Final Project Report

PROJECT TITLE	
Principal Investigator / Email Address	Elena Arvanitis
Project Team Lead	Siemens Corporation, Technology
Project Designation	20-17-01
MxD Contract Number	2021-05
Project Participants	Fast Radius Siemens Industry Software
MxD Funding Value	N/A
Project Team Cost Share	N/A
Award Date	01/27/2021
Completion Date	12/30/2022

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MxD PROJECT FINAL REPORT SUMMARY

MxD 20-17-01: Rapid and Secure Deployment of Medical Devices and Instrumentation

MxD Project Close Out Summary | February 20, 2024

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I. EXECUTIVE SUMMARY

In this project, the team led by Siemens used the ventilator example case (two patients with similar lung conditions connected to a single ventilator) to demonstrate how simulation can play a significant role in the development of medical devices by supporting their rapid design, prototyping and validation in emergency situations, such as the COVID-19 pandemic, that require a rapid turnaