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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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Modular, Manikin, Open Source

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Table of Contents

1.	Introduction	3
2.	Keywords	4
3.	Year 3 Accomplishments	5
A.	Finalized the AMM 1.0 standards	6
B.	Construction of a series of prototypes	7
i.	Mule II – full integration without human form	7
ii.	Alpha – system as will be used during ACS study	9
iii.	Beta – system as will be delivered at end-of-project	18
C.	AMM developers kit design released	20
i.	Electronics	20
ii.	The AMM C.O.R.E.	23
D.	CREST Universal Segment Connector (CUSC)	25
E.	Verification Testing of ARA BioGears Physiology Engine	30
G.	American College of Surgeons (ACS) Field-Test Study	36
i.	Major Activities	36
ii.	Specific Objectives	36
iii.	Key Outcomes	36
H.	Support for ACS, Division of Education study	38
i.	Study Preparation	38
ii.	Training Resources	40
iii.	Changes Made	40
iv.	Key Outcomes:	42
4.	Impact	42
5.	Changes/Problems/Risks	43
A.	Change/Problems	43
B.	Risks	44
6.	Products	45
A.	Publications	45
B.	Presentations	45
C.	Data, Models and Software	45
D.	Hardware	46
i.	CREST Universal Segment Connector (CUSC)	46
ii.	Advanced Modular Manikin Developers Kit AMMDK	46
iii.	AMM Central Operating REsources (AMM C.O.R.E.)	46
7.	Participants & Other Collaborating Organizations	47
8.	Special Reporting Requirements	48
9.	Appendices	49
i.	Quad Chart	49

1. Introduction

As stated in the announcement for the Advanced Modular Manikin ™ (AMM™) 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 addressed 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.

Completed deliverables on the project include; digital male and female anthropomorphic datasets, testing of the open source physiology engine: Biogears, the establishment of data libraries that allow AMM compatible vendors to publish and subscribe data elements, as well as technological standards for access as open source resources. The AMM software CORE has been developed, tested and integrated. In addition, a tool-less standard uniform "CREST" connector providing data, power, air and fluid has been designed, prototyped, tested and integrated in alpha-modules for connection of modules to other modules. To demonstrate the capabilities of the platform across military healthcare Roles and learners, a multimodal alpha-

prototype has been developed that integrates independent industry and academic developed modules that have conformed to the standards to be interoperable. Future deliverables include field-testing data under the direction of the American College of Surgeons Division of Education and completion of the beta-prototype.

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 Sims, PhD
Subcontract: American College of Surgeons – PI: Ajit Sachdeva, MD, FRCSC, FACS
Subcontract: STTC Army Futures Command – 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 physical or digital capability or system that can be connected to the AMM platform.
6. “Smart Compatible Module”- A module that transmits data bidirectionally to and from the CORE system and therefore contributes and/or responds to changes in conditions communicated across the system.
7. “Dumb Compatible Module” – A module that may be physically compatible, but 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/Roles.

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 and receive 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 device and software engines, etc. Our platform will demonstrate interoperability between and among examples of each of these entities.

3. Year 3 Accomplishments

Specific Year 3 accomplishments are detailed below and include:

a. Finalized AMM 1.0 standards
b. Construction of a series of prototypes
   - Mule II – full integration without human form
   - Alpha – system as will be used during ACS study
   - Beta – system as will be delivered at end of project
c. Final AMM developers kit design released (AMMDK and Network Manager)
   - AMM Reference Design “Black Box”
d. CREST Universal Segment Connector (CUSC) – Successfully passed all tests. 2000 mate/de-mates, 300 lb. torque test, 200 lb. axial pull, and a “worst case” helicopter vibration environment. Two sources of supply for the connector were qualified as a result of the testing.
e. BioGears integration, modifications and verification of physiology engine to accommodate scenario requirements was successfully completed. Verification testing

completed on versions v6.1, v6.3, v7.0 including Sepsis and Pain. Overall our input has led to the BioGears v7.0. It was significantly improved and the final recommendations were made to include this version in the ACS field-testing study.

f. New Module Integration – support to external researchers and companies to help them be AMM compatible
g. Completion of the American College of Surgeons (ACS) field-testing study
h. Support for ACS, Division of Education study

A. Finalized the AMM 1.0 standards

The AMM data model and standards underwent iteration and were refined significantly, leading to an upcoming official 1.0 'release' of the AMM Standard for data and connectivity. This includes changes and expansion of the documentation around the Module Behavioral Requirements, Operational Data Model and Configuration Data Model.

Changes from the pre-1.0 standard included:

- Addition of a SimulationControl (START, HALT, SAVE, etc.) topic.
- Addition of Event Records, Event Record Fragments, Fragment Amendment Request and Omitted Event topics.
- Restructuring "Physiology Modification, Render Modification and Performance Assessments" to be tied to an Event ID (using UUID)
- Restructuring of "Log" topic to clarify and to convey more information
- Changing of the 'handshake' flow to include:
    - Publishing initial Operational Description (including capabilities sent from module) upon connection.
    - Publishing and subscribing to the "ModuleConfiguration" upon a module's connection to receive its configuration from the Module Manager when a scenario is loaded.
    - Maintenance of a module's publish per-capability Status information when configuration is received/applied.
- Changing of Physiology node data and high-frequency node-data to Physiology Value and Physiology Waveforms.
- Removal of other non-Standard data types such as Tick and Command, leaving only AMM Standard DDS topics in the IDL.
- Tick and Command are now AMM Extended Datatypes, not part of the official Standard - this reflects that they are implementation details. These are documented within the AMM Reference Implementation software.

The published release has had some minor adjustments from the prior draft documents to account for some missing identifying information, and to streamline some of the data representations. The documentation and code references have been published in a public GitHub repository, ensuring future changes, as well as discussions, proposed changes, bugs, etc., will be captured and disseminated as part of the open-source project.

At a high level, the AMM Data Models consist of a set of Configuration Data, which describes module functionality and settings needed to configure an AMM system for a specific simulation, and a set of Operational Data, which describes how modules function together as a cohesive unit during the course of a simulation. Along with these two data models, behavior expectations and connectivity-related rules have been documented to ensure complete module interoperability.

The Configuration Data Model is centered around the idea of Capabilities of a module, which are logically encapsulated units of functionality. Using standard naming conventions for Capabilities helps ensure that module functionality can be readily compared, and enables scenario definitions to be evaluated and compared with the Capabilities of the available modules. In order to maintain extensibility of the AMM standard, while also minimizing complications due to version compatibility between modules, the definitions for Capabilities are maintained in a glossary that can be readily updated as new features are developed. Our approach maintains compatibility with older modules even as new modules are created.

The Operational Data Model is broadly centered around three concepts: The first is the state of the scenario being simulated, which broadly consists of the state of both the patient and their environment. The second category represents data that are generated as a result of some event. Events are frequently caused by a user intervention, but are sometimes triggered by the scenario. The third category of data is information about the state of the simulator, including configuration of Modules and control of the simulation data & progression. To practitioners, Events, as a record of 'what happened', are of most interest. As with module Capabilities, Event definitions are maintained in a glossary separate from the rigid data types definition. This, again, enables extensibility and development of new features while maintaining backward compatibility.

All of the specific data types used by the AMM Data Models are captured in an Interface Definition Language (IDL) file, a format which is commonly used by DDS software to define data types. Additionally, many fields in the AMM Data Models are structured XML, with contents defined by XML Schema definition files also included in the repository.

B. Construction of a series of prototypes

A series of prototypes of a full body manikin was developed utilizing the emerging components of the AMM platform development effort. This work commenced in Year two and was continued in Year 3.

i. Mule II – full integration without human form

Integration work for Mule II was completed in October 2018 and represented the first full integration of smart modules and platform components into a physical form. The basic structural components for the manikin torso: spine, neck, shoulders and lower torso are shown below in Figure 1. Note that the chest, head and torso components/interconnections were added. The skeleton infrastructure provided the rigidity for mounting components and allowed for open areas for fluid and electrical cable routing. The manikin's infrastructure allowed for easy assembly and maintenance.

The shoulder joint structure was designed and built with CAD and 3D printed parts where possible. The shoulder joint design provided strength as well as freedom of movement of the arms in motions that similar to a human.

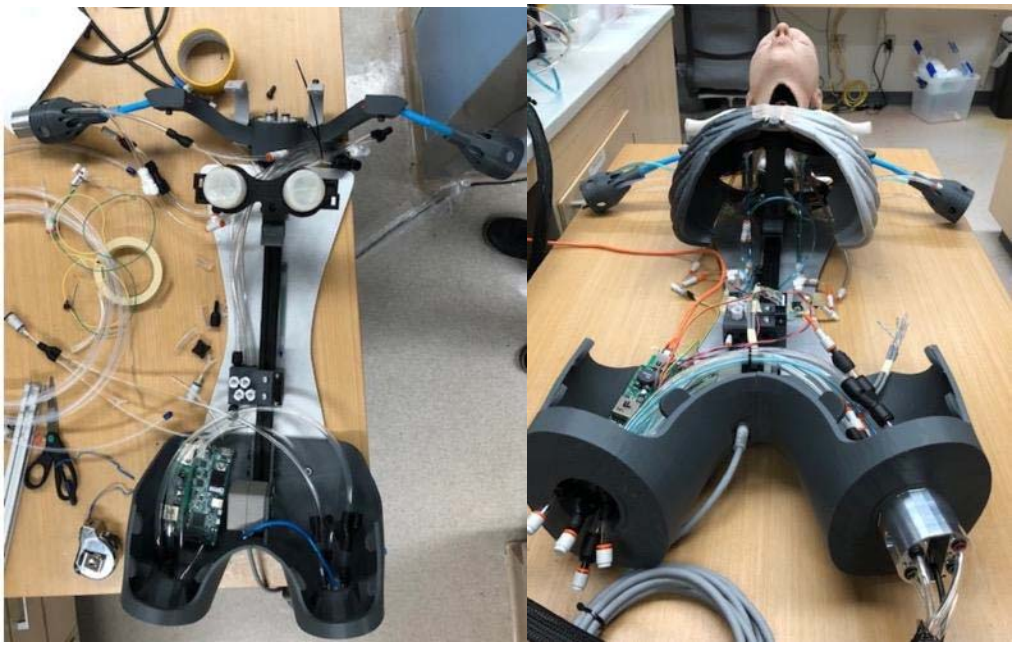


Figure 1: Left side: skeleton infrastructure, right side: chest, head and torso/leg components added.

A close-up of the head/neck/shoulders is shown on the left side of Figure 2. On the right side of Figure 2 is a close-up of the lower torso showing the routing of fluid lines, placement of electronics and the universal connector interface.

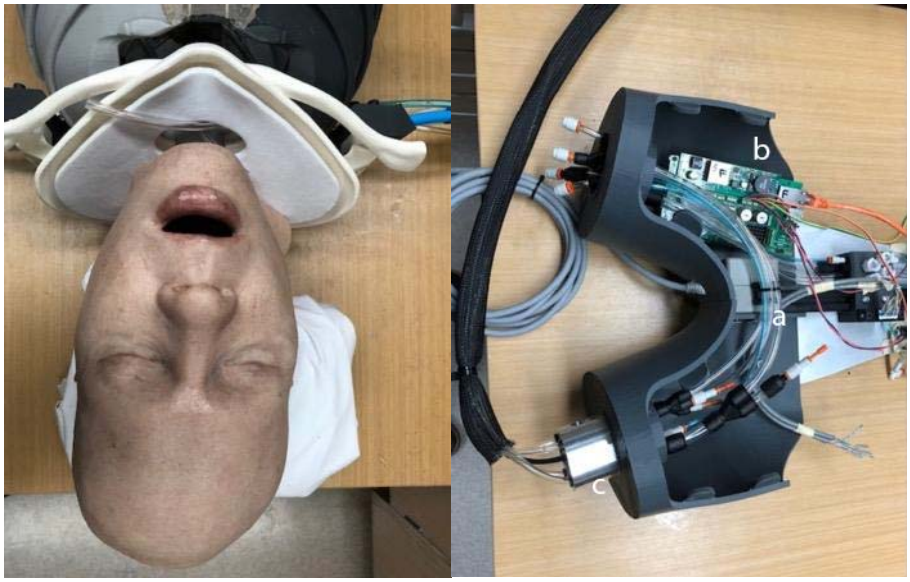


Figure 2: Left side: close-up of head/neck, right side: torso with fluid lines (a), electronics(b) and universal connector (c) between the torso and leg segments.

The torso controller executed core software services and also controlled the chest rise of the manikin in accordance to information obtained from the physiology engine. This demonstrated the operation of the full stack of subsystems from core software to physical display of clinical cues.

ii. Alpha – system as will be used during ACS study

The Alpha system was integrated and tested in a number of stages. Initial integration was completed for the pre-pilot demonstration in January 2019. Based on results and feedback from this demonstration a number of issues were addressed, and improvements integrated on an ongoing basis into the prototype. The prototype was tested in a clinical setting again during the study pilot in March of 2019. Numerous improvements and refinements have been implemented since the study pilot in order to prepare this prototype for the ACS study.

a. Pre-Pilot

The pre-pilot was completed with the involvement of University of Washington clinicians and the help of COL Rob Rush, MD, FACS (ret).

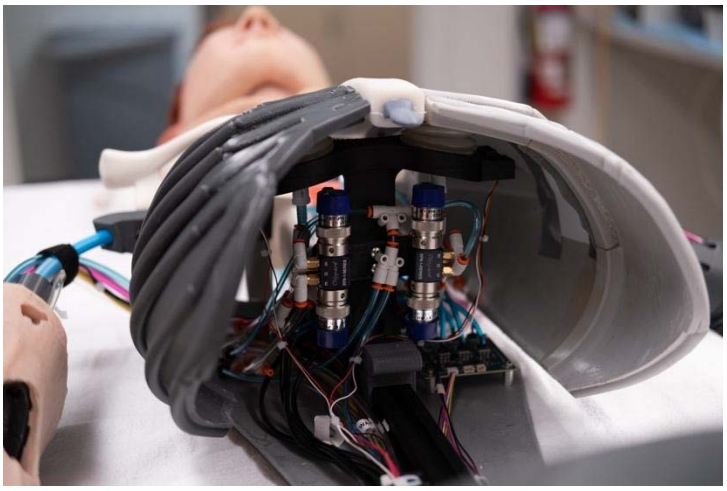


Figure 3: Torso, view of chest rise mechanism.

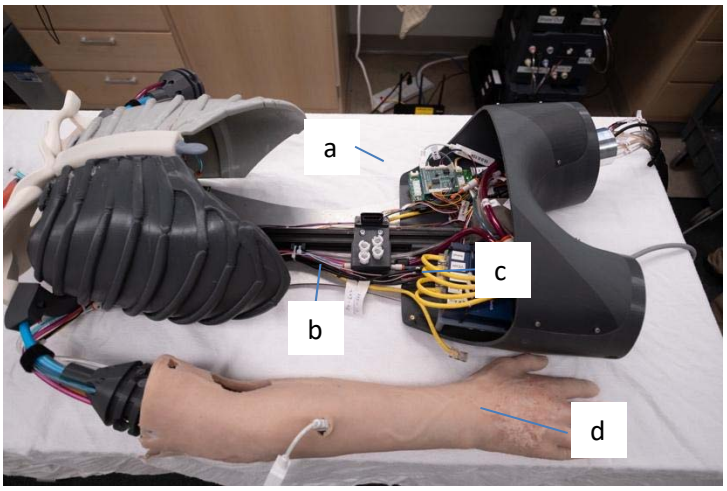


Figure 4: AMM Core (a), "spine" connector (b), network switch(c), and IV arm (d).

Figure 5: Army Futures Command/CREST Intubation head.

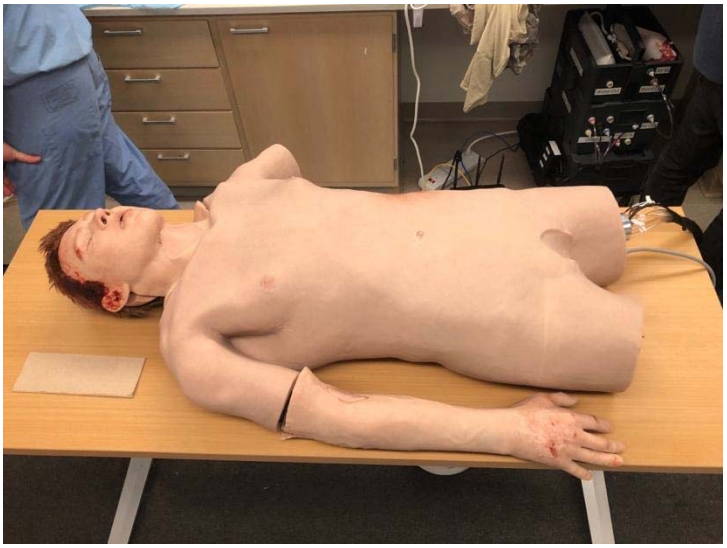


Figure 6: Skinned pre-pilot manikin with IV arm and intubation head.

Figure 7: Intubation using a CMAC with data communicating across core to other modules.

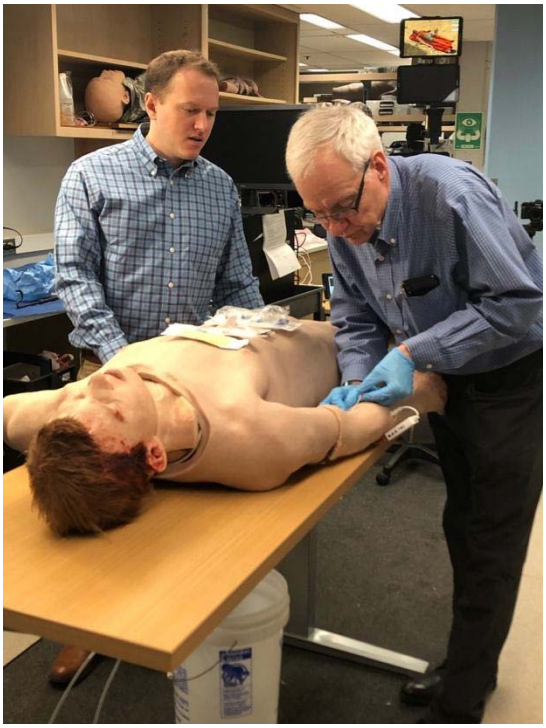


Figure 8: Insertion of catheter into pre-pilot IV arm with data communicating across core to other modules.

Figure 9: Surgeons interacting with the standalone CREST laparotomy trainer.

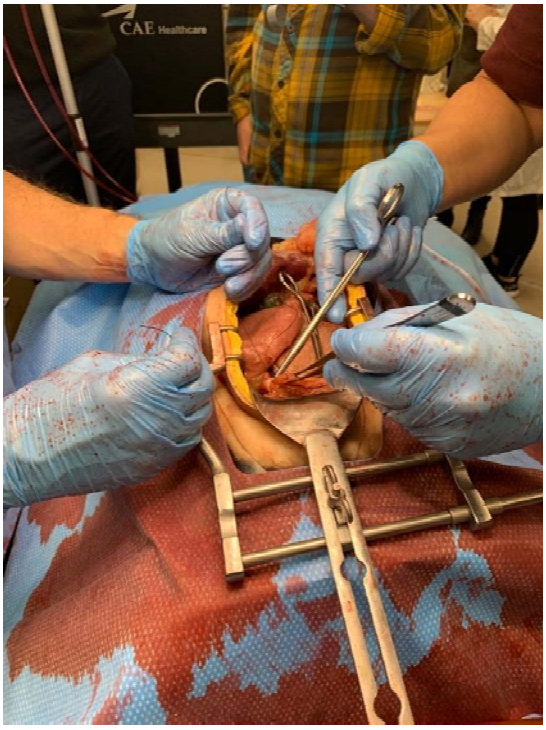


Figure 10: Trauma Cystorraphy (urinary bladder repair): CREST Trauma laparotomy module

b. Pilot

The pilot run was performed in Seattle over two days with the attendance of the ACS-AEI team participating.

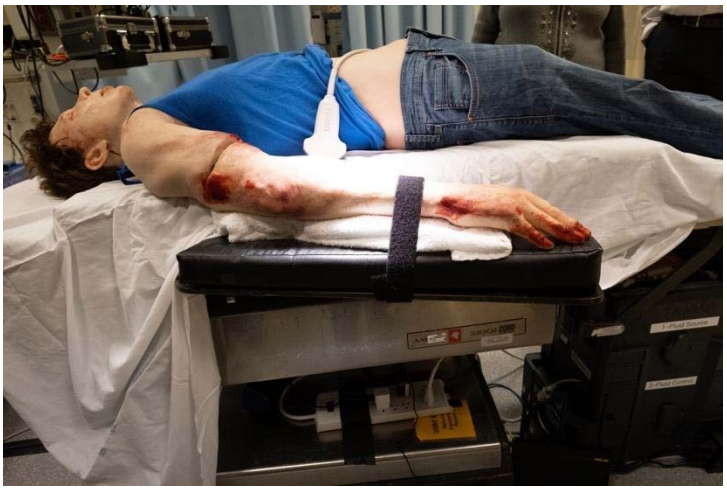


Figure 11: Integrated manikin in the virtual OR.

Figure 12: Virtual patient, virtual IV pump, virtual ventilator, Propac, and labs tablets.

Figure 13: First responders apply BVM in Scene 1 of scenario with data communicating to and from, the core to other modules.

Figure 14: Scenario scene 2: first responder performs intubation with data communicating to and from, through core to other modules.

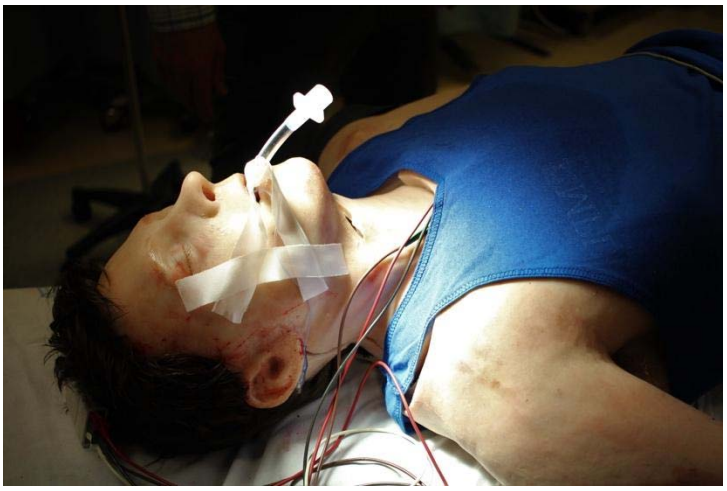


Figure 15: Integrated manikin intubated.

Figure 16: Scenario scene 2, integrated CAE virtual FAST exam with data communicating from ACDET abdominal exam sim through core to other modules.

Figure 17: Scenario scene 2, manikin with Bag-valve-mask ventilation with data communicating across core to other modules.

Figure 18: Scenario scene 3 "walk phase", monitoring of patient vitals/data before surgery begins.

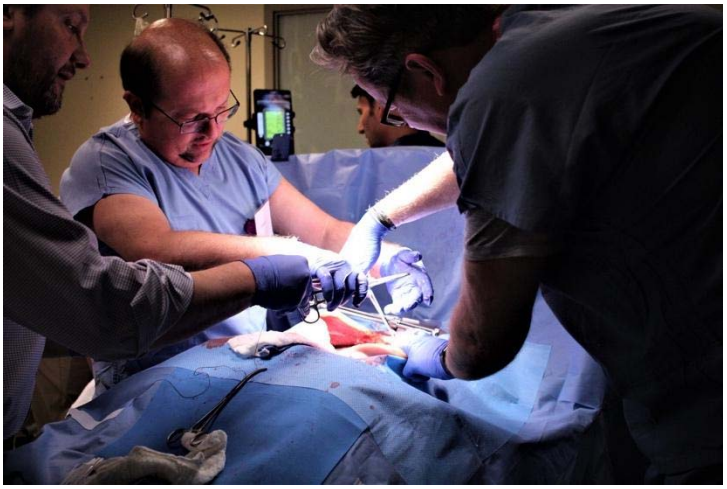


Figure 19: Scenario scene 3 "run phase", surgeons repairing injuries in trauma laparotomy module with data (blood loss) communicating to and from across core to other modules. Anesthesia managing the patient simultaneously.

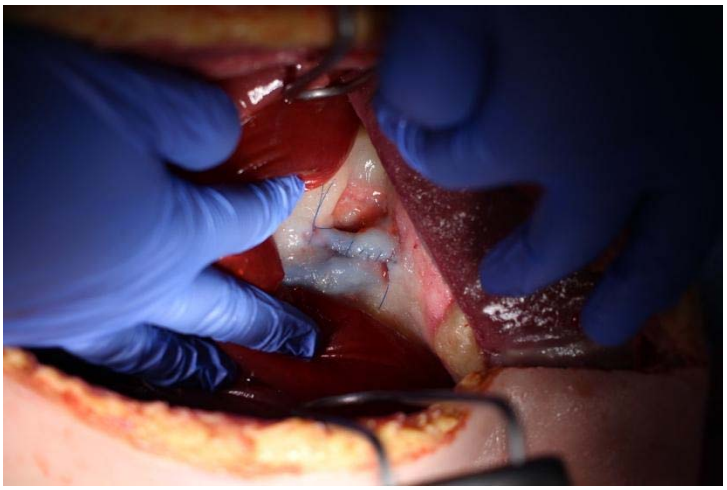


Figure 20: Close-up of trauma laparotomy module, Inferior Vena Cava laceration repair.

Figure 21: Intubation, IV arm, palpation, and FAST exam part-task trainers (second arm of ACS study).

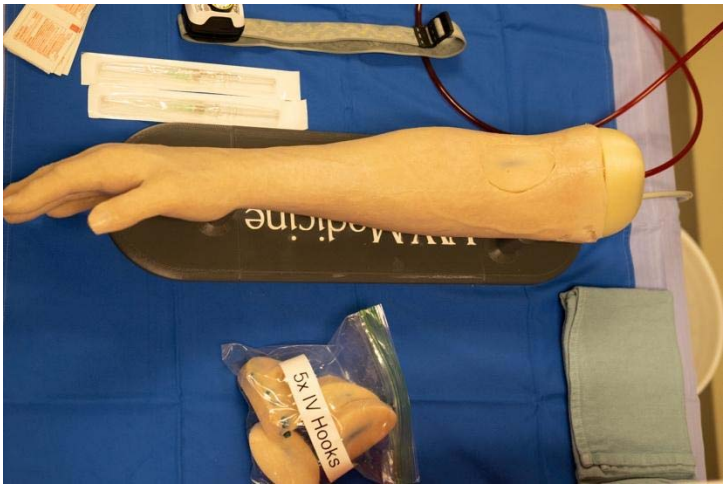


Figure 22: IV arm part-task trainer.

