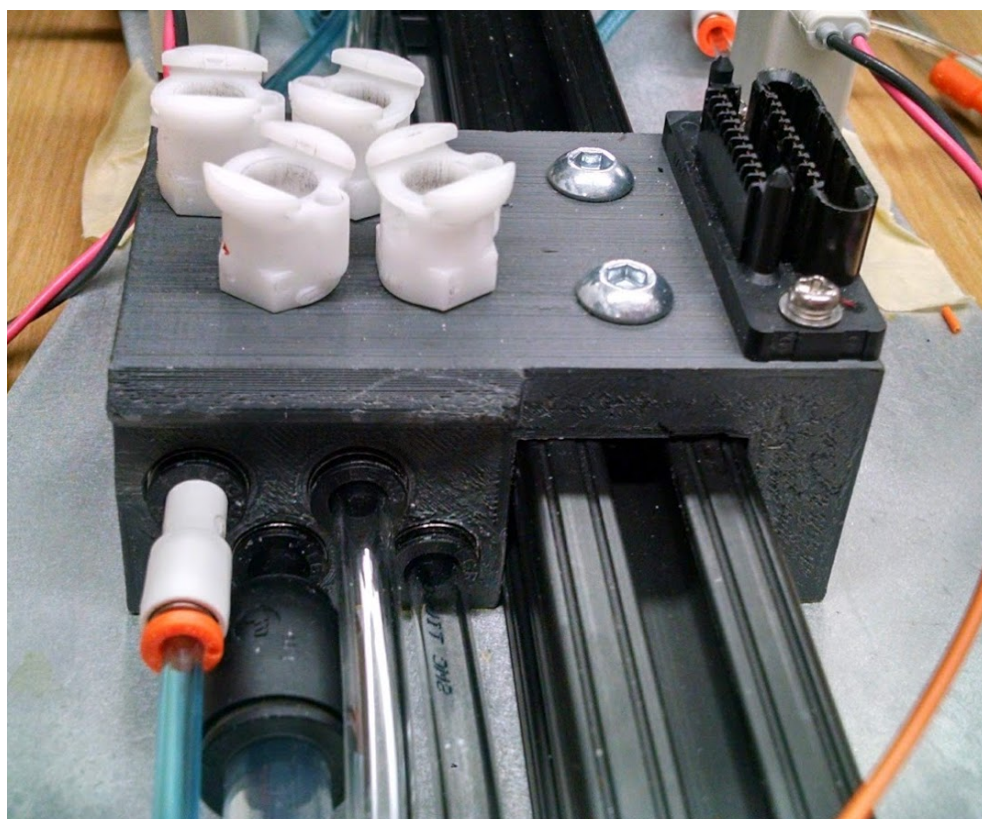


Figure 36. Spine connector prototype, fluid connections shown on the left, electrical on the right of the structural chassis profile

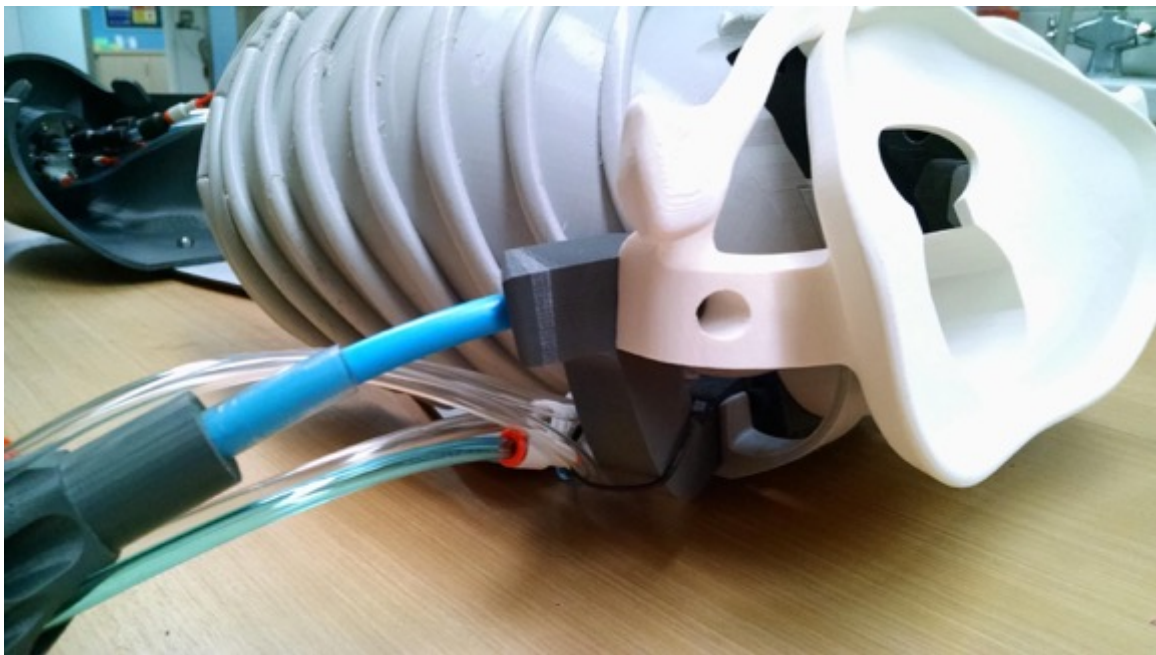


Figure 37. Prototype of shoulder joint, head connector plate and rig cage



Figure 38. Chest rise actuation bellows with support and displacement sensor mounting locations; rib cage with floating sternum

During year 2 performance period of the AMM project two system integration events were held. For these week-long events the components and software developed by sub-contractors and vendors were brought together and integrated to access state of progress, system performance and work out interoperability issues. The Mule 1 event was held in May 2018 and Mule 2 in October 2018. During Mule 1 the electronics, fluidics and several software

modules were successfully integrated as seen in Figure 39. To demonstrate the fluidics system capabilities a bleeding vena cava prototype module was shown Figure 40. During the Mule 2 event the manikin in development for the ACS study was physically integrated. Major components that were included in this effort were structural torso chassis, segment connectors, spine connector, shoulders, airway head, electronics, fluidics routing, chest rise ribcage and control system. The manikin (without skin) is shown in Figure 41. The chest rise functionality successfully tied in with the AMM core's physiology engine.

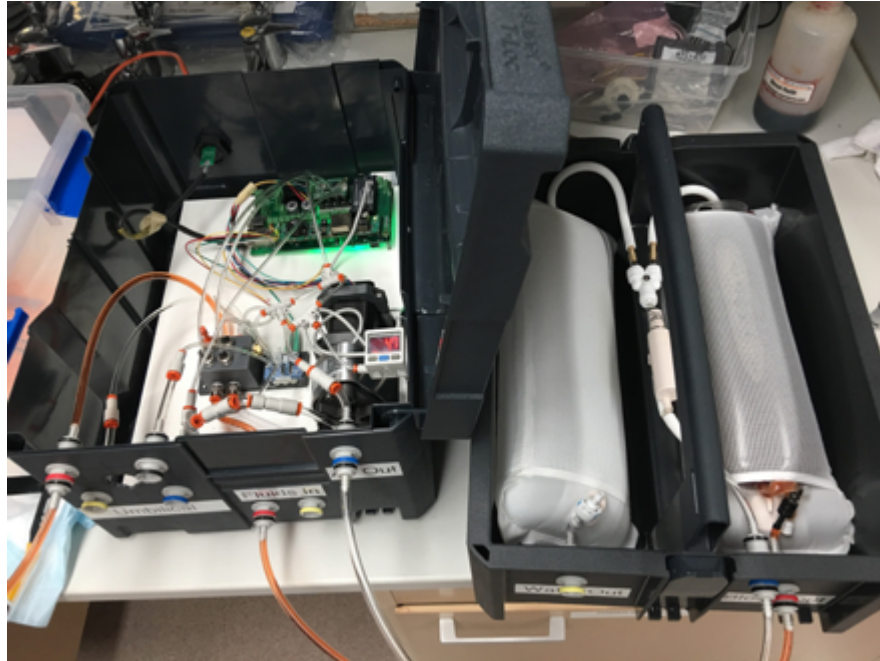


Figure 39. Mule 1 Integration: Fluidics System being controlled by the AMM boards

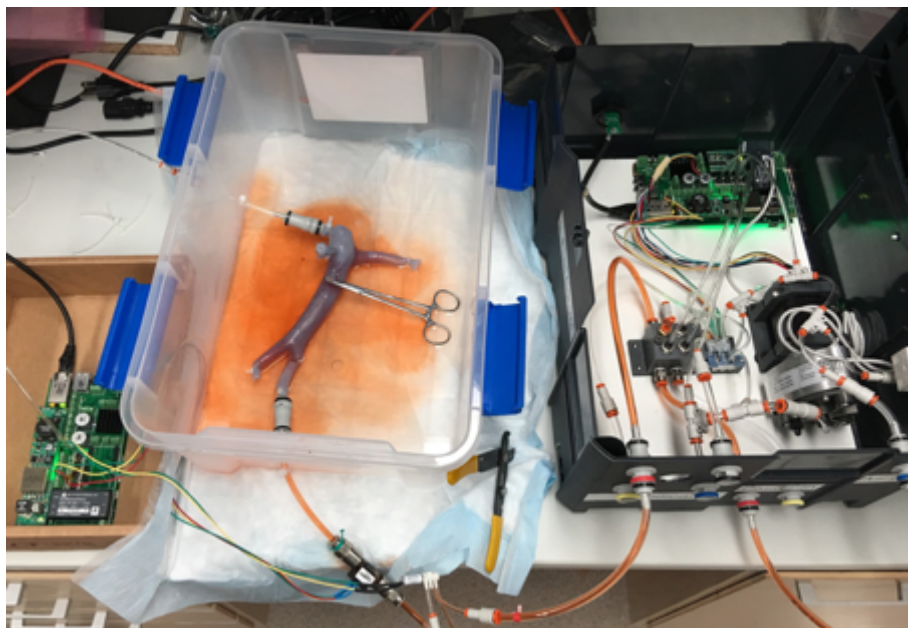


Figure 40. Mule 1 Integration: Bleeding Vena Cava prototype module connected to Fluidics system, both running on identical sets of AMMDK CCB & Application Boards

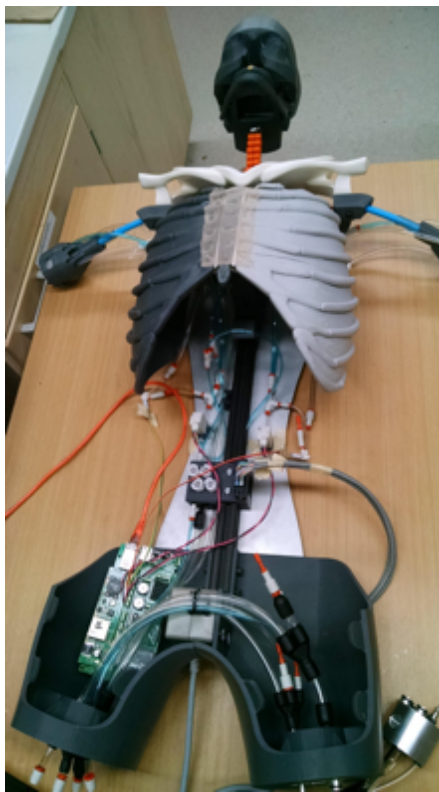


Figure 41. Mule 2 integration of prototype manikin with chest rise module, the abdominal space is open to accept an abdominal training module

H. Module Integration

As part of the Year 2 effort the CREST team has been working with a number of external researchers and industry partners to begin integration of select modules/part task trainers. The purpose of this effort is to test the completeness of data models, standards, and ease of working with the Advanced Modular Manikin Developers Kit (AMMDK).

The following is a partial list of such modules:

Company/Institution	Module	AMM Version
ARA/BioGears	Physiology Engine	Alpha
Vcom3D	Virtual Patient, Patient Monitor	Alpha
CAE	VR Ultrasound FAST exam	Alpha
SIMETRI	Fasciotomy Leg	Beta
ACDET	Abdominal Palpation Trainer	Alpha
Entropic	Intelligent Syringe	Alpha
Charles River Analytics Inc.	MEDIC	Beta
University of Illinois	ECMO Simulator	Beta
OHSU	Neurosurgical Simulator	Beta

I. Verification and Validation Testing

Significant progress has been made in the AMM test verification and validation effort over the past year. Year 1 was for high level test design, test architecture, and defining the test strategy/plan. In year 2, the focus was on testing critical component and basic integration of subsystems. In Year 3 the focus will be on testing the completed manikin system and clinical trials.

The UMN test team consists Dr. Mojca Konia, Dr Kenneth Kiberenge, Dr. Jon Keller (UW), John Hoschette, Dr. Tim Kowalewski, and students Rebecca Smith and Mark Gilberston. (Figure 42). The students started setting up the AMM verification lab, writing detailed protocols and obtaining test equipment. The students are receiving mentoring from Professor Timothy Kowalewski, PhD and Entropic Engineering.

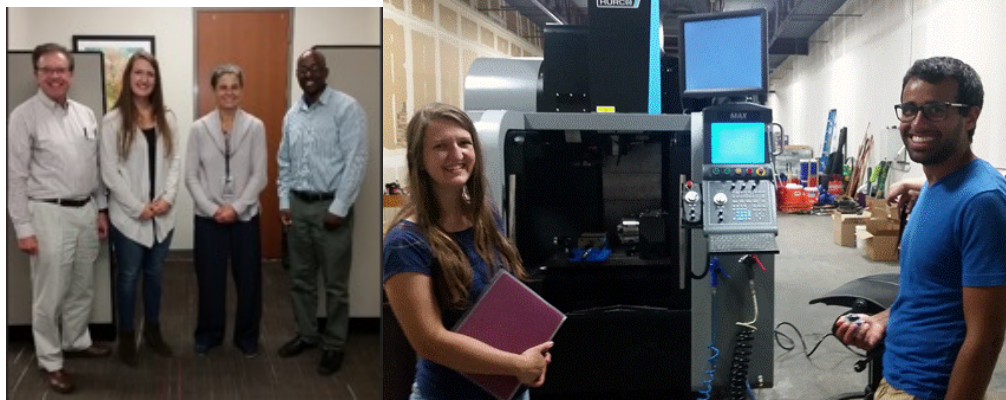


Figure 42. Left: (L-R) John Hoschette, Rebecca Smith, Dr. Mojca Konia, Dr. Ken Kiberenge. Right: Students at Entropic Observing Connector Manufacturing

1. Connector Testing

In year 1 the team unsuccessfully pursued the path of working with commercial off the shelf connector vendors to create a blind mate hybrid connector for the electrical and fluid lines to be used for connecting manikin modules. At the start of year 2, a custom hybrid connector concept was designed which allowed for use of low cost electrical and fluid inserts into a custom holding shell.

Mid-way through Year 2, prototype connectors were built and evaluated. Early prototype models are shown in Figure 43. Estimated cost for this low-cost connector were in the range of \$100 to \$150.

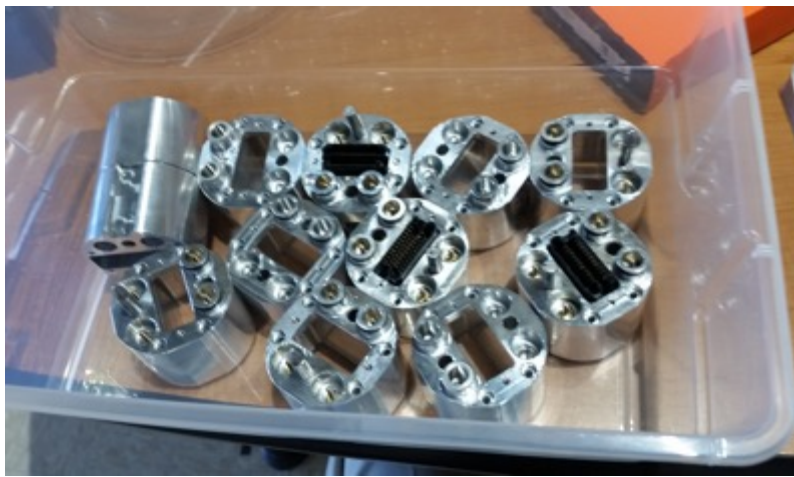


Figure 43. Early Prototypes

In the last portion of Year 2, connector prototypes were fabricated and completed mate/demate tests, pull tests and torque tests. The further testing for vibration is planned in first part of year 3. This section describes the results of testing completed in year 2.

1.1 Connector Mate/Demate Testing

The first test conducted was the mate/demate test. For this test the connector was mated and demated over 2000 times by hand. 2000 was chosen based on low cost standard connector specifications and the estimated number of times the AMM manikin modules would be connected and disconnected in a life time. Visual inspection of the connector showed some wear, but fluid and electrical lines were functional as well as the latch mechanism. The latch pins used were noted for rusting, so a new rust resistant latch pin material was selected and used on next version of prototypes.

Conclusion from this test was the connector design approach was good for the AMM application.

1.2 Connector Axial Pull Testing

The goal for the pull test was set at 200+ lbs. This goal was established based on pulling the arm or leg module when a 190 manikin is full dressed with back pack.

The pull test for electrical continuity was conducted first. Using a simple electrical circuit with visible LEDs the test was conducted and the electrical connectors maintained continuity up to 200+lbs.

The test setup to check for the leakage of fluid during an axial pull is shown in Figure 44. Each of the four valves were tested individually. The test was performed four times, one test for each valve.

For each test, an axial load of at least 200 lbs was applied (first test: 207 lbs, second and third test: 219 lbs, fourth test 223 lbs).

A DC motor pump was used to run water through the fluid line. While there was no way to measure the pressure directly in this experiment, it is estimated that the applied pressure was ~13 psi, based on previously measured motor performance.

During and after each test, the connector was inspected for leakage. In each case, no fluid appeared to be leaking. The exterior of the connector, as well as the fixture holding it, remained completely dry throughout the entire experiment.

Our conclusion from this test is that the connector is successfully able to withstand a load of 200+ lbs without leaking fluid.

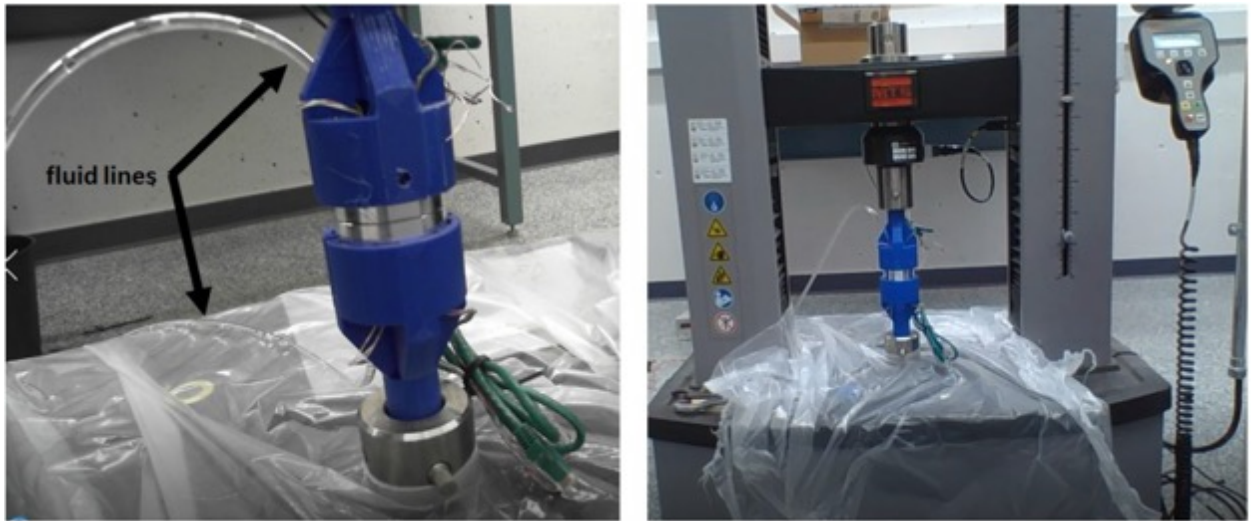


Figure 44. Pull Test for Fluid Leaking

1.3 Connector Torque Test (Three Point Bending Test)

The test setup for the Torque test (three-point bending) is shown in Figure 45. For each test, the maximum applied load was 700 lbs (3.1 kN), and the two supports at each end were 1 foot apart. Since the maximum applied moment in a three point bending test is equal to $[(\text{Applied Load}) \times (\text{Distance between Supports})]/4$, the maximum applied moment was equivalent to $(700 \text{ lbs}) \times (1 \text{ ft})/4 = 175 \text{ ft} \cdot \text{lbs}$. Fluid and electrical lines were connected to determine if electrical contacts were opened or fluid lines leaked.



Figure 45. Connector Torque Testing (Three Point Bend)

The test was performed for two orientations of the connector. Water was run through the fluid line using a DC motor pump. In both orientations, there was a significant amount of fluid leakage. Additionally, there was a significant amount of deformation observed, as shown in the Figure 45.

Unfortunately, most of the leaking which occurred cannot be seen in the videos recorded during this test. However, a video that shows a small amount of leaking and deformation can be seen at the following link:

https://drive.google.com/file/d/1CwkSNjfZrvfZobWjxumssBDa_Kj6UmJL/view?usp=sharing

The electrical continuity of 6 of the contact pins was tested using 6 LED's. The experimental setup is shown in Figure 46.

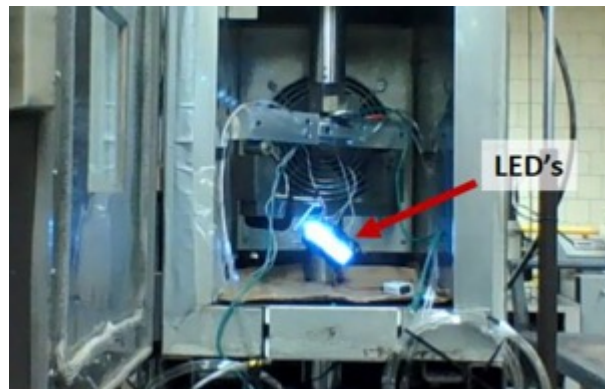


Figure 46. Connector Torque Test for electrical contacts

The test was performed in the same two orientations as in the mechanical test. Throughout both tests, the LED's remained on, indicating that the electrical connector remained in contact for the entire experiment.

Conclusions from Torque Testing

The conclusions from each of these tests are as follows:

- 1) The connector is able to withstand a moment of 175 ft-lbs a couple of times with minimal deformation. However, upon applying the moment 5+ times, significant deformation starts to occur.
- 2) The electrical connection is unaffected by the application of a 175 ft-lb moment.
- 3) The fluid lines leak under an applied moment of 175 ft-lbs.

1.4 Connector Vibration Testing

An initial vibration test was performed on the connector to determine the resonant frequency at which the connector exhibits the strongest response. A white noise test was run with a frequency spectrum of 0-6 kHz, and an accelerometer was used to measure the response. Several different tests were run, including measuring the response of both vibration fixtures by themselves, as well as measuring the response of the connector mounted in the fixture. Shown in Figure 47 are the two ways the accelerometer was mounted: mounted on the horizontal fixture alone (left), and mounted on the connector inside the vertical fixture (right).

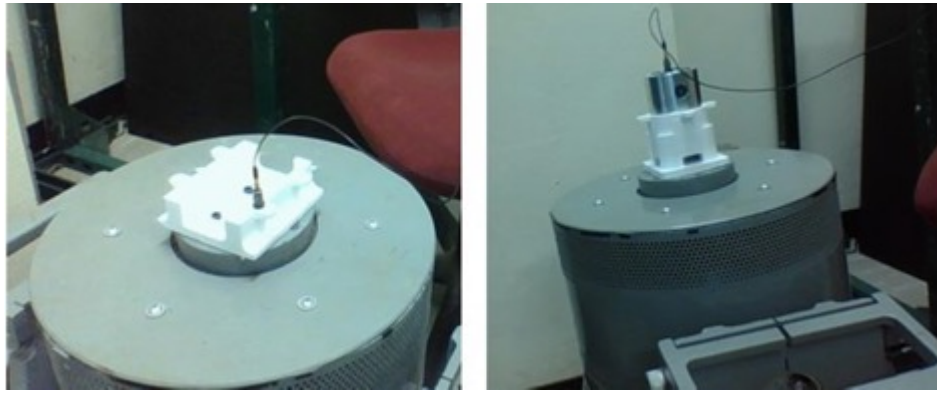


Figure 47. Accelerometer Mounting for Characterization of Vibration Tests

Only one of the horizontal directions was tested (latching button pointing up). This is because the connector did not fit into the fixture after rotating it 90 degrees. If it is deemed necessary, a new fixture will be printed in order to measure the response in the third direction. The following plots depict the accelerometer data which was collected for each of the cases.

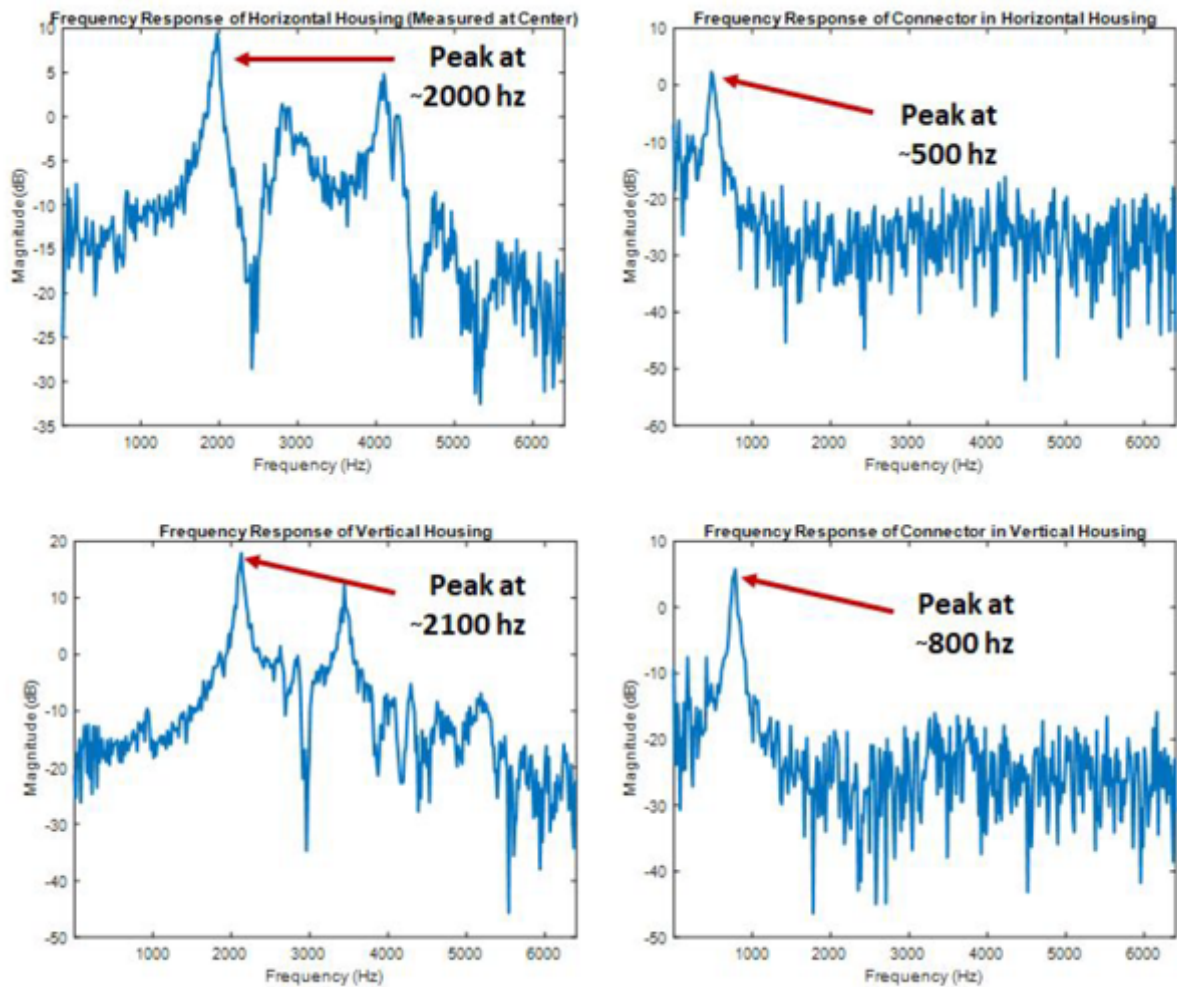


Figure 48. Plots of resonance frequency

As can be seen in the plots in Figure 48, in the cases where the response of the connector was measured, the resonant peak was determined to be around 500 hz (horizontal), and 800 hz (vertical). These values are well within the frequency range expected in helicopter transit. Therefore, one of the next steps will involve checking the performance (particularly electrical continuity) while vibrating the connector near the resonant frequency.

Additionally, because the resonant frequency of a system is largely dependent on the geometry of the system, it is recommended that the connector be tested under the conditions in which it will be mounted in the manikin. It is anticipated that testing the connector as it will be mounted in the manikin (e.g. surrounded by artificial skin, attached to supports, etc.) will be much more informative regarding how the connector's performance will be affected by vibration.

On 8/21/18, the first vibration test was performed. The test conditions included a sinusoidal sweep from 10 Hz to 1.5 kHz. This frequency range was selected based on the possible frequencies expected on a military helicopter, per mil-std 810F. The test was first performed without electrical or fluid hookups to check for mechanical failure (e.g. latch coming undone), but when no failure occurred, the test was repeated with the fluid lines connected. Each test condition was performed along each of the 3 axes of the connector (x,y,z). The Test setup is shown in Figure 49.