Figure 23: First responder inserts IV in part-task trainer.

Figure 24: Part-task trainer, trauma laparotomy setup for scene 3.

Figure 25: Scenario scene 3, surgeons repairing injuries in trauma laparotomy module part-task trainer.

iii. Beta – system as will be delivered at end-of-project

The Beta system is a full body manikin prototype that implements the AMM platform including final software and connector standards. It is aimed at demonstrating the functional performance of the platform. Two units are required for the delivery. These will be produced in the coming months to be completed by the end of the performance period.

Beta deliverables (2x):

- prototype airway torso
- head w/ airway sock
- IV arm
- dummy arm
- dummy legs
- central supply stack
- tablet with user interface
- CAE fast exam unit

From the end-user's perspective, the Alpha and Beta systems will be identical in operation but will differ in modules included. Internal changes made between Alpha and Beta do not affect the end-user's interactions with either systems. For verification, a use case test was designed and is to be performed on both systems.

The test is designed with a fixed set of inputs executed via macros such that the timelines associated with each test will be identical. The outputs of the Alpha system will be compared to the outputs of the Beta system. The expectation is that both systems will have the same output, indicating that a user of either systems would not be able to differentiate the two. The test scenario is a list of inputs, derived from the ACS scenario, simplified, and focused on final deliverables at the end-of-project. The test scenario will be executed with Selenium IDE, which will script all the necessary clicks on the User Interface. The same script will be applied to the Alpha and Beta Systems, and the log files will be saved and compared as system outputs. Below is the developed test scenario that the Selenium IDE script executes:

Alpha vs Beta Test Scenario	
Input:	**Purpose:**
Power on the system	Provide power to the supply stack/manikin
Click services page, stop all core services.	Demonstrating how to initialize the system
Restart the Module Manager	Turn on the Module Manager
Restart the Physiology Manager	Turn on Physiology Manager functions
Restart the Rest Adapter	Turn on Rest Adapter functions
Restart the Sim Manager	Turn on Sim Manager functions
Restart the TCP Bridge	Turn on TCP Bridge functions
Restart Fluidics Services	Turn on fluidics services functions
Restart Torso Services	Turn on torso services functions
Restart IV Arm	Turn on IV arm functions
Click Actions -> Technical -> Start Fluidics -> Main Dashboard	Pressurize the fluidics system so that it reaches a ready status
Click ACS Scene 2 page -> Load Scenario 2	Scene configurations are published to connected modules
Click Load Patient State Scene 2	Patient conditions are published to connected modules
Start Scenario	Begin simulation
Click Insert IV Cath	Verify that a catheter is inserted into the IV Arm module and it is registered by the system
Click Give Succs	Administer drugs to the patient to observe patient state changes
Click BVM On	Resuscitate the patient and observe patient state changes
Click BVM Off	Remove BVM and observe patient state changes
Click Intubate -> Tape and Ventilate	Intubate the patient correctly to resuscitate the patient and observe patient state changes
Give Saline 2L	Administer fluids to observe patient state changes
Give Blood 2U	Administer fluids to observe patient state changes

C. AMM developers kit design released

The AMM team has prepared two levels of developer's kits to support adoption of the standard by industry and fellow researchers. One level includes only the electronics that is delivered with all software pre-installed and ready to go. The second level, our reference design, includes the AMM Central Operating Resources, or C.O.R.E., the compute platform, as well as the central resources: fluid, power and air delivered across a CREST Universal Segment Connector (CUSC). It has been fully documented in CDRL A004.

i. Electronics

As a subcontractor on the AMM project, Entropic Engineering developed a set of electronics capable of running the core AMM software and providing power and network connectivity for physically-attached segment modules. We have chosen to call this component the "Network Manager" in order to distinguish its functionality from that of the core software stack, which is not required to be run on the same hardware. In practice, we expect users to run the core software stack on the network manager, effectively turning it into the 'core' of the manikin.

Figure 26: Top of Network Manager

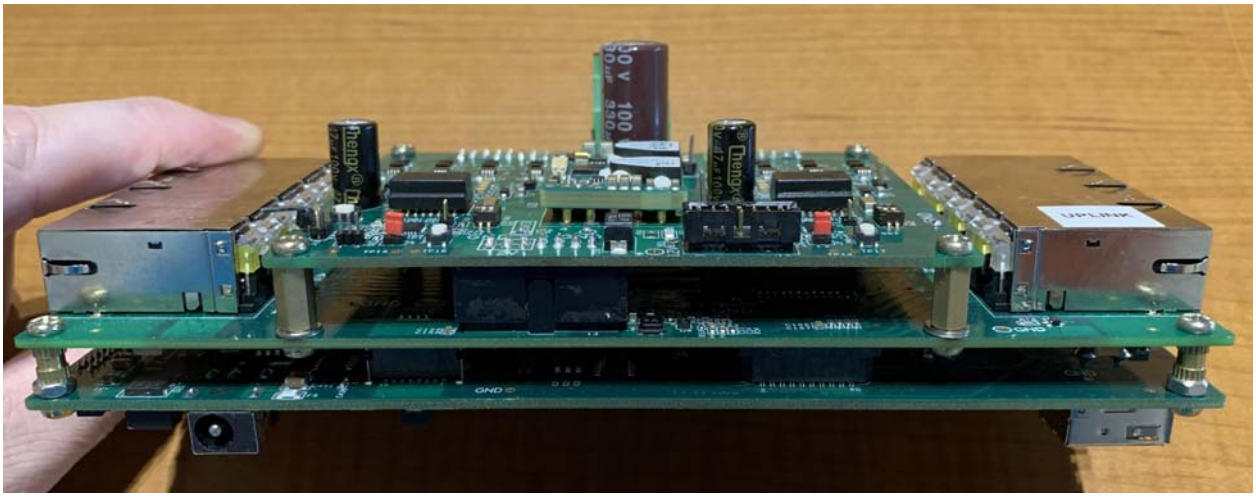


Figure 27: Side view of Network Manager

The Network Manager provides one ethernet uplink port and seven Power-over-Ethernet (PoE) enabled ethernet ports for Local Area Network (LAN) connectivity within the AMM. These seven ports provide power and data connectivity to all of the attached segment modules. Additionally, the Network Manager provides Wi-Fi connectivity and full Internet Protocol (IP) router functionality.

Figure 28: Bottom of Network Manager

Figure 29: Rotated side view of Network Manager

The Network Manager is designed as an extension to the AMM Developers Kit Common Compute Board (AMMDK-CCB), maintaining all of the functionality of the AMMDK-CCB, while providing additional power & networking capabilities. This enables the Network Manager to serve as the sole computer inside (in this case), the torso segment, providing both core AMM functionality, along with connecting to any hardware needed for torso module capabilities. The Network Manager runs the same "AMMDK OS" (based on Debian Linux) as the AMMDK, simplifying the overall software development and maintenance requirements for the project.

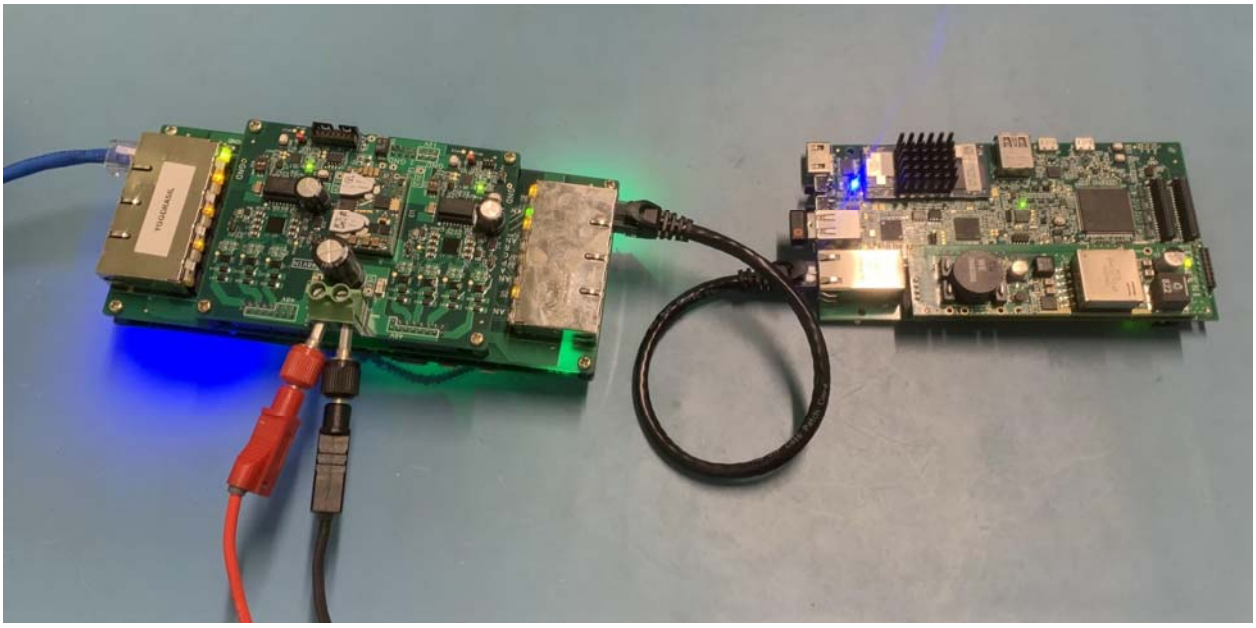


Figure 30: Network Manager providing power & data for an AMMDK

The Network Manager is fully compliant with the very latest and most powerful PoE standard, IEEE 802.11bt. This enables compatibility with nearly all PoE Powered Devices (PDs) available on the market today, and will provide compatibility with the next generation of PoE devices. Each of the seven LAN ports can provide up to 75W of power and one gigabit of data throughput, ensuring ample resources for the development of a wide array of module capabilities, including robotic actuators.

ii. The AMM C.O.R.E.

Within the scope of the AMM project CREST has created a number of manikin prototypes that implement the AMM platform. These prototypes implement the AMM platform in the human form and are aimed at specific training scenarios integrating with specific training modules to accomplish this. In order to present AMM as a platform and provide developers with and essential tool for AMM compatible module development a reference design is proposed that integrates the platform systems into a single non-manikin unit. These are the AMM Central Operating REsources or C.O.R.E.

This design will run a complete set of AMM software, provide system resources and allow connection of one external AMM compatible module or task trainer. The self-contained unit is externally powered from 120V mains. It provides pressurized air, two individual fluids to an external AMM module according to the standard fluidics specifications. A pass-through is provided for waste fluid such as IV fluid. The compute platform consists of an AMMDK embedded system to control the fluidics system and a Network Manager embedded system to run the AMM system software, provide networking services and PoE power injection for the AMM connector. A network uplink to the internet is provided for connectivity. The Network manager also provides wireless (Wi-Fi) connectivity for peripherals such as tablets and instructor interface. Service access to fluids is separated from power equipment and electronics such that fluids can be refilled safely while the system is powered on.

The design has been documented for public distribution. This documentation has been submitted to the DoD with the project CDRLs. It contains BOM, electrical and fluidics schematics, solid models of custom parts and assembly documentation. CREST is in the process of building a

version of this system for final delivery at the end of the contract period. The design is shown in Figures 31-33).

Figure 31: Rendering of the AMM C.O.R.E. Enclosure

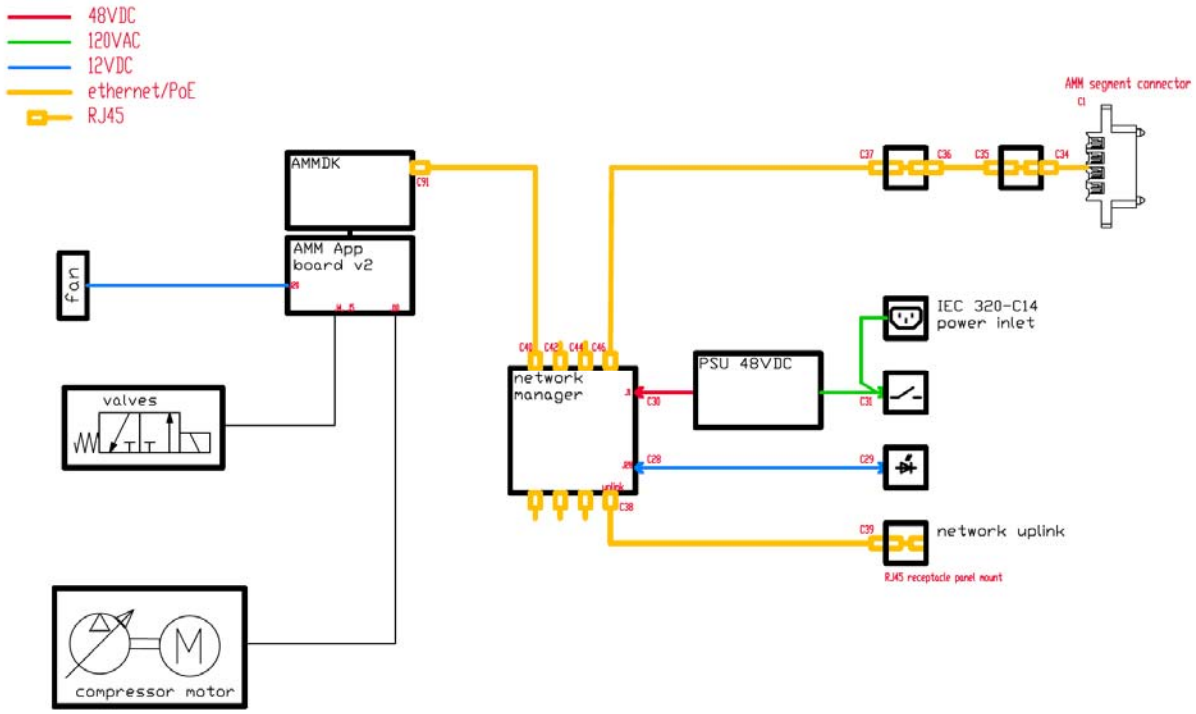


Figure 32: AMM C.O.R.E. block diagram

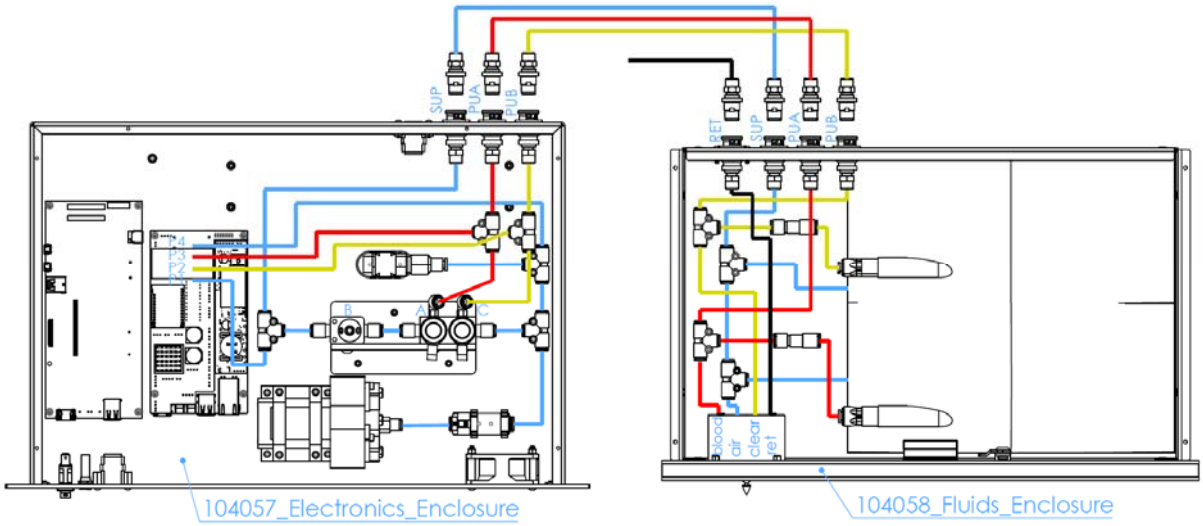


Figure 33: AMM C.O.R.E components and hose routing schematic

D. CREST Universal Segment Connector (CUSC)

The University of Washington and Entropic Engineering teams designed and fabricated a universal connector for AMM physical modules, as shown in the schematic in Figure 34 and photo in Figure 35.

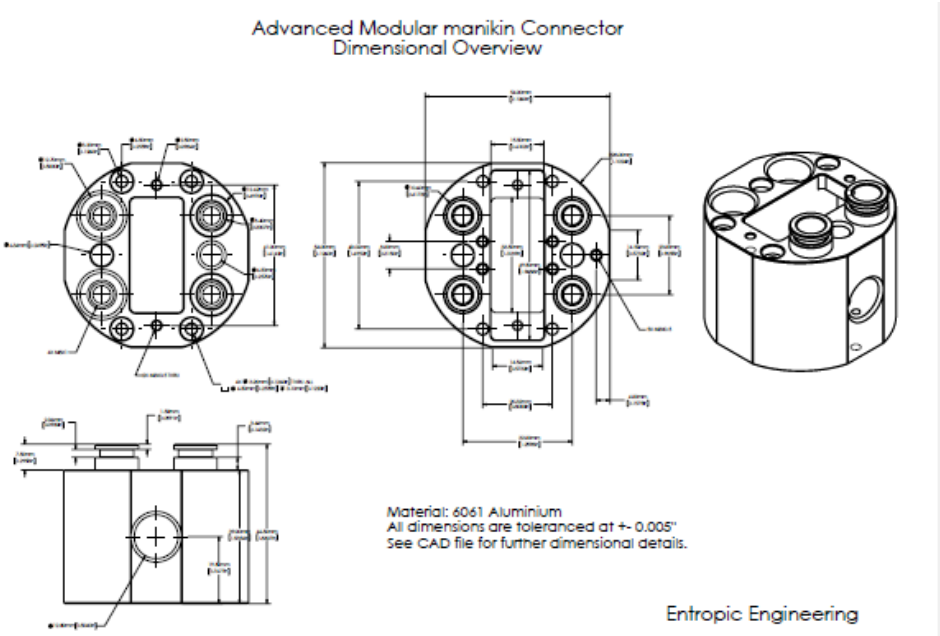


Figure 34: CREST Universal Segment Connector (CUSC)

Figure 35: AMM Universal Connector, Entropic connector (left), second party vendor connector (middle), hybrid connector (right).

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 36 (along with an earlier connector design).

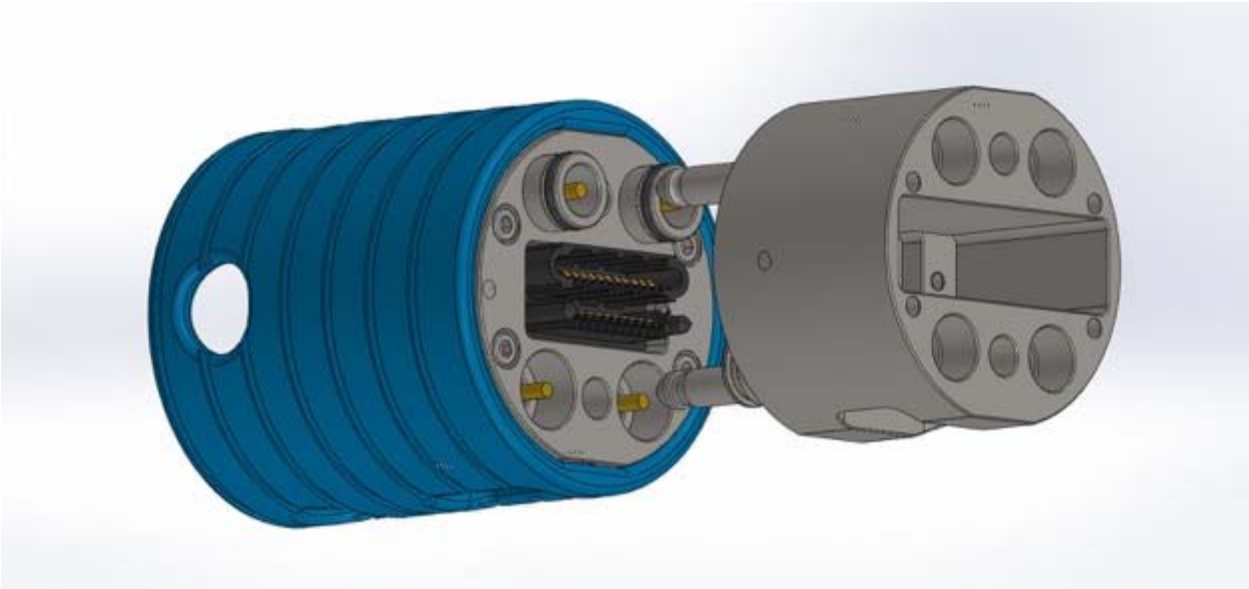


Figure 36: Example ‘sleeve’ for integrating Universal Connector into an arm module.

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, providing resilience against minor damage and debris on the surface of the connector face.

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. 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 35, both halves of the connector are identical, reducing part count and overall manufacturing cost.

The connector testing was performed at the University of MN Civil Engineering labs. This is a certified lab with the capabilities to perform pull, torque and vibration testing.

The UMN test team consisted of Dr. Mojca Konia, Dr. Kenneth Kiberenge, Dr. Jon Keller (UW), John Hoschette, Dr. Tim Kowalewski, and students Rebecca Smith and Mark Gilbertson. (Figure 37). The students started setting up the AMM verification lab, writing detailed protocols and obtaining test equipment. The students received supervision and mentoring from Professor Timothy Kowalewski, PhD and Entropic Engineering.

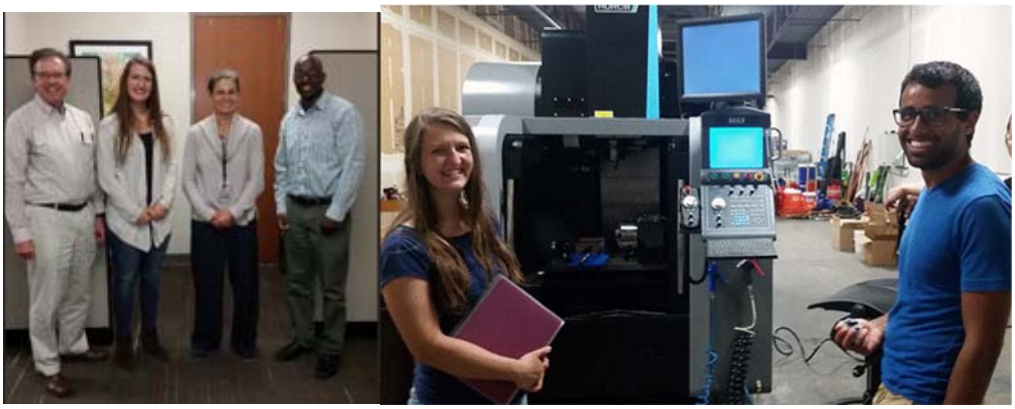


Figure 37: Left: (L-R) John Hoschette, Rebecca Smith, Dr. Mojca Konia, Dr. Ken Kiberenge. Right: Students at Entropic Observing Connector Manufacturing.

For each test, the criteria for success are as follows:

1. Mate/De-mate
   Mate/De-mate 2000 times without degradation in performance to latch or electrical pins or fluid connectors.
2. Axial Load Test:
   MECHANICAL The connector is able to withstand an axial load of at least 300 lbs.
   ELECTRICAL: The electrical contacts inside the connector remain in contact under an axial load of 200 lbs.
   FLUID: Fluid can be run through the connector's fluid lines without leakage while the connector sustains an axial load of 200 lbs.
3. Three Point Bending Test:
   MECHANICAL: The connector is able to withstand a bending moment of 100 ft-lbs. without sustaining any mechanical failure or deformation
   ELECTRICAL: The electrical contacts inside the connector remain in contact under an applied moment of 100 ft-lbs.

FLUID: Fluid can be run through the connector's fluid lines without leakage while the connector sustains an applied moment of 100 ft-lbs.

4. Vibration Test:
   MECHANICAL The connector is able to experience vibrations of frequencies ranging from 10 Hz - 1.5 kHz without sustaining any mechanical failure or deformation
   ELECTRICAL: The electrical contacts insider the connector remains in contact and operational while connector is subjected to vibration with frequencies ranging from 10 Hz - 1.5 kHz
   FLUID: Fluid can be run through the connector's fluid lines without leakage while the connector is subjected to vibration with frequencies ranging from 10 Hz - 1.5 kHz

All tests were performed on three different sets of connectors: (1) a connector manufactured by Entropic Engineering, (2) a connector manufactured by a second party vendor, and (3) a hybrid connector with one half manufactured by Entropic, and one half manufactured by the second party vendor. Photographs of the connector undergoing the various tests are shown in Figure 38.