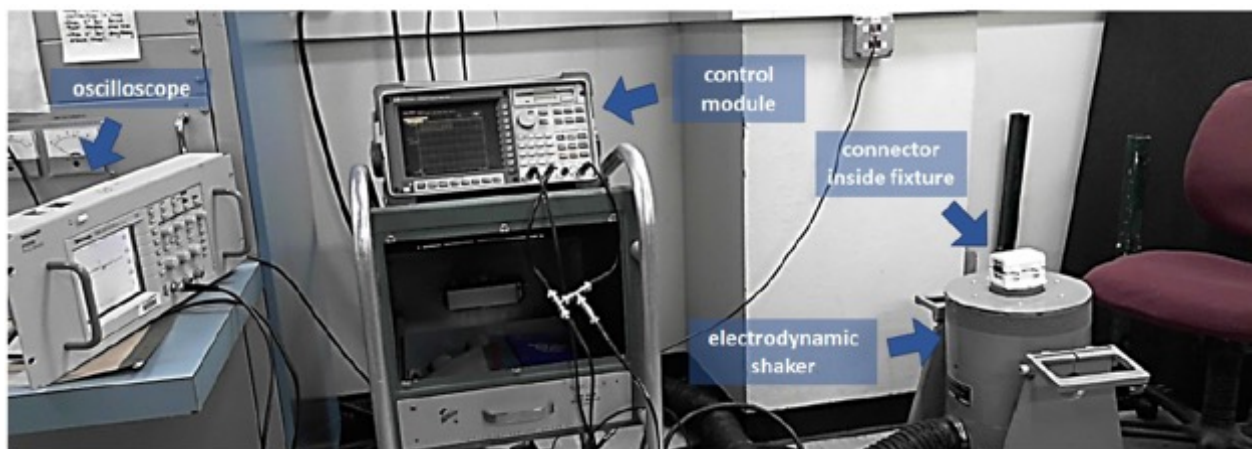


Figure 49. Vibration Testing Setup

Two videos of the test can be seen here:

https://drive.google.com/file/d/17Oqx4oqv_t9Vs09KXqts-69jtbOV5RCR/view?usp=sharing
<https://drive.google.com/file/d/1fkeyNOsoanf2C88p94TwAoKjnzps5kYK/view?usp=sharing>

Figure 50 depicts the test being performed at two orientations:

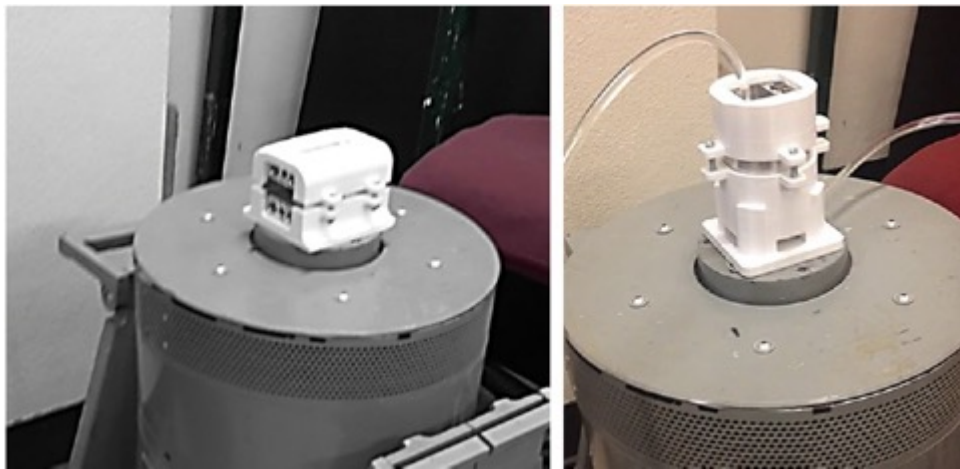


Figure 50. Orientation of Connector on Shaker Table

The fluid system setup is shown in Figure 51.



Figure 51. Fluid System Used for Vibration Testing

Note that, as seen in the figure 52, only one fluid line was used at a time. This was done so that if a valve leaked, it would be easy to identify which valve was faulty. Consequently, each orientation underwent four fluid tests, one for each valve.

Almost all tests were performed without failure. However, after one of the tests, there was a significant amount of water in the base of the fixture upon removing the connector, as can be seen in the following video.

https://drive.google.com/file/d/1zAN_rLWRj_fMMp6nIJgoEq-K3iyPqtIx/view?usp=sharing

Upon first impression, it seemed clear that this water leakage was due to valve failure, as the fluid lines were firmly connected, and there did not seem to be any other potential source of failure. However, after repeating the test several times, we were unable to repeat these results, and there was no leakage after any of the following tests. Therefore, the results of this aspect of the experiment are inconclusive.

The future work to be done on vibration are as follows:

- 1) Repeat the experiment with the electrical connectors intact to check connectivity. In order to do this, we are currently waiting on the tools necessary to assemble the wiring harness.

2) If there is no electrical failure, we will perform a multi-hour vibration test to simulate the vibration life cycle anticipated. This will be based on anticipated helicopter transportation within a single connector's lifetime.

J. BioGears Modification by ARA

Response to the finalized scenario required ARA to implement some modifications to the BioGears physiology engine. The following actions were taken.

For Sepsis (Planned for Beta AMM):

ARA incorporated a mathematical model from literature describing the interaction of a pathogen population and the immune system. A "Sepsis Action" was created that establishes an infection (i.e. an initial amount of pathogen) in the body. The Sepsis Action allows the user to specify a location and severity. The location describes the BioGears compartment which will first begin to experience altered blood flow. The severity establishes how quickly the infection evolves and the time it takes for the virtual patient to enter septic shock.

ARA linked the evolution of the pathogen and immune cell populations to symptoms consistent with systemic inflammatory response syndrome (SIRS), such as fever and elevated heart rate, respiration rate, and white blood cell count. Increased endothelial permeability and tissue hypoxia as a function of pathogen population were included in the model. These events produce systemic symptoms of severe sepsis (hypotension, increased blood lactate levels, decreased urine production rate) via the physiologically-based feedback models already existing in BioGears. A system variable to track Total Bilirubin, which is used to diagnose liver failure during Sepsis, was created. Norepinephrine was added to the BioGears substance library. Norepinephrine is a pressor used during Sepsis treatment to support blood pressure. An action was established supporting Antibiotic administration. The Antibiotic gradually eliminates the pathogen, eventually returning the virtual patient to a normal state. Several example scenarios were created with different severities to illustrate the range of responses that can be produced by the Sepsis action.

ARA highlighted treatment actions (saline infusion, norepinephrine infusion, antibiotic administration) in the examples. A dynamic sepsis and treatment protocol were created in the BioGears Software Development Kit (SDK) and the BioGears Graphical User Interface was patched to include support for Sepsis.

For Pain:

ARA created a "Pain Stimulus" action in BioGears defined by a location and a severity. The location identifies which part of the body is in pain. The severity correlates with the Visual Analogue Score (VAS). ARA included a "Pain Susceptibility" parameter that describes how the virtual patient perceives pain. The Pain Susceptibility parameter modifies the VAS. When a pain stimulus is initiated, virtual patients with high susceptibility report a higher VAS than patients with low susceptibility.

ARA modeled physiological responses to pain severity. Heart rate, respiration rate, and blood pressure increase as pain severity increases. Epinephrine production is stimulated in response to pain. ARA modeled the mitigating effect of BioGears analgesic drugs (Morphine and Fentanyl) on pain severity. As the concentration of an analgesic increases in the body, the

VAS reported by the virtual patient decreases. Finally, ARA created an example Pain scenario in the SDK.

For Action Recognition:

The BioGears team has provided functional patches to the upstream repository <https://github.com/AdvancedModularManikin/DDS>.

The BioGears development team submitted functional patches to the AMM DDS repository on 10/1/2018. Summary of pull request:

- Added types to AMM.idl
- Extended ListenerInterface to use new types
- Provided publishing examples to amm_sim_manager
- Provided listening examples to amm_physiology_manager
- Modified PhysiologyThread to accept lambda functions for execution.
- The BioGears team has extended the AMM/DDS repository to recognize the Sepsis and Pain Response actions.

ARA has introduced the following types to the AMM.idl

- AMM::Physiology::CMD
- AMM::Physiology::TissueCompartment
- AMM::Physiology::Command
- AMM::Physiology::PainStimulus::Data
- AMM::Physiology::Sepsis::Data

The method of initiating and responding to these two actions will model the existing framework of the AMM/DDS repository. Testing using this data will ensue implementation is in-line with AMM generic implementation. Following recognition, BioGears has simulated the physiology for these actions. If the AMM/DDS does not contain messages designed to carry Sepsis and Pain Response physiology, then new messages will be developed and submitted to the AMM/DDS repository.

ARA has performed the following code modifications to support the Sepsis and Pain actions.

- ListenerInterface modified to allow subscription of AMM::PhysiologyCommands
- DDS_Listeners modified to allow subscription/publishing of AMM::PhysiologyCommands
- PhysiologyEngineManager now subscribes to AMM::PhysiologyCommands
- PhysiologyEngineManager now reacts to AMM::Physiology::PainStimulus
- PhysiologyEngineManager now reacts to AMM::Physiology::Sepsis
- The BioGears team has supported data passed over the data bus to flag both actions through BioGears (dynamically). This will not be using the .xml legacy format. Care will be made to ensure that data definitions defined by AMM are used to interpret and initialize BioGears physiology engine.

The following interfaces were modified to accommodate the non-XML based action initiation and initialization.

- PhysiologyThread now process custom BioGears API based lambda functions
- PhysiologyThread now reacts to Pain stimulus and Sepsis commands over the DDS through the lambda interface.
- BioGears patched to 7.1.1 which simulates human physiological response to PainStimulus and Sepsis.

- Use BioGears' simulation to drive AMM manikin response.
- The BioGears team will extended the AMM/DDS driver to react to Sepsis and Pain Response actions and return accurate physiological data to modules. Individual AMM modules will then be responsible for correctly interpreting the documented data.
- amm_sim_manager has been patched to allow the input of pain and sepsis events. This simulates the type of relationships that will occur on a full AMM Manikin network where BioGears is responsible for receiving events and simulating the results that will be published to various modules on the network.

K. Physiology Validation and Verification

During Year 1 of the project, our team worked to understand the usability and limitations of the three physiology engines proposed for use in the AMM project. The team also worked to define the proposed scenarios as well as to perform literature searches in peer reviewed journals on the appropriate physiologic responses for each scenario.