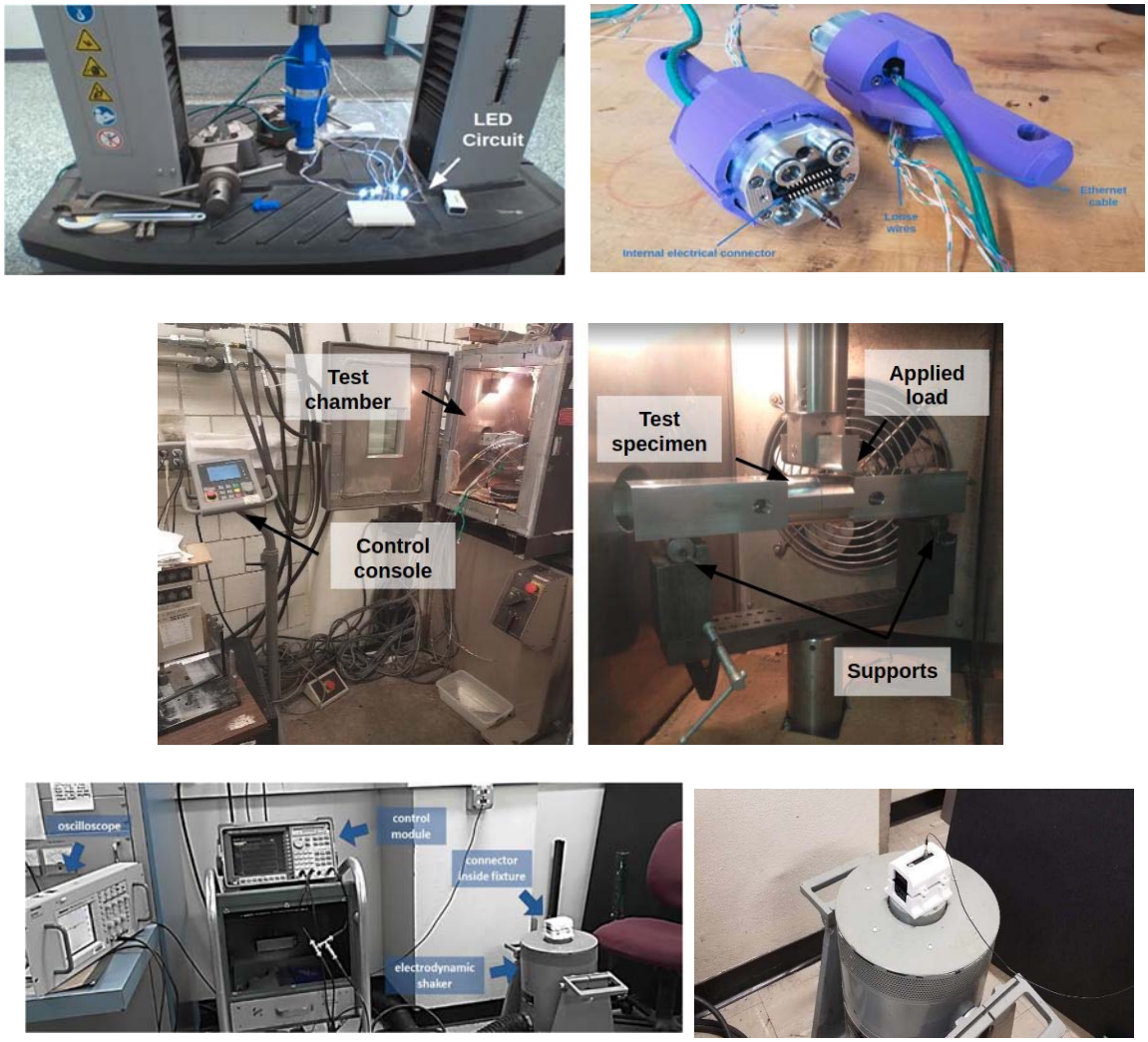


Figure 38 Top: Axial Pull Tests, Middle: 3 point Bending Tests, Torque, Bottom: Vibration Testing

Mate/De-mate Lifetime Testing

The first test conducted was the mate/de-mate test. For this test the connector was mated and de-mated over 2000 ties by hand. 2000 was times 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 to rust, so a new rust resistant latch pin material was selected and used on next version of prototypes.

Test Performed	Sub-Test	Connector	Test Spec.	Pass/Fail
		Entropic	300 lbs.	Pass
	Mechanical	2nd Party	300 lbs.	Pass
		Hybrid	300 lbs.	Pass
		Entropic	200 lbs.	Pass
Axial Load	Electrical	2nd Party	200 lbs.	Pass
		Hybrid	200 lbs.	Pass
		Entropic	200 lbs.	Pass
	Fluid	2nd Party	200 lbs.	Pass
		Hybrid	200 lbs.	Pass
		Entropic	100 ft-lbs.	Pass
	Mechanical	2nd Party	100 ft-lbs.	Pass
		Hybrid	100 ft-lbs.	Pass
		Entropic	100 ft-lbs.	Pass
3 Point Bending, Torque	Electrical	2nd Party	100 ft-lbs.	Pass
		Hybrid	100 ft-lbs.	Pass
		Entropic	100 ft-lbs.	Pass
	Fluid	2nd Party	100 ft-lbs.	Pass
		Hybrid	100 ft-lbs.	Pass
		Entropic	10 Hz - 1.5 kHz	Pass
	Mechanical	2nd Party	10 Hz - 1.5 kHz	**Fail***
		Hybrid	10 Hz - 1.5 kHz	Pass
		Entropic	10 Hz - 1.5 kHz	Pass
Vibration	Electrical	2nd Party	10 Hz - 1.5 kHz	Pass
		Hybrid	10 Hz - 1.5 kHz	Pass
		Entropic	10 Hz - 1.5 kHz	Pass
	Fluid	2nd Party	10 Hz - 1.5 kHz	Pass
		Hybrid	10 Hz - 1.5 kHz	Pass

Table 1: Summary of test results.

*This was considered a failed test because, during the vertical orientation test, one of the internal screws became unscrewed and fell out of the back of the connector. The proposed steps

necessary to prevent this mode of failure in future connectors is to ensure that Loctite is used when mounting all screws in the connector. See Figure 39.

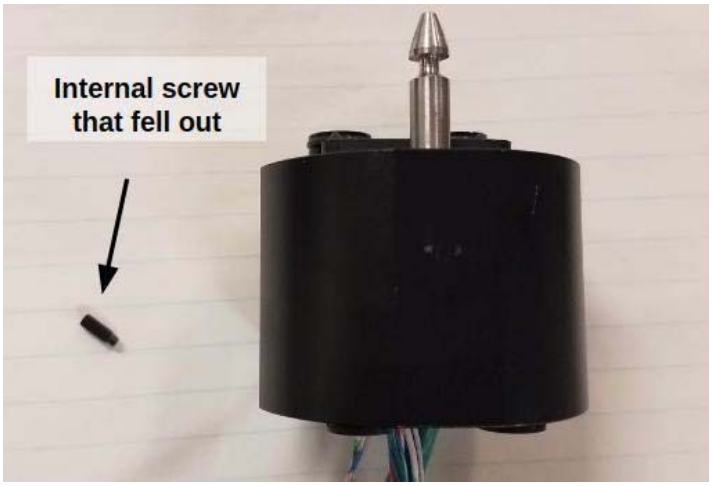


Figure 39: Connector with screw that backed out during vibration.

Conclusion and Recommendations

The AMM connector successfully passed all tests and the recommendation is use the connector on the AMM manikin modules interfaces where required. For details on the connector test protocols used refer to CDRL A009 Test Procedures. For details on the test results obtained refer to CDRL A010 Test Results.

E. Verification Testing of ARA BioGears Physiology Engine

Even though the AMM platform was designed to allow to accommodate different physiology engines, because of its Open source status, ARA BioGears was selected as the physiology engine for the alpha AMM unit. The physiology engine simulates the patient's response to therapy, intervention, and drug administration. The AMM program developed a scenario whereby the patient has suffered trauma and needed medical treatment in the field, in the Emergency Department and in the Operating Theatre.

The BioGears physiology engine simulated the patient vitals and provided detailed information to the instructor/trainee during the exercise. The BioGears physiology engine was programmed for initial conditions and then updates were sent as to the patient's condition as the scenario unfolds.

The initial testing of the of the BioGears physiology engine dealt with how well it could simulate the patient's condition during the scenario. Initial testing showed the BioGears models lacked significant capabilities which, with iterative feedback, were corrected/added. This report summarizes the testing completed on versions v6.1, v6.3, v7.0 including Sepsis and Pain. The pain module has been successfully integrated. The sepsis model has not been integrated into alpha.

Overall the BioGears v7.0 was significantly improved and the recommendation was made to include this in the ACS study. For details on the test results obtained refer to CDRL A010 Test Results.

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

The first three are being implemented in the alpha scenario.

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 40. 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.

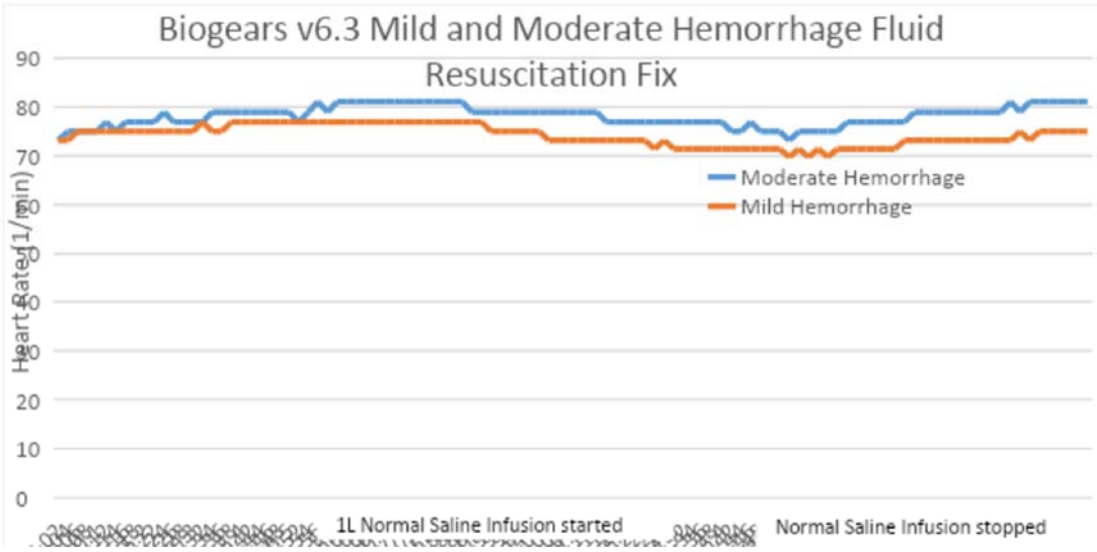


Figure 40: BioGears v6.3 testing with the saline .xml fix.

Heart rate (beats per minutes) is graphed across time (s) for mild and moderate hemorrhage treated with saline fluid infusion at 180 seconds.

Mechanical Ventilation: Identical settings were used to test v6.1 and v6.3. The settings were cross checked for accuracy.

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

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 v7.0 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 41)

- 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 42)

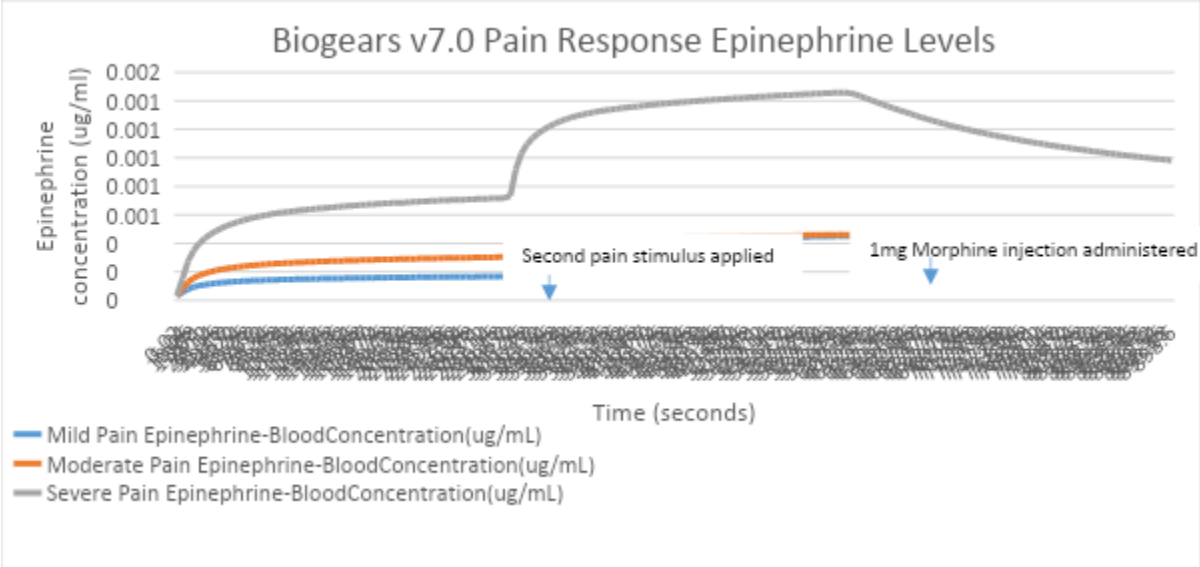


Figure 41: BioGears v7.0 Blood epinephrine concentration for mild, moderate and severe pain.

Epinephrine concentration (µg/ml) graphed across time (s) for mild, moderate and severe pain severities that are treated with 1mg of morphine at 600seconds

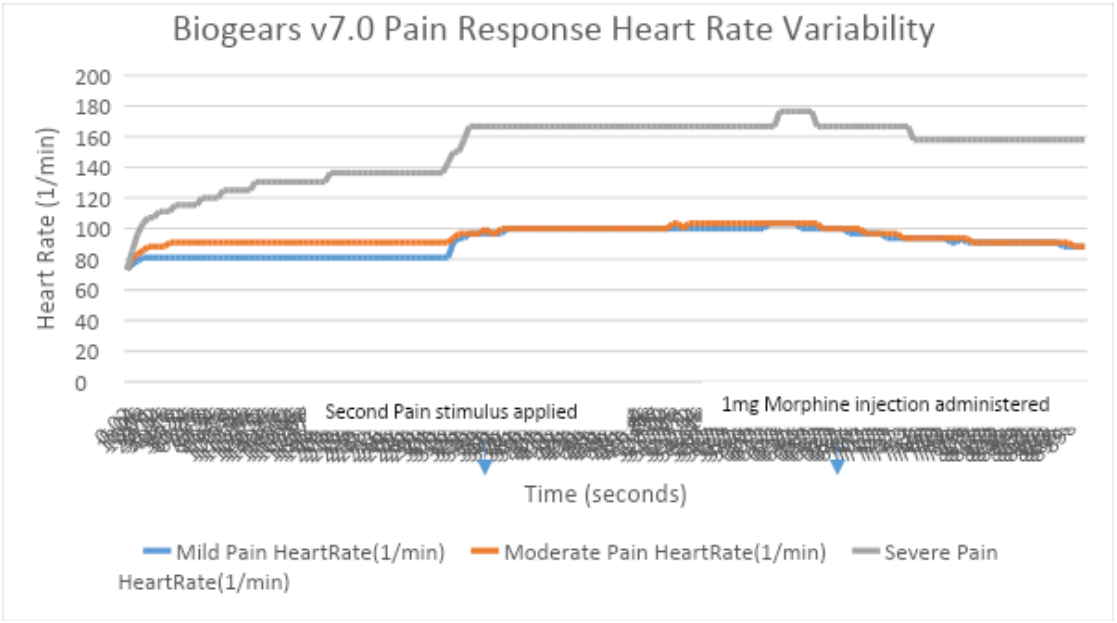


Figure 42: BioGears v7.0 Heart rate response for pain stimulus.