During Year 2 of the project, our efforts focused on robust testing of the BioGears physiology engine, chosen for the AMM project. Additionally, we provided guidance to BioGears on the creation of new actions which include pain and sepsis. The team also worked on creating testing protocols for the validation of the proposed scenarios in preparation for the Alpha prototype. We also provided input on the creation of Vcom3D virtual patient testbed applications, as well as the testing of these applications.

Future efforts for the upcoming Year 3 will include publication of scientific papers highlighting the testing of the various physiology engines, further validation of the new BioGears sepsis action and validation of the new virtual patient test bed applications in preparation for the ACS study.

Verification and Validation Testing:

Over the past year BioGears has released 3 versions of the physiology engine (v6.1, v6.3, v7.0). Validation of the accuracy of each version as well as recommendations to improve the physiology engines was performed throughout the year.

Physiology conditions/states:

The 4 main physiology conditions/states that were verified for use in the AMM include:

1. Hemorrhage
2. Pain response
3. Mechanical Ventilation
4. Sepsis

Hemorrhage Testing: The verification efforts included testing 3 different severities. A hemorrhage rate of 50ml/min for mild hemorrhage, 100 ml/min for moderate hemorrhage and 500ml/min for severe hemorrhage. The scenarios were run for 3minues then a 1L normal saline infusion running at 300ml/min was started. Further testing was performed using packed red blood cells for resuscitation, in place of normal saline.

Mechanical Ventilation: The testing of mechanical ventilation utilized 3 ventilator settings including hypoventilation, hyperventilation, and standard mechanical ventilator (ARDSnet protocol) settings. The testing was run for 150min and the level of PaCo₂ was recorded.

BioGears v6.1:

Hemorrhage Testing: Verification testing recorded the responses to hemorrhage via the heart rate. All levels of severity caused the development of tachycardia with a temporary response to a fluid bolus, as would be expected. Challenges / Limitations: Extensive tachycardia following 1L saline infusion suggestive of fluid overload was noted in the mild and moderate severity testing.

Mechanical ventilation: The mechanical ventilation testing utilized ARDSnet setting, hypoventilation and hyperventilation. The testing was run for 150 min and the level of PaCo₂ was recorded. Challenges / Limitations: The PaCO₂ climbs substantially for ARDSnet mechanical ventilator setting which is suggestive of hypoventilation

BioGears v6.3:

Hemorrhage Testing: The testing was done with the same hemorrhage rates as the previous BioGears version and the results were compared for accuracy.

Challenges/ Limitations:

- In this version, the hemorrhage severity scale ranges from 0-1 using the MCIS rating system and has a variable rate of bleeding depending on blood pressure and volume. This provided a challenge when trying to estimate the exact hemorrhage rates.
- Both mild and moderate levels of severity developed an exaggerated and unrealistic heart rate response to 1L NS suggestive of fluid overload.

Improvements: An update to v6.3 was released with a potential fix to the issue of fluid overload. Testing of this version showed that the issue noted in the previous BioGears versions was resolved. The heart rate decreased appropriately in response to fluid resuscitation as seen in Figure 52. Heart rate (beats per minutes) is graphed across time (s) for mild and moderate hemorrhage treated with saline fluid infusion at 180 seconds. The testing shows the development of tachycardia due to hemorrhage, with an appropriate reduction in the Heart rate after fluid is administered. Mechanical Ventilation: Identical settings were used to test v6.1 and v6.3. The settings were cross checked for accuracy.

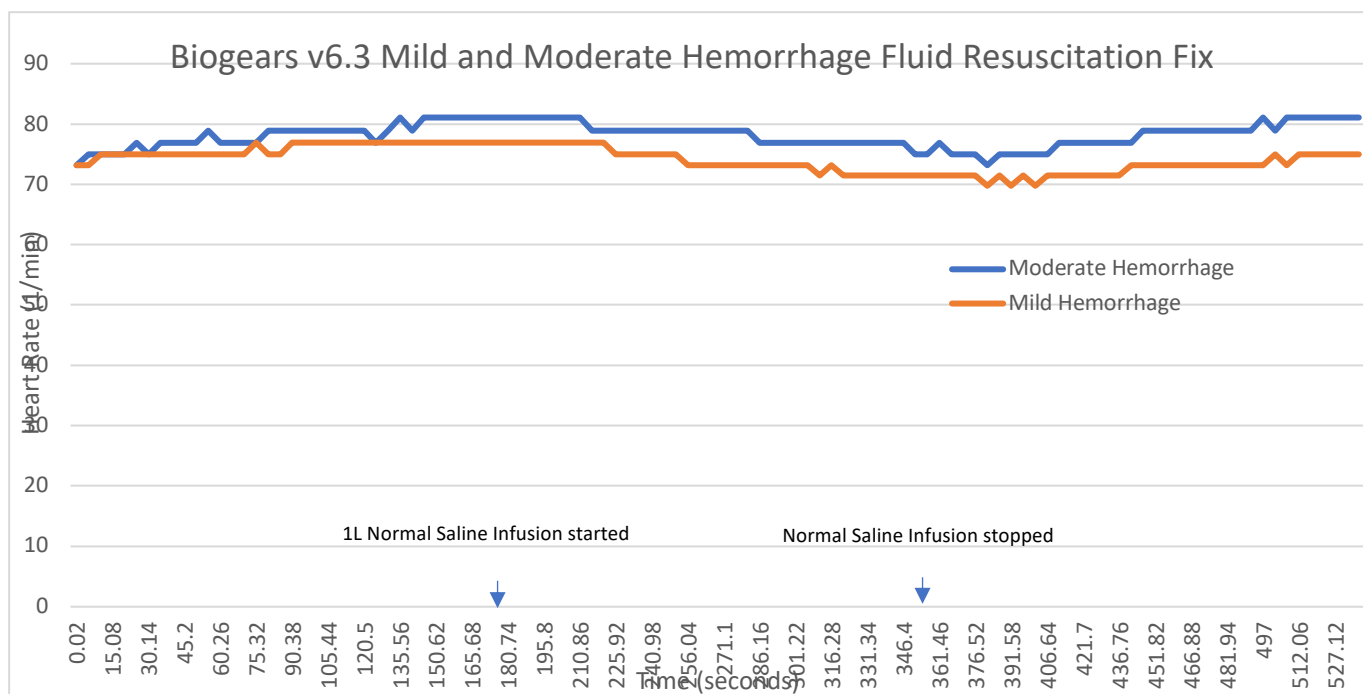


Figure 52. BioGears v6.3 testing with the saline .xml fix.

Improvements: BioGears v6.3 appears to have significantly improved the issues with unrealistic accumulation of Co2. This was particularly clear with standard mechanical ventilation settings (titled ARDSnet settings).

BioGears v7.0

New Actions: Over the past year, extensive recommendations were provided, based on research from textbooks and peer reviewed journals, on the development of an acute pain model and a sepsis model. The latest BioGears version includes these new actions.

Pain Response: To validate the pain action, the scenarios were ran using 3 different pain severities. The severity scale for the pain action ranged from 0-1. The testing used 0.3 for mild pain, 0.5 for moderate pain and 1.0 for severe pain. These scenarios were run for 5mins then an additional pain stimulus was added thereby “stacking the pain response”. The scenario was then run for an additional 5min after which 1mg of morphine was administered. Serum epinephrine levels and heart rate levels were recorded for each run and analyzed for accuracy.

- **Epinephrine Level:** All the pain severities have a rapid rise in blood epinephrine concentration on administration of the first pain stimulus and an additional increase in the epinephrine levels on administration of the second pain stimulus as expected. There is a decrease in the epinephrine concentration on administration of 1mg of morphine. (Fig 53)
- **Heart rate:** All pain severities have a rapid rise in the heart rate on administration of the first pain stimulus and an additional increase in the heart rate when the second pain stimulus is administered. Heart rate decreases on administration of morphine. (Fig 54)

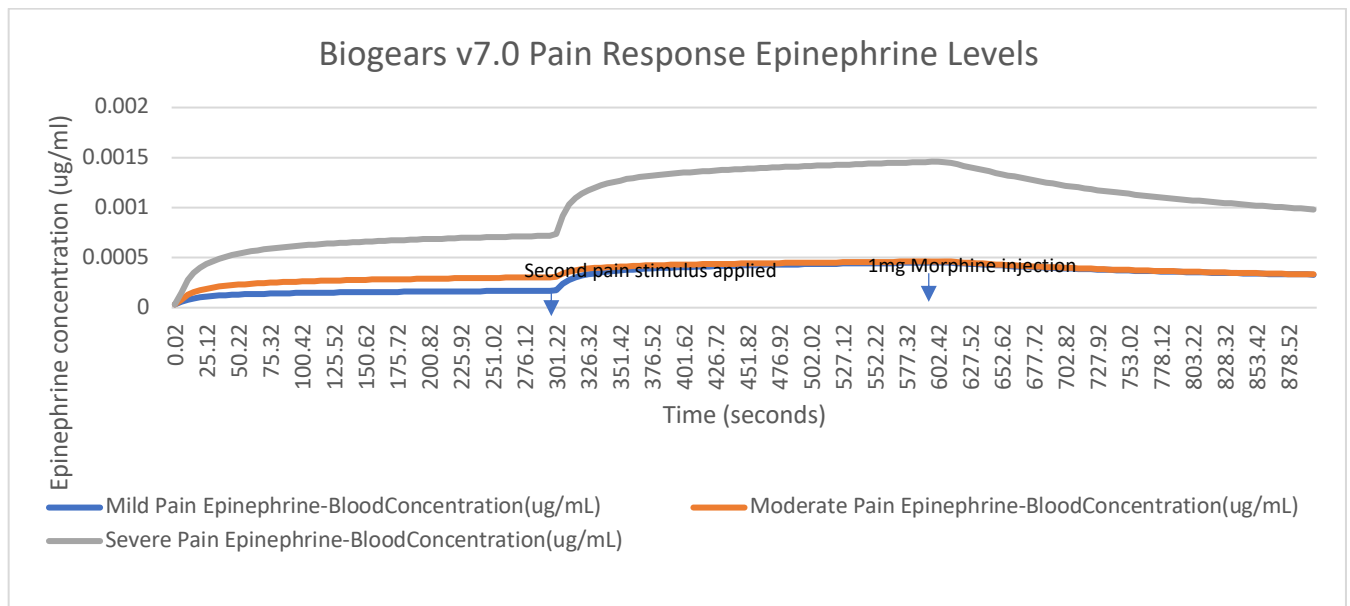


Figure 53: BioGears v7.0 Blood epinephrine concentration for mild, moderate and severe pain. Epinephrine concentration (ug/ml) is graphed across time (s) for mild, moderate and severe pain severities that are treated with 1mg of morphine at 600seconds