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.

Test results of Respiratory and arterial blood pH during Hemorrhage

In addition, BioGears implemented a fix in order to correct the respiratory rate as well as the arterial blood pH during severe hemorrhage. Previous testing had revealed that the respiratory rate did not increase as expected during severe hemorrhage and the blood pH did not change as expected. Testing done by Vcom3D and reviewed by University of Minnesota showed that no significant improvements had been made to correct the issues highlighted.

Vcom3D, independent of ARA, instituted various patches to the physiology engine to further improve it and efforts included verifying that the changes made were in line with expected physiology. These patches were implemented as a temporary patch to the BioGears "wrapper", not to BioGears code, such that they can be removed when the BioGears model is improved.

Respiratory Rate - The improvements made by Vcom3D were able to accurately model the expected change in the respiratory rate during severe hemorrhage. The respiratory rate increases with severe hemorrhage and decreases once the hemorrhage action is stopped and whole blood is transfused.

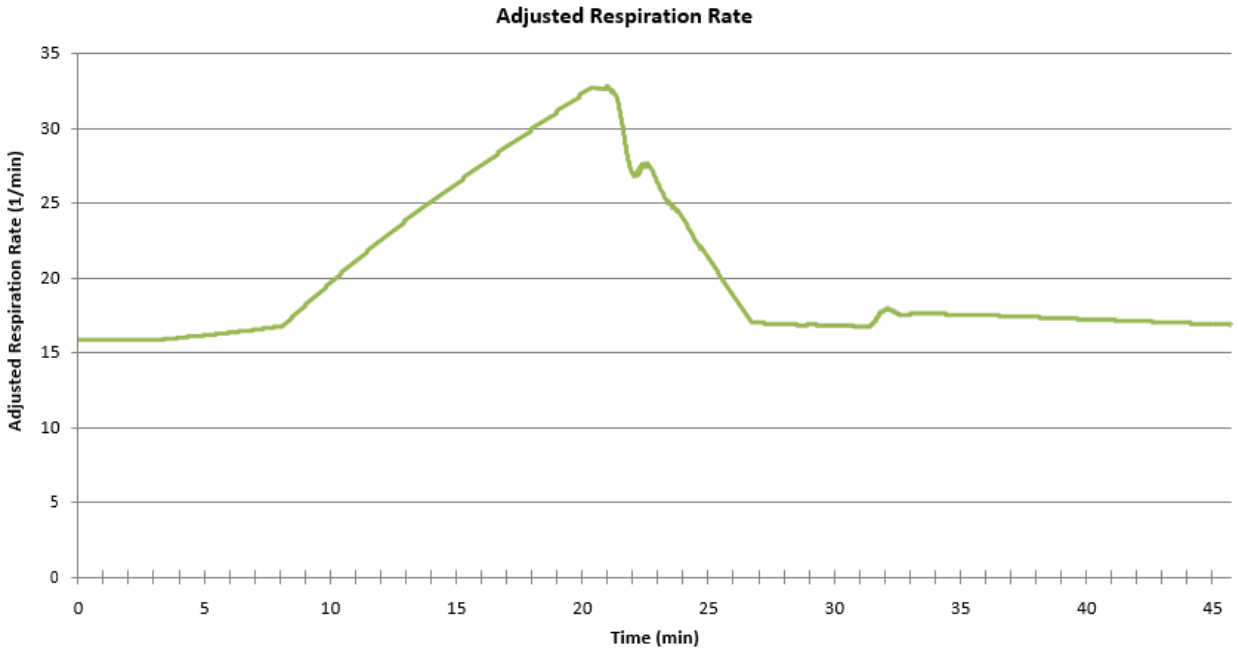


Figure 43: Respiratory Rate 1/min graphed across time(min) for Severe Hemorrhage with whole blood transfusion at 20min.

Lactate - The lactate levels increase in severe hemorrhage and slightly decrease once the hemorrhage is stopped and whole blood is transfused. However, the lactate levels seem to further increase without any additional hemorrhage, and after the transfusion of whole blood. This is unusual as we would expect a gradual and sustained decrease in serum lactate after hemorrhage is stopped and whole blood is transfused.

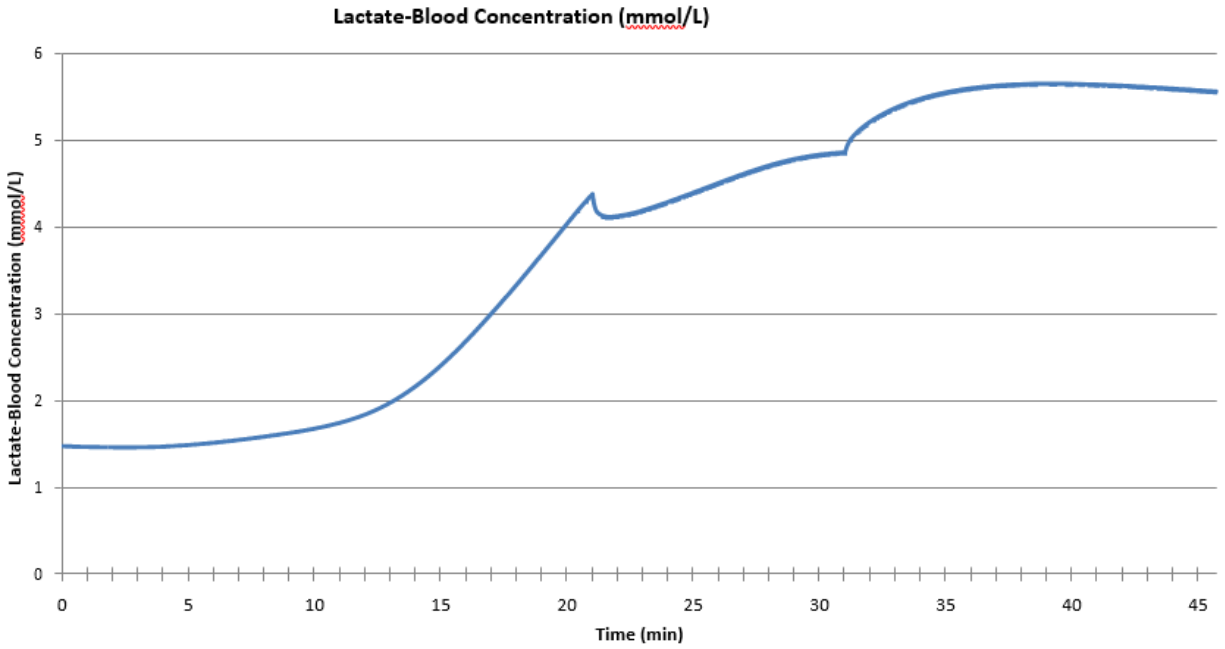


Figure 44: Lactate(mmol/L) graphed across time(min) for Severe Hemorrhage with whole blood transfusion at 20min.

Blood pH – The improvements made to the pH were also tested. There is a drop in blood pH during hemorrhage and an increase in the pH when whole blood is transfused, as would be expected. However, we would expect the decrease in pH to be much more robust to move the levels into acidosis. Additionally, the pH level further decreases to its lowest level after the hemorrhage is stopped and the whole blood is transfused. This runs counter to what would be seen clinically.

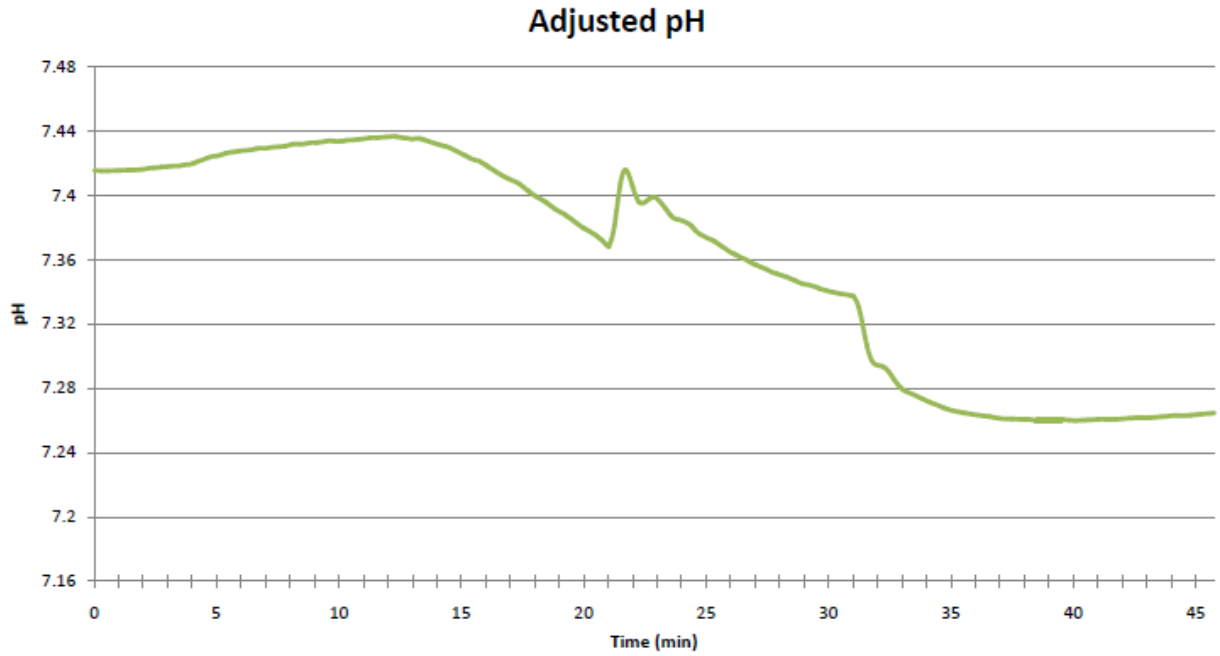


Figure 45: pH graphed across time(min) for Severe Hemorrhage with whole blood transfusion at 20min.

F. Software development for core and modules to match AMM 1.0 requirements

As part of finalizing the AMM 1.0 standard, much of the reference software we developed during the project needed to be updated and cleaned up to properly reflect and conform to the documented standard. This includes refactoring the CORE modules to be entirely compliant with the AMM standard as well as expanding features and functionality of the reference implementation. Significant developments also include:

- Physiology Manager updated to take AMM 1.0 compliant XML (per published schema) for physiology modifications and apply them to BioGears via API calls
- Command line utility for arbitrarily publishing any AMM message
- Simple web interface for basic simulation operation

G. American College of Surgeons (ACS) Field-Test Study

i. Major Activities

During Year 3 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. This year, major activities included the following: a draft study protocol including all assessment instruments was developed and pilot tested with the AMM platform and peripherals; the protocol was finalized based on results from the pilot test; a request for applications was developed and disseminated to 92 sites; applicant sites were reviewed and three were selected; an IRB application for the ACS was submitted and approved by American Institutes for Research; the local IRB processes are well underway at each of the three selected sites; and specific implementation plans are being developed for training staff at each site and ensuring data collection and management mechanisms are in place.

ii. Specific Objectives

Goals for Year 3 included finalizing the study design, study protocol, and assessment instruments; identifying the corresponding types of sites and resources needed to conduct the study; recruiting and selecting the sites through a competitive and fair process; completing the needed IRB processes; and effectively implementing the study at each site to collect the requisite high quality data.

iii. Key Outcomes

Work continued on finalizing the study design and protocol based on continued development of the AMM platform. Refinement efforts continued on the comprehensive study protocol, including the components of study design and hypothesis, simulation set up (simulator, scene details, space), roles of participants, roles of study team members (site investigator, project administrator, confederates, simulation technicians, data collectors), study procedures, site selection, role of the ACS Division of Education, study participant recruitment, consent and randomization processes, video/audio recording, assessment instrument administration, detailed participant flow, troubleshooting, data collection, protections, and confidentiality. Attachments to the protocol include consent forms, confidentiality agreements, assessment instruments (for first responder, anesthesiologist/CRNA, surgeon, simulation technician, and confederate), scripts for each scene of the scenario for each role (data collector, project administrator, confederate,

focus group facilitator, and simulation technician) and checklists (simulation technicians, participant recruitment plans).

A two-day pilot test was conducted in March 2019, at University of Washington. On the first day, the ACS study team was able to work with the mannikin platform and peripherals for the first time, provide some initial feedback to the AMM team, perform a test run of both conditions of the study, and refine plans for next day. On the second day, two teams of recruited participants (one first responder, anesthesiologist and surgeon on each team) concurrently completed all components of the study, from the initial orientation and consent processes, to completion of both conditions (AMM platform and peripherals only) of the study including data collection forms, to the end of the debriefing session. Participants provided important feedback regarding the AMM platform, timing, fidelity of the modules and scenario, and the relevance of assessment instruments. In addition, a final debriefing session was held between the ACS study team and the AMM study team to exchange feedback and identify next steps. As a result of the two-day pilot, adjustments were made to the manikin platform and peripherals; the planned simulation scenario; the site personnel roles, scripts and training needs; the room sets, timing and flow of the simulation scenario; the assessment instruments for data collection; and the data flow and reconciliation processes.