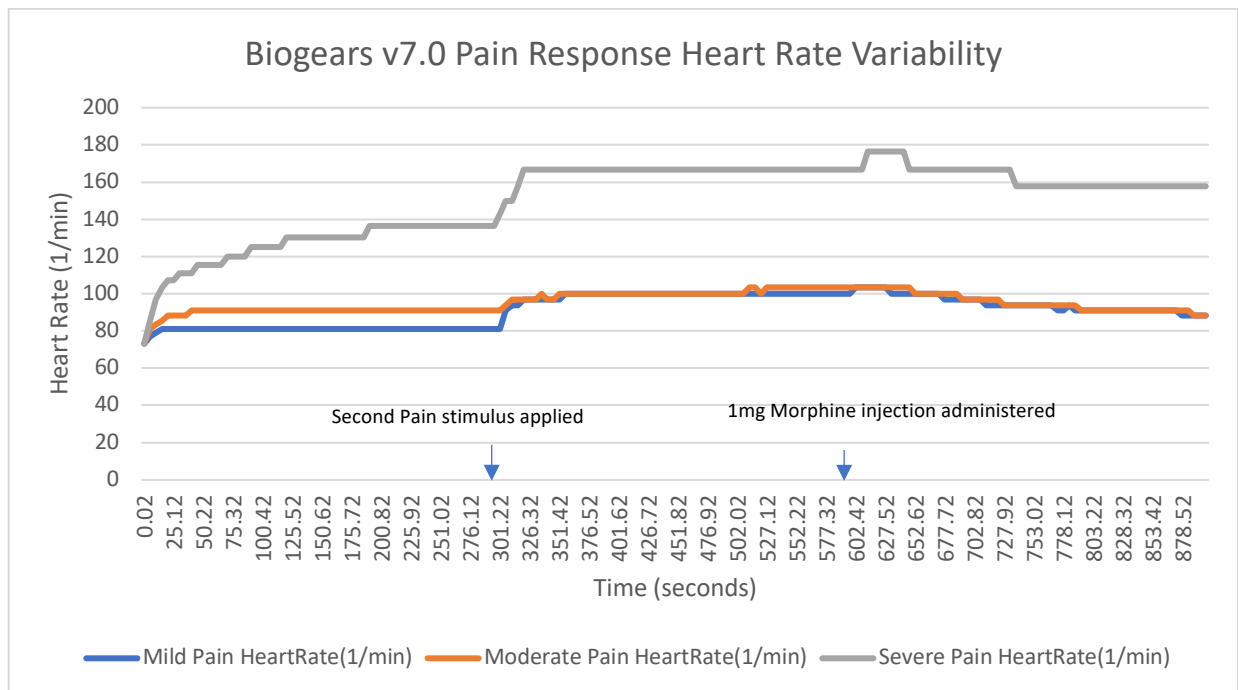


Figure 54: BioGears v7.0 Heart rate response for pain stimulus. Heart rate (beats per minutes) is graphed across time (s) for mild, moderate and severe pain severities that are treated with 1mg of morphine at 600 seconds.

Virtual Patient Test Bed Applications:

VCom3d released a series of applications which represented an integrated virtual patient benchtop testbed (Figure 55). Verification efforts included testing this application and providing feedback to further improve the applications.



Figure 55: Vcom3D Virtual Patient testbed

- Evaluating patient monitor (Figure 4A): The patient monitor system gave outputs for blood pressure, heart rate, respiratory rate, oxygen saturation, CO2 and central venous pressure. The system also has running waveforms for EKG, CVP and SpO2.
- Evaluating the labs module (Figure 4B): The lab module system consists of various hematological tests including; complete blood count, metabolic panel and arterial blood gases.
- Evaluating the Web interface / AMM Dashboard (Figure 4C): The Web interface consists of preloaded scenarios which were utilized to test the system.
- Evaluating the virtual patient (Figure 4D): The virtual patient consists of a female patient with a left chest wound.

Challenges:

- The virtual patient system intermittently “freezes” and the scenarios have to be restarted.
- Actions applied in the web interface take a long time to be reflected on the patient monitor.
- The lab values available in the lab sheet did not reflect all the pertinent lab values to be used for our scenario.

Recommendations:

- Provided a list of additional lab values to be included in the lab sheet.
- Have the ability to look at the last set of lab values in order to observe the trends in the lab values.
- Have a notification system when the lab values became available
- Have a different font color for abnormal lab values.
- Provided guidance on creating a new mechanical ventilator application.
- Provided guidance on creating a new I.V. pump application.

Ongoing Efforts:

- Extensive testing of the new sepsis action to ensure that the results are in line with the known sepsis response based on clinical research in peer reviewed journals.

- The Virtual patient application testing is also ongoing. This includes the testing of the new applications which include an updated lab sheet and mechanical ventilator. A new I.V. pump application is scheduled to be released and will be evaluated.
- Publication of scientific papers: Work is ongoing on the completion a scientific paper highlighting the work done on the comparison testing of three physiology simulation engines.

L. American College of Surgeons (ACS) Validation Study

MAJOR ACTIVITIES

During Year 2 of the Advanced Modular Manikin™ (AMM) project, the core group of staff from the American College of Surgeons Division of Education (Ajit K. Sachdeva, MD, FRCSC, FACS, as principal investigator; Patrice Gabler Blair, MPH; Gyusung Lee, PhD; Kathy Johnson, EdM; and Cathy Sormalis) continued working on the project with Dimitrios Stefanidis, MD, PhD, FACS; Robert Rush, MD, FACS, and Raj Aggarwal, MD, PhD, FRCS, FRCSC, FACS in continuous communication with the UW CREST team (Hananel) and the PI of AMM (Sweet). This year, a small, two-hour focus group was held on September 8, 2017, in Portland, Oregon to discuss the study design, and a one-hour in-person meeting was convened on March 16, 2018, in Chicago. Both meetings were held in conjunction with other meetings that most members of the core group were attending. The substantive progress was made through ongoing conference calls and e-mail communications.

SPECIFIC OBJECTIVES

Activities during Year 2 focused on making final adjustments to the study design, completing the simulation scenario to be used for validation purposes and defining its specific requirements, and establishing the initial operational processes needed to clarify eligibility requirements for the sites.

KEY OUTCOMES

Discussions during Year 2 addressed a broad range of issues and the most important decisions are described below. The group has continued to discuss and refine the study design to ensure its rigor and feasibility. Various options have been debated for over a year, and the group was hoping to be able to use a three-arm validation study to ensure the highest rigor. This year, however, discussions led to the ultimate conclusion that a three-arm study is not feasible given the time frame and available resources. Thus, the study will have two arms and the design will be a two-arm cross-over study as follows: Condition 1 will evaluate the peripherals while connected to the AMM platform, and Condition 2 will evaluate the peripherals without the AMM. The purpose is to assess the differences in experiences (with the AMM and without the AMM) as reported by study participants using a standardized simulated scenario. The design is shown below in Figure 56.

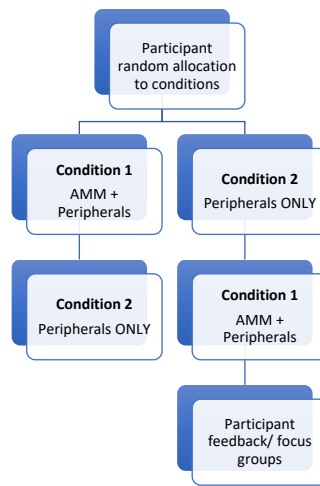


Figure 56: 2-arm validation study as modified by ACS.

Significant progress has been made in development of the simulation scenario that will be used to test and evaluate the AMM. Factors considered in the scenario development process included the capabilities of the AMM to be evaluated and peripherals being developed, the range of clinical expertise of civilian and military participants, the procedures to be performed, and estimated length of the simulation. In its current form, the scenario has three scenes and follows a patient from on-site at a motor vehicle accident to the emergency department trauma bay, to the operating room. The scenario will require a team of three healthcare providers (a first responder, an anesthesiology chief resident or CRNA, and a surgery chief resident) and two confederates (in assistant roles) to perform the following:

- Field assessment
- Monitor placement
- Obtain and continuously monitor vital signs
- Oxygen administration
- IV placement and drug administration
- Immobilization for transfer
- Primary and secondary survey
- Airway assessment
- Venipuncture for laboratory analysis
- IV placement and fluid resuscitation
- Initiation of massive transfusion protocol
- Focused Assessment with Sonography for Trauma (FAST) exam
- Induction of anesthesia
- Intubation
- Nasogastric/orogastric tube placement
- Foley catheter insertion
- Exploratory laparotomy for trauma (splenectomy, cystorrhaphy, and inferior vena cava repair)
- Abdominal closure, or application of open abdominal wound vacuum
- Utilize appropriate communication throughout the scenario

The decision regarding the types of study participants (first responders, anesthesiology chief residents or CRNAs, and surgery chief residents) to be used in the scenario seems to have

been finalized. Also, the number of sites has been defined as five based on the number of mannikins expected to be available for circulation to the sites and the anticipated time available for evaluation. The specific number of participants needed at each of the five sites, however, is still under discussion. Various power analyses have yielded a variety of results based on different assumptions and consensus regarding the appropriate sample size at each site has not yet been achieved.

Three assessment instruments have been drafted for quantitative and qualitative data collection and analysis. The assessment instruments include:

1. The global rating scale asks participants to rate their perceptions across three constructs: simulation, fidelity, and engagement. The instrument allows researchers to gauge a scenario's alignment with clinical objectives; the level of physical, conceptual, and emotional fidelity; and the extent to which the participant feels engaged in the scenario.
2. A second instrument captures data related to set-up and flow of the simulator and simulation from the perspectives of various individuals, i.e., educators, simulation technicians and operations specialists, and administrators.
3. The post-simulation evaluation allows participants to rate specific AMM system features, to assign priority levels to potential items for improvement, and to describe how potential new features of the AMM system would benefit educational programs.