The Request for Applications (RFA) was finalized and distributed electronically on March 6, 2019, to over 200 institute directors, surgery directors, and administrators of the 92 American College of Surgeons (ACS) Accredited Education Institutes. Mechanisms were established to manage the submission of applications and responses to inquiries. In addition, a special, two-hour informational session was offered on March 15 during the 2019 ACS Simulation Summit for those interested in the project and approximately 15 individuals attended representing seven programs.

Eight applications were received by the April 1, 2019, deadline and underwent a very thorough review and rating process. Discussions regarding use of a Canadian site for a United States federal grant ultimately resulted in consensus that the site was admissible. By the end of April 2019, the following three sites had been selected and invited to participate in the study:

- Naval Medical Center San Diego (NMCSD), San Diego, California
- Penn State Health Milton S. Hershey Medical Center, Hershey, Pennsylvania
- Canadian Surgical Technologies and Advanced Robotics (CSTAR), London, Ontario, Canada

Each of the three sites agreed to participate and have been engaging in ongoing discussions with ACS staff since that time.

Following finalization of the study protocol and supporting documents, an Internal Review Board (IRB) application was submitted to the American Institutes for Research (AIR) and the decision was received on July 5, 2019. A Human Research Protocol Submission Form with the AIR IRB application package was submitted to the Human Research Protection Office (HRPO) for a pre-review and initial feedback was received on July 11. Based on the pre-review and additional documentation was secured regarding training and conflicts of interest. The accepted study protocol and supporting documentation from the IRB reviews were shared with the three study sites in mid-July so that they could begin preparing their local IRB applications. As of this report all three sites have submitted applications to their respective IRBs. ACS staff members have assisted with questions from the sites during the application preparation processes, as well as in response to questions from the local IRBs. As of the end of October 2019, none of the three

sites has received a decision from their IRB, even though the Request for Applications stipulated that the site be able to complete the IRB process within six weeks. Plans are in place for a rapid submission to HRPO upon receipt of local IRB decisions.

A project manager has been recruited and is now working with ACS staff on the study. This individual has programmed the final assessment instruments into RedCap to allow the correct sequential presentation based on each role and condition. Study participants at each site will be able to use a tablet or computer to complete the assessments electronically and submit the data in real time in a secure and confidential fashion. One site will not allow data to be entered on electronic devices, and those participants will be using paper forms. Thus, two parallel systems have been developed to collect the data across sites. In addition, ACS staff members have been preparing orientation materials to train staff at each site and have been developing specific implementation strategies to conserve time and ensure consistency across sites.

H. Support for ACS, Division of Education study

The activities during Year 3 are focused on completing the ACS Field-Test Study designed in Year 2 by the end-of-project date, January 25th, 2020. Preparation, execution and analysis of the study are the responsibility of the ACS team, but technical support is being provided by the UW CREST and UMN Teams. Completion of the ACS Field-Test Study will lead to a final report, written by the ACS and data that will inform future development by the UW CREST Team.

i. Study Preparation

a. AMM Study Technician:

A Study Technician for the ACS Field-test Study was hired by UMN to support the ACS Field-test Study. The technician understands the full-body AMM system, modules of interest, and the respective peripherals. They will be traveling to each of the three sites to provide training to local technicians, operational guidance, troubleshooting, and maintenance/repairs.

The UMN Study Technician has been preparing for the study by working at the University of Washington Medical Center, with the UW CREST Team. After learning how the system functions and how to run the ACS scenarios, additional activities performed by the Study Technician included developing AMM training resources and scenario test procedures, providing planning support, and refining and testing of the existing full-body manikin and peripherals (see "Changes Made" section).

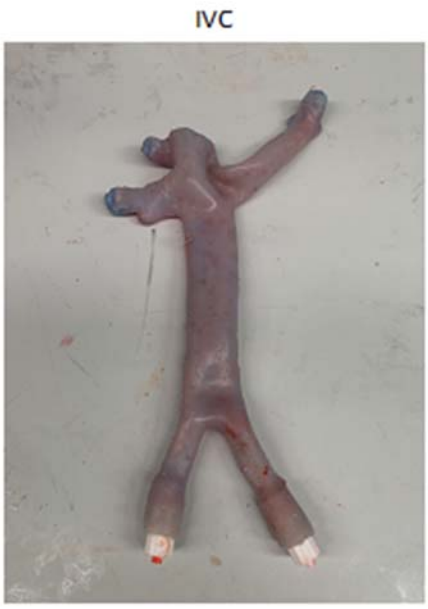
b. Disposables and Spares:

Based on the study protocol written by the ACS, the UW CREST Team fabricated the necessary quantity of disposable and spare parts, which both study conditions require. "Disposable" parts are parts that will undergo permanent damage and will no longer function appropriately (Fig. 46). The number of disposables provided were based on how long the part is expected to last. The "In-Use" parts are the parts that will be used during Condition 1 and Condition 2 but are not expected to undergo intentional damage. They are to be shipped with "Spare" parts, which will be used in case there is damage and the part needs to be replaced. Table 2 describes the list of disposables, spare, and in-use parts that are prepared to be shipped to a participating site.

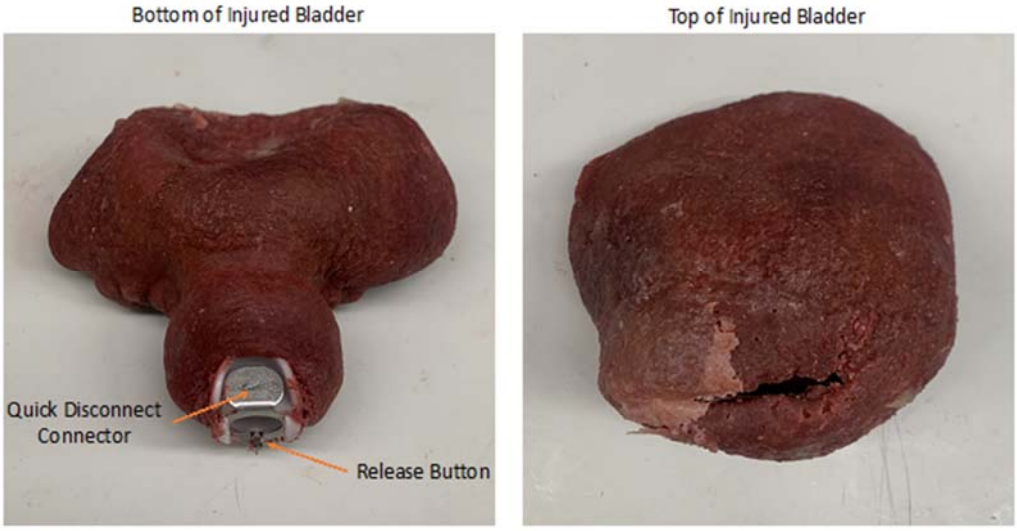
Disposables and Spares for ACS Study					
Training Purpose:	Part:	Disposable Quantity:	In-Use Quantity:	Spare Quantity:	Total Quantity:
Laparotomy	Laparotomy Shell		2	2	4
	Kidney Plate		2	1	3
	Liver		2	3	5
	Stomach		2	4	6
	Pancreas		2	2	4
	Spleen		2	3	5
	Spleen Plate	44			44
	IVC	33			33
	Bladder	40			40
Airway	Airway Sock		2	2	4
	Face Skin		2	1	3
IV Arm	IV Puck	40			40
Abdominal Palpation	ACDET AbSim		1	1	2

Table 2: Inventory list of disposable and spare parts for the ACS Usability Study.

a)



b)



c)

d)

Figure 46: Disposables fabricated during Year 3 include a) spleen plates, b) inferior vena cava's, c) bladders, and d) IV pucks.

ii. Training Resources

Training resources, in the format of written documents, images, and videos were produced by the Study Technician. These resources provide the participating on-site technicians with information regarding the scenario, AMM system, and peripherals before the Pelican Cases and Study Technician arrive on site. The resources detail how to set-up the system, technical operations/functions, running the ACS scenario, maintenance, and troubleshooting.

The intention behind these resources are to better orient the on-site technicians prior to arrival, such that training and scenario run throughs with the manikin will be more efficient.

iii. Changes Made

Year 3 afforded the UW CREST Team with additional time and effort devoted to adjusting and refining the system, such that it is prepared to fulfill the needs of the ACS scenario, study design, and expectations.

During this year, the UW CREST Team received specific feedback from ACS and other clinicians and results from trial runs to determine the need for additional changes. Several decisions were made to allow for physical changes to the AMM system and peripherals. For

reference, see the report from Quarter 10, which describes the outcomes of the pre-pilot and pilot conducted at the University of Washington. Firstly, the decision was made to add "dumb module" legs to the integrated manikin; the manikin now has all anatomical parts a medical provider would expect. The laparotomy module also underwent further improvements after the pilot, such that the fidelity, anatomical accuracy, and clinical relevance will more closely align with what was described in the official ACS scenario. The synthetic fat recipes were adjusted to improve fidelity and to accurately represent the health of the 30-year-old patient described in the ACS scenario. Furthermore, the fabricated injuries found on the bladder and spleen were decreased, to match the injuries the scenario describes. In order to improve set-up and anatomical accuracy, a spleen plate was fabricated, which includes the kidneys and the aorta embedded into connective fat (Fig. 47). Outside of physical manikin changes, additional supplies and equipment were obtained to also support the medical realism of this scenario. For instance, medical equipment made available at the point of injury reflects what a first responder would experience. Room set up in the emergency department and operating room closely mirror clinical expectations.

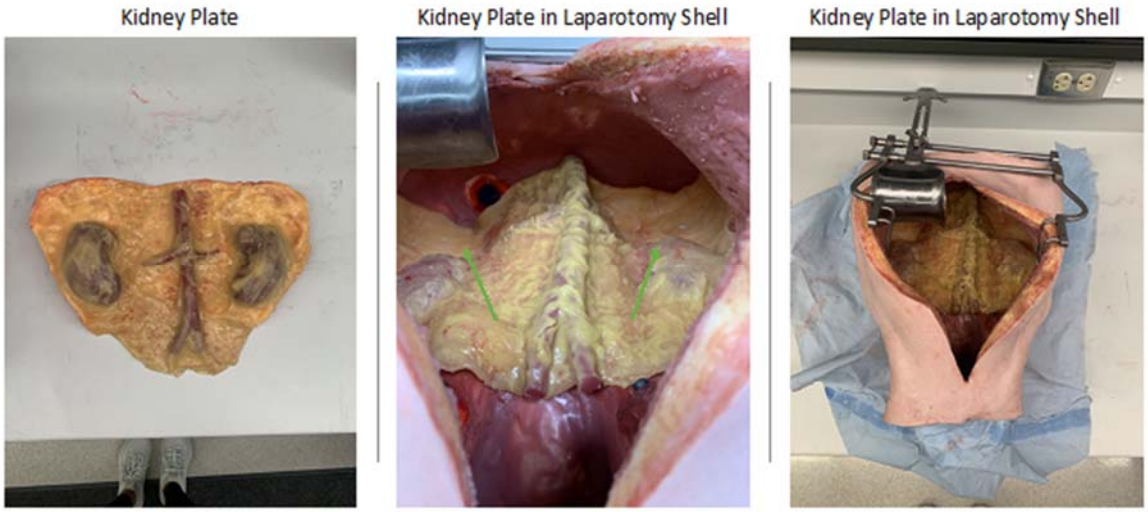


Figure 47: The kidneys and aorta are embedded into connective fat to improve fidelity and usability.

Additional changes were made to the system to prevent damage on-site. One major concern was spilling and staining due to the fake blood stimulant. This year, an enclosed waste bucket was designed to replace the previous open waste containers, which was susceptible to spills. These were added to the integrated manikin and the peripheral IV arm. The blood bags in the supply stacks were replaced with a more robust bag and angled fittings, which decreased leaking from the bags during operations.

To support the realism of the ACS scenario, software changes were also made. The ACS scenario calls for a starting patient state unique to each scene, where each team is expected to experience the same starting patient state, regardless of previous actions performed on the manikin. Saved patient states were produced by Vcom3D running scenarios to adjust the physiology of the patient overtime. Once the physiology is as described in the ACS scenario, the state of the patient was saved to the system.

The Study Technician learned how a technician would interact with the AMM system through the User Interface and digital modules developed by Vcom3D. By focusing on the human factors, changes were made to the design of the interface to improve usability while running the ACS scenario. When software changes were implemented, the Study Technician at UW would test and verify the changes made. Major changes included:

- Creation of specific pages for scenes 1-3, which populated information and action buttons that were relevant to the scene only.
- Implementation of a tracking mechanism for the number of times an action button is clicked; the button changes colors when a click occurs.
- Providing of real time updates from the AMM system include the status of the fluidics system, if the IV puck is initialized, number of modules connected (total and scene specific).
- Recording of actions performed on either the User Interface or the digital modules, such that all relevant data is the same.
- Implementation of a "pause setting" on the digital modules, which may be controlled from the User Interface.
- Implementation of clinician feedback to adjust Vcom3D digital modules to fit the scenario developed by the ACS.

The study demands consistent use of a prototype, that has yet to be tested for durability. In order to prevent internal damage to the fluidics lines, a cleaning and purge feature was added to the alpha-AMM system. This allows for a technician to flush the blood stimulant out of the manikin with clear fluid, then purge the system with air. The addition of this maintenance step is intended to sustain maintain functionality over the duration of the ACS study.

iv. Key Outcomes:

In Year 3, the ACS Field-Testing Study support provided by the UW CREST Team was motivated by the ability to fulfill the needs of the two-arm study. Fabrication and building outcomes include an available full body manikin, relevant peripherals, spare parts, and disposables. Pre-pilot and pilot outcomes, as described in the Quarter 10 Report, informed necessary changes to the system, both physically and digitally. The improved and current AMM system and the peripherals closely follow the expectations outlined by the ACS scenario. UW CREST Team has defined the logistics of shipping, storage, and preventative maintenance required for execution of the ACS Field-Testing Study.

4. Impact

Adoption of AMM Standards by other Projects.

AMM™ interoperability standards have been adopted by other projects, including both commercially-funded development and projects funded by DHA. These early-adopter projects are providing further feedback on the usability of the standards and they demonstrate an 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 using inexpensive hardware.

In addition to the modules that are demonstrated in *alpha* AMM™, projects developing or incorporating trainers using the standards that our team is aware of as of the time of this report include a Point of Injury Training System (POINTS) prototype led by IVIR, Sarasota, Fl and SimQuest, Annapolis, Md, a Humeral Head Intraosseous (HHIO) Infusion trainer being developed by Strategic Operations, San Diego, CA, an Abdominal Simulator (AbSim) by ACDET, Fort Worth, Tx, a lower-leg fasciotomy training system funded by Army Futures Command and led by Simetri, Orlando, FL , the Advanced Female Trauma Training System (AFTTS) led by Vcom3D, Inc. and Immersive Modular Patient Care Team Trainer (IMPACTT), a second project led by Vcom3D. UW CREST and VCOM3D are exploring the development of middle-ware to facilitate the integration of CAE's commercial physiology engine as well.

The AFTTS, Contract No. W81XWH-17-C-0181, led by Vcom3D, with University of Washington CREST as subcontractor, was demonstrated to JPC-1 integrated into a prototype Point of Injury Training System (POINTS) on June 19, 2019. While the AFTTS modules communicated via the AMM™ Distributed Data Services (DDS) bus, the system was integrated with other POINTS systems via a High-Level Architecture (HLA) gateway. One of these POINTS systems was the HumMod Physiology Engine, which modeled patient physiology response to injuries and interventions. As part of the demonstration, a decompression needle was used to deflate a tension pneumothorax in the AFTTS manikin. After decompression, bilateral chest motion resumed in the AFTTS manikin, and vital signs returned to normal.

Most recently, a prototype IMPACTT system, shown in Figure xx, was demonstrated to staff at the Army's Simulation and Training Technology Center (STTC) in Orlando. IMPACTT enables four or more providers, including a physician, nurse, respiratory specialist, and technician, to practice teamwork skills while treating a virtual trauma victim in an austere emergency room environment. A built-in assessment tool provides a summary of both individual and team performance. IMPACTT will be demonstrated to JPC-1 at an IPR in late October 2019.

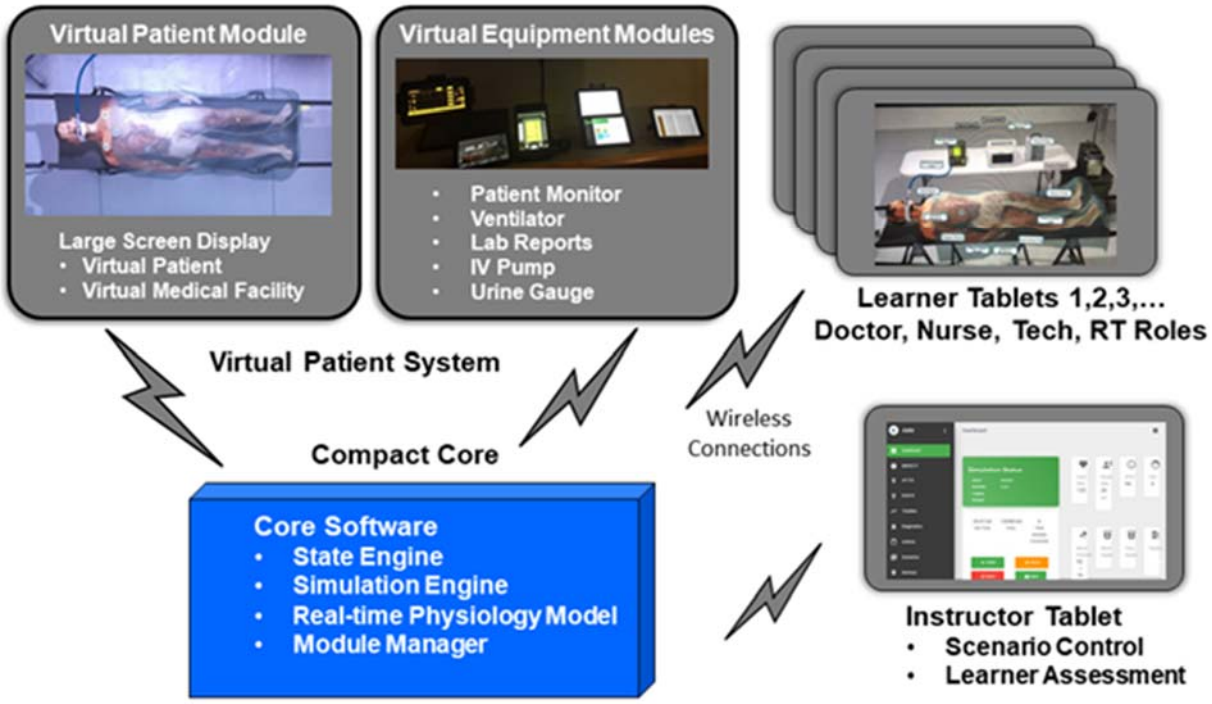


Figure 48: Vcom3D, Inc. Virtual Patient System.

5. Changes/Problems/Risks

A. Change/Problems

Based on the results the platform development and of a pilot study conducted in March 2019 at the University of Washington, Dr. Sweet requested a second in-scope re-budget and a No Cost Extension (NCE) of the AMM award. There were three parts to the request.

First, it was requested to transfer $287,093 from the American College of Surgeons (ACS) subcontract to the University of Washington (UW) subcontract. The education division of ACS will be conducting the AMM verification /usability study at ACS Accredited Education Institutes

and the original budget was based assuming that all of the expenses for the study would be covered by ACS. In finalizing the study design and logistics, it was determined that for efficiency and consistency across sites some of the costs originally included in the ACS budget would best be paid through the University of Washington (UW) subcontract or funded directly from the University of Minnesota.

Secondly, the pilot study also made clear that a skilled technician would be required to be present at the ACS study sites to set up the study, change modules or components during the study, maintain the platform along with the modules and trainers, and pack and ship the equipment from the site. The original plan was for each site to provide a technician, but in order to provide proper training and for consistency across study sites it was determined that it would be best to have the same technicians at each site for the duration of the study. Therefore, there was a request for an internal re-budgeting at the University of Minnesota to accommodate hiring of the techs and their travel to each of the sites for up to 30 days of the study at each site.

The ACS study design was also finalized based on the results of the pilot study. It became clear there would not be enough time to obtain the IRB/HRPO approval at multiple sites, collect the data sequentially at the sites, and analyze the date before the September 25, 2019 end date of the project. Therefore, a No Cost Extension (NCE) was requested from the original end date of September 25, 2019 through January 25, 2020.

The request for the re-budget and No Cost Extension was approved by the Sponsored Projects Administration at the University of Minnesota and submitted to the Contracting Officer on May 20, 2019. Notification of the approval of the amendment as described above was received from the Contracting Officer on August 2, 2019.

B. 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. Delays in site specific IRB/HRPO approvals will likely necessitate shorting of the period of the American College of Surgeons study at each site or elimination of one of the study sites. Given the nature of the data being collected, we still believe the data collected will accomplish our goals for a field test.

6. Products

A. 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. PubMed PMID: 29771813.

B. Presentations

Sweet, RM., International Meeting on Simulation in Healthcare, "JPCI Advanced Modular Manikin Phase II Update", Jan. 30, 2019, San Antonio TX.

Sweet, RM., Society Academic Urologists, "Novel Education Tools that Work", Feb 1, 2019, Houston TX.

Sweet, RM., UCF 1st Partnership II, "AMM JETS Core Presentation", Feb. 12, 2019, Orlando FL.

Sweet, RM., ACS Surgical Simulation Summit, "Surgeons and Engineers: A Dialogue on Surgical Simulation", Mar. 16, 2019, Chicago IL.

Sweet, RM., Engineering and Urology. Translational Success State-of-the-Art and Future: "Simulation in Urology: Where we are and where we are going". May 5, 2019, Chicago IL.

Sweet, RM., American College of Surgeon Committee Presentation, "Surgical Skills Training for Practicing Surgeons", June 28, 2019, Chicago IL.

Sweet, RM., Chehalis STEM Academy, "Simulation Design Process and Engineering Considerations: Surgery on the Manikin", July 18, 2019, Chehalis WA.

Sweet, RM., Surgery Grand Rounds at Walter Reed National Military Hospital, "Advancement in Simulation Science and Technologies for Military Medical Training", Aug. 14, 2019, Bethesda MD.

Sweet, RM., Military Heath Systems Research Symposium (MSHRS), "Training Effectiveness for Point of Injury Medical Care - Advanced Modular Manikin Phase 2 Update", Aug. 20, 2019, Kissimmee FL.

Sweet, RM., The Society of Laparoscopic Surgeons MIS Week, "It's Alive": The Advanced Modular Manikin Platform", Sept. 5, 2019, New Orleans, LA.

Sweet, RM., International Society for Medical Innovation and Technology. *Gerhard Buess Keynote Lecture*. "The Advanced Modular Manikin Platform: A disruptive technology for Surgical Simulation". October 11, 2019, Heilbronn, Germany.

C. Data, Models and Software

All work products created under this contract are being published under Creative Commons 4.0 Attribution on the AMM web site: www.advancedmodularmanikin.com. These include the data

models, anatomic data sets, instructional manuals, source code and drawing files. The current available data represents the first formal release, AMM 1.0.

D. Hardware

i. CREST Universal Segment Connector (CUSC)

The final design of CUSC is published on the AMM website and is available from a vendor through the website. The design files are part of the open source package, thus interested parties can also choose to produce their own copies as long as they use the published information to ensure compatibility.

ii. Advanced Modular Manikin Developers Kit AMMDK

AMMDK is a powerful board set intended for development work that includes pre-installed software to run the full AMM platform and the necessary development environment. The final design of AMMDK is published on the AMM website and is available from a vendor through the web site. The design files are part of the open source package, thus interested parties can also choose to produce their own copies as long as they use the published information to ensure compatibility. Alternately, they can create their own board set as long as they follow the published standards on DDS implementation and the Data Models.

iii. AMM Central Operating REsources (AMM C.O.R.E.)

In order to present AMM as a platform and provide developers with and essential tool for AMM compatible module development a reference design is provided that integrates the platform systems into a single non-manikin unit. These are the AMM Central Operating REsources or C.O.R.E.

The final designs and Bill of Material of AMM C.O.R.E. are published on the AMM web site. The design files are part of the open source package, thus interested parties can also choose to produce their own copies as long as they use the published information to ensure compatibility. We are still working on identifying a vendor that can provide a built-up kit to interested developers.

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:	Kenneth Kiberenge, MD
Project Role:	Post Doc Researcher – physiology verification
Nearest person month worked:	6
Contribution to Project:	Dr. Kiberenge was responsible for verification of physiology for the manikin and modules.

Name:	Rebecca Smith
Project Role:	Graduate Research Assistant – hardware/software verification

Nearest person month worked:	3
Contribution to Project:	Ms. Smith was responsible for testing and verification of the hardware/software design including the fluid system and connectors

Name:	Kai-bin Ooi
Project Role:	Research Professional/Technician
Nearest person month worked:	4
Contribution to Project:	Ms. Ooi is responsible for stress testing the AMM platform, developing protocols for operation, maintenance of the AMM platform during the ACS study as well as troubleshooting issues.

Change in Other Support for Robert M. Sweet, MD since 26 Sep 2018

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)
9/30/2016-10/30/19
$ 1,914,133
Sweet effort: 0.60 calendar month/yr

PI: Sweet
Development of an Advanced Airway Trainer Phase II
W911NF-17- C-0043
Army Futures Command
9/29/2017-12/28/2019
$ 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

Integration and Study Preparations

Accomplishments:

- **AMM Manikin configuration and functionality finalized for ACS study**
- **ACS study protocol approved by IRB and HRPO.**
- **ACS study protocols submitted for approval by local site IRBs.**
- **Study tech fully trained and training materials developed.**
- **Disposables, supplies and packing materials ready for shipping to ACS study sites.**
- **CDRLs delivered per approved schedule.**

Timeline and Cost

Activities	Year 1	2	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

Approved No Cost Extension through 25 JAN 2020
Use of "AMM" by companies for products not build with AMM standards

Budget Expenditure to Date

Budgeted Expenditures: $769,962
Actual Expenditures Recorded as of 25 SEP 2019: $6,483,809

Updated: 25 SEP 2019