A number of operational factors and strategies have been discussed throughout the year to help ensure the standardization and rigor of the study. Plans being considered include having an AMM technician available for the evaluation periods at each site to ensure the AMM is operating correctly and to make any needed adjustments or repairs. In addition, the importance of having a data officer travel to each site to ensure data are being appropriately collected is being discussed. Development of the research protocol is underway. Specific roles and scripts are being defined for site staff, scenario trainers, and confederates. Lists of equipment, instruments, and disposables to be used in the scenarios are being compiled. Data collection and storage methods and processes are being discussed and developed to ensure the completeness and integrity of the data. A pilot test is planned for early 2019 to allow additional details to be finalized.

An Institutional Review Board (IRB) application has been drafted in initial form and, once additional study details are available, the application will be submitted to the American Institutes for Research (AIR) for review. The results and application will be shared with the local sites as a model for submission of applications to their respective institutions. A draft of a Request for Application (RFA) has been prepared and will be finalized concurrently with the simulation scenario and capabilities of the AMM peripherals to be used for the study. The RFA includes a brief introduction of the AMM project, the roles and expectations of the selected sites, resources required and to be made available to each site, and timelines.

Administrative progress this year includes the negotiation and full execution of agreements with both surgeon consultants and their respective institutions. Updated information from the University of Minnesota was most helpful in this process and established language that could be agreed upon by all parties. The agreements have allowed payment to each surgeon for their efforts in Year 1 and Year 2; thus, the invoices from the ACS have been generated and are being submitted to the University of Minnesota.

During Year 2 of the AMM validation project, important progress continued, and substantive decisions were made regarding the development and implementation of the validation study. A definitive conclusion regarding sample size is needed to move the project forward and timely receipt of the mannikins will be key to completion of the study. Budget review and recalibration, now that the effort is becoming more clearly defined, is near completion.

4. Impact

Adoption of AMM Standards by other Projects.

AMM interoperability standards have been adopted by two DHA-funded Small Business Innovation Research (SBIR) projects and, more recently, an Army Broad Agency Announcement (BAA) project. These early-adopter projects are providing further feedback on the usability of the standards and demonstrate its adaptability to a range of medical treatment facility roles, patient conditions, and provider capabilities. They also show the ability to tailor the implementation for use with part task trainers and virtual simulations using inexpensive hardware. Results of the two SBIR projects were demonstrated at the International Meeting on Simulation in Healthcare (IMSH) in January 2018.

Blended Reality Medical Training System, (BRMTS), Contract No. W81XWH-17-C-0161.

For this project, Strategic Operations (STOPS), with Vcom3D as subcontractor, is developing a Humeral Head Intraosseous (HHIO) infusion training system. Vcom3D integrated the AMM Core on a credit card-size SoM embedded in a Humeral Head Intraosseous (HHIO) trainer as seen below in Figure 57. Also embedded is a microcontroller (shown in correct size proportion to the SoM). The system also includes a virtual patient, virtual patient monitor, and instructional software, all of which interface with the CORE. Thus, the virtual patient responds appropriately to simulated blood loss and infusion of fluids.

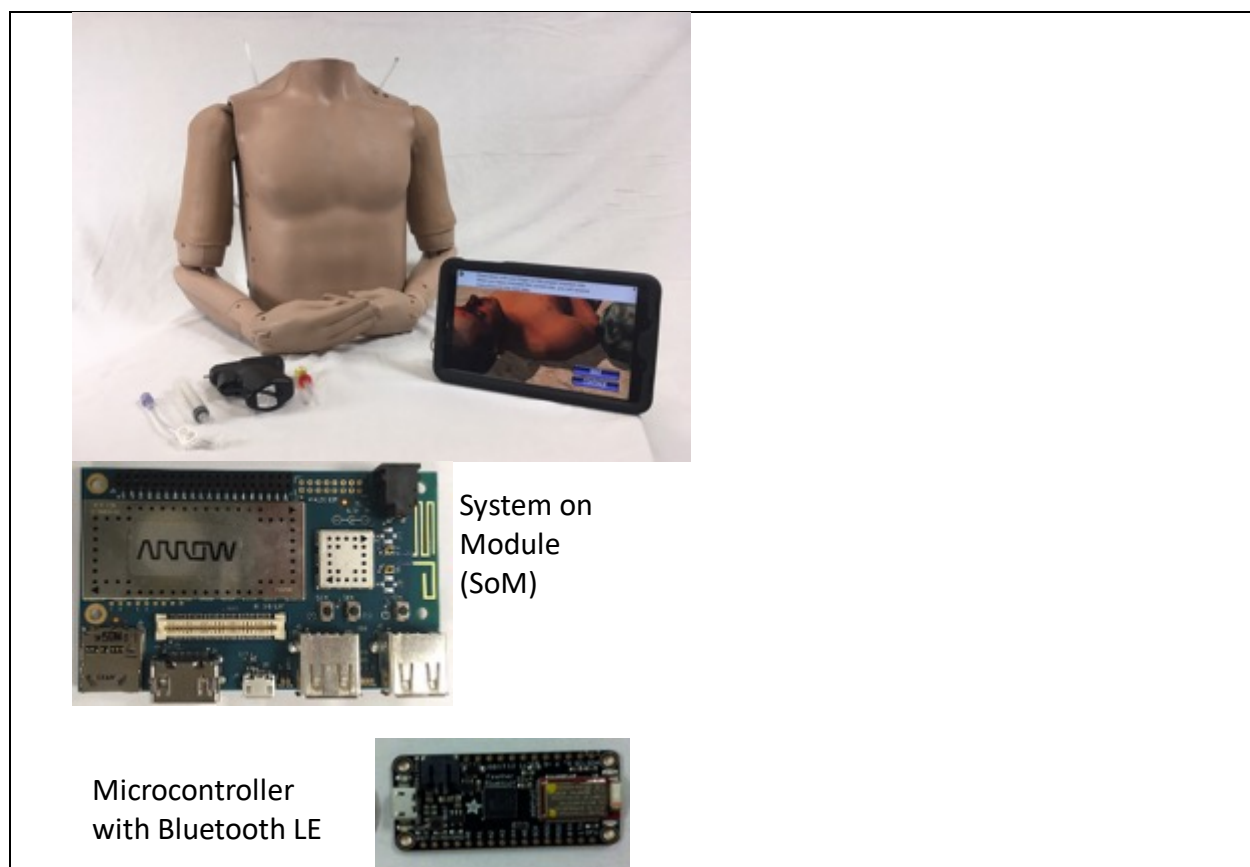


Figure 57. The BRMTS implements the AMM Core on a credit card-size computer embedded in the HHIO trainer.

Advanced Female Trauma Training System (AFTTS), Contract No. W81XWH-17-C-0181. For this project, Vcom3D, with University of Washington CREST as subcontractor, is developing a manikin and virtual patient for training Combat Medics and other providers in treating female victims of battlefield injuries. As with the BRMTS, the AFTTS implements the AMM Core on a credit card-size SoM and integrates a virtual patient, virtual patient monitor, and a manikin with sensors. However, the AFTTS includes lab reports and the manikin includes actuators as well as sensors. For the Phase I prototype, we simulated a tension pneumothorax and the response to needle decompression, infusion of fluids, and pain medication. Response to the pneumothorax and decompression includes uneven chest rise (both in the manikin and in the virtual patient) and poor oxygenation. For the current Phase II, we are developing a simulation of chest rise and its response to pneumothorax and its treatment by needle decompression, as shown in the Figure 58 below.

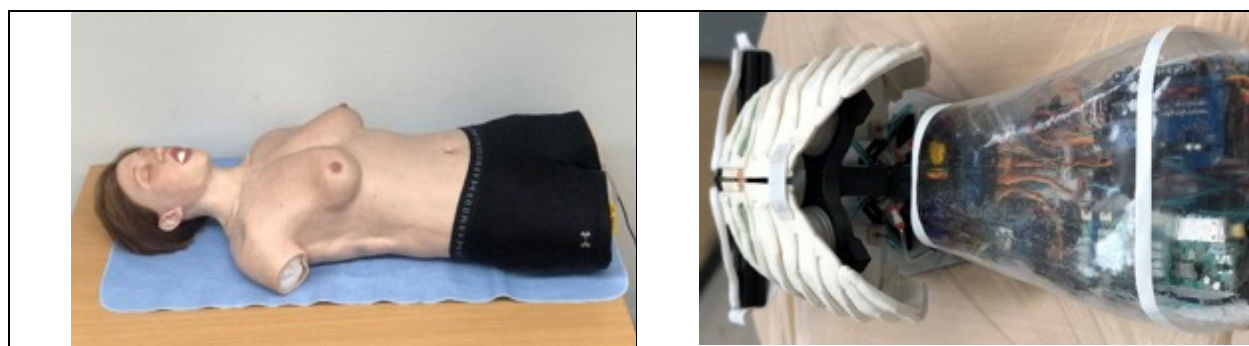


Figure 58. AFTTS Manikin and Chest Rise Mechanism

Immersive Modular Patient Care Team Trainer (IMPACTT), Contract No W911NF-18-C-0040. Vcom3D was recently awarded a project to develop an Advanced Virtual Patient with team training capabilities. This system will use the same messaging, scenario control, and physiology modeling infrastructure as AMM and AFTTS. The initial training scenarios will include burn patients who receive resuscitation, wound management, and rehabilitation care.

5. Changes/Problems/Risks

Approved in-scope re-budget:

On June 5, 2018, the contracting officer, Wayne A. Medina, approved an in-scope re-budgeting request to accommodate for a shift in timing and location of planned research efforts and to shift funding to a current subcontractor for previous to be determined fabrication of components and modules. The award amount remained unchanged.

Year 1 of the project ended 25 Sept 2017 with a total budget surplus of \$518,178. The surplus was due to several factors:

1. As a cost saving, testing personnel were not hired at UMN pending modules/manikin to test. The Phase I manikin was not returned for testing as expected and the Phase II hardware/software components were not planned to be ready for testing.
2. Professional services from ARA BioGears, IngMar, KGS and for fabrication were not needed at the level projected when the budget was formulated.
3. Funds for the verification study at American College of Surgeons (ACS) were not needed as projected but were shifted for efforts in Year 2 and 3.

The following modifications were approved:

1. The surplus \$50,000 for ARA BioGears was shifted to Year 2.
2. The surplus \$84,039 for ACS subcontract was shifted to Year 2.
3. A total of \$582,036 was shifted to the University of Washington (UW) subcontract. These funds included the remainder of the surplus from Year 1 plus additional funds that were budgeted in Year 2 to the University of Minnesota (UMN) for professional services to fabricate components and modules.
 - a. \$198,625 was for salary, fringe, supplies and the requisite indirect charges for UW CREST staff to produce components for the prototype units that was originally budgeted for manufacture as a TBD professional service at UMN. UW is developing the design requirements for these components and CREST will be able to produce higher fidelity components within the lab.
 - b. \$383,411 was shifted to the UW Year 2 budget to include \$247,361 for contractual services at UW and associated indirect charges. These funds were to extend the UW contract with Entropic and continue managing their effort at UW. At the end of AMM Phase I we had three full time team members at UMN – CREST that were employed by the University of Minnesota supporting development of the Module side real-time hardware and software. As the center moved to the University of Washington, the three team members could not be employed by UMN. As the transition for CREST took place during the time the budget was developed, and personnel decision were not made, the bulk of the budget to support those team members were left in the UMN budget as TBD's. Since then those engineers formed a small company (Entropic) as they choose not to move to UW, but we needed to continue to work with them, as we did during Year I of Phase II.
 - c. The University of Minnesota Year 2 budget was be adjusted to reflect these

modifications and the change in indirect charges. The total Year 2 budget reflected these changes with the total \$3,538,655 equal to the Year 1 surplus of \$518,178 plus the originally budgeted \$3,020,477. Please note these figures did not include the \$100,000 budgeted each year to the Army Research Laboratory as these funds are MIPRd directly and do not pass through the University of Minnesota.

Schedule Delay:

Due to the issues encountered with the blind mate connector approach, the program has encountered a delay of 4 months to the ALPHA delivery, but at this point is not projecting a need for an extension of the contract end date. A re-plan with workarounds has been developed. The original ALPHA date was Sep 2018, which has now moved to Jan 2019. Also, leading up to the ALPHA, there will be 3 intermediate demonstrations of functionality referred to as Mule #1, Mule #2 and Mule #3. The purpose of these demonstrations is to show integration and testing along the way thus greatly reducing the risks for the ALPHA demo. Mule #1 was held at UW during the first week of May 2019. Mule #2 is scheduled for Oct. 8-12, 2018.

Second in-scope re-budget:

It is expected that another in-scope re-budget will be requested in the near future. Planning for the ACS study are being finalized and it is becoming apparent that providing technician support from UW will be more consistent and cost effective than hiring a technician at each site as originally envisioned. ACS has not yet invoiced against any of the Year 1 and Year 2 funds allocated for the study. The re-budget is being done, but it is expected that those funds already allocated to ACS should be sufficient to cover their costs and that the funds allocated to ACS for Year 3 will be requested to be transferred to UW.

Risks:

The following have been communicated with the COR previously and still remain open issues.

1. Patent application (US20160055767A1-Harvard AMM) by the CIMIT team. This application is a concern given the similarities in direction and the potential impact on the plan to provide AMM II as open and royalty free. We have discussed this at the IPR with JPC-1 as a risk and discussed coordinated strategies to mitigate this risk with JPC-1.
2. SynDaver use of Advanced Modular Manikin name for their manikin.
3. Trademark of the AMM name - University expert suggested renaming the program as neither AMM nor Advanced Modular Manikin could successfully be protected as they are too obvious for a trademark.
4. U.S. tariffs imposed on China (and vice-versa) have caused instability, delays in the supply chain, and increased costs for the electronics needed to build the AMM common compute and application module boards.

6. Products

Publications:

Barnes JJ 3rd, Konia MR. Exploring Validation and Verification: How They Are Different and What They Mean to Healthcare Simulation. Simul Healthc. 2018 Oct;13(5):356-362

7. Participants & Other Collaborating Organizations

Name:	Robert M. Sweet, MD, FACS
Project Role:	Principal Investigator
Nearest person month worked:	1
Contribution to Project:	Dr. Sweet is the principal investigator on this project, overseeing development through subcontractors, verification testing, validation plans and project management.

Name:	Mojca Konia, MD,
Project Role:	Co-Principal Investigator
Nearest person month worked:	1
Contribution to Project:	Dr. Konia is co-principal investigator overseeing verification testing and project management at the University of Minnesota.

Name:	John Hoschette, MSEE, MBA
Project Role:	Project Manager
Nearest person month worked:	9
Contribution to Project:	Mr. Hoschette is responsible for project management along with verification of hardware and software.

Name:	John Raymond, MS
Project Role:	Contracts Manager
Nearest person month worked:	6
Contribution to Project:	Mr. Raymond is responsible for contract management, monitoring subawards, monitoring deliverables and submitting reports.

Name:	John (Jake) Barnes II, MD
Project Role:	Researcher – physiology verification
Nearest person month worked:	9
Contribution to Project:	Dr. Barnes is responsible for verification of physiology for the manikin and modules.

Name:	Kenneth Kiberenge, MD
Project Role:	Post Doc Researcher – physiology verification
Nearest person month worked:	4
Contribution to Project:	Dr. Kiberenge is responsible for verification of physiology for the manikin and modules.

Name:	Mark Gilbertson
Project Role:	Graduate Research Assistant – hardware/software verification
Nearest person month worked:	2
Contribution to Project:	Mr. Gilbertson is responsible for testing and verification of the hardware/software design including the fluid system and connectors

Name:	Rebecca Smith
Project Role:	Graduate Research Assistant – hardware/software verification
Nearest person month worked:	2
Contribution to Project:	Ms. Smith is responsible for testing and verification of the hardware/software design including the fluid system and connectors

Change in Other Support for Robert M. Sweet, MD since 26 Sep 2017

Co-PI: Sweet

Next Generation Integrated Curriculum and Trainer for Neonate

National Institute of Health

6/19/2018-6/30/20

\$260,000

7.5% Funded Salary Support

PI: Sweet

Tissue Characterization Cooperative Agreement

W911NF-16- 2-0147

US Army Research Office (ARO)

9/30/2016-4/30/19

\$ 1,914,133

Sweet effort: 0.60 calendar month/yr

Subaward PI: Sweet

Advanced Female Trauma Training System – Phase II

W81XWH-17- C-0181

Prime Contract: Vcom3D from US Department of Defense (DOD)

9/23/2017-9/22/19

\$301,230 (subaward)

Sweet effort: 0.12 calendar month/yr

PI: Sweet

Development of an Advanced Airway Trainer Phase II

W911NF-17- C-0043

Army Research Laboratory

9/29/2017-6/28/2019

\$ 2,610,794

Sweet effort: 0.60 calendar month/yr

Partner Organizations – No Change in Subawards

Subcontract: University of Washington CREST – PI: David Hananel

Subcontract: Vcom3D – PI: Ed Sims, PhD

Subcontract: American College of Surgeons – PI: Ajit Sachdeva, MD, FRCSC, FACS

Subcontract: Army Research Laboratory – PI: Jack Norfleet, PhD

8. Special Reporting Requirements

Does not apply.

9. Appendices

i. Quad Chart



Advanced Modular Manikin – Phase II

ERMS# 14210007
Award# W81XWH-14-C-0101



PI: Robert M. Sweet, MD Org: University of Minnesota

Award Amount: \$7,769,962

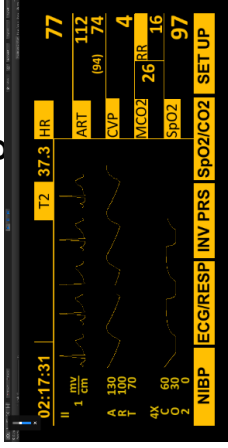
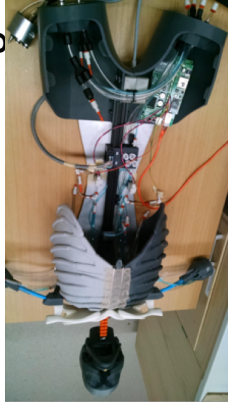
PROJECT AIMS

- Design, refine and verify core architecture to support modular & open standards (UMN and UW)
- Build and Bench Test core and modules
- Verification, usability, acceptability and early validity studies (American College of Surgeons)
- Demonstrate core capabilities

Approach

- What: Build/modify Phase I concepts
- Who: Multidisciplinary team of doctors, medics, and engineers and have engaged simulation industry to demonstrate interoperability
- How: Focus on interoperability, robustness and diverse functionality across roles and disciplines.
- Design: Reference system for concept demonstration and dissemination

AMM Integration and Testing



Accomplishments:

- Demonstration of integration of electronics, software, and physical components
- Testing and verification of connectors and fluidics systems
- Continued development and verification of virtual system and core electronics
- Progress on module development and integration
- Validation study design

Timeline and Cost

Activities	Year 1	Year 2	Year 3
Design & build core & modules			
Test & verify core & modules			
ACS studies & refine AMM			
Demonstrate & deliver AMM			
Estimated Budget (\$7,700K)	\$2,548K	\$3,020K	\$2,132K

Goals/Milestones

Year 1 Goals

- ✓ Develop standards for manikin core and modules for AMM
- ✓ Develop verification and testing procedures

Year 2 Goals

- ✓ Progress on verification and testing of modules and AMM
- ✓ Progress on integration of core and modules into functional AMM

Year 3 Goals

- ✓ Verification, usability, acceptability and early validity studies
- ✓ Refinement of AMM
- ✓ Demonstration and delivery of AMM system and documentation

Comments/Challenges/Issues/Concerns

Alpha model delay due to finalization and testing of connector design
Patent application by Massachusetts General/Harvard group

Budget Expenditure to Date

Budgeted Expenditures: \$5,668,269

Actual Expenditures Recorded as of 25 SEP 2018: \$4,172,943

Updated: 25 SEP 2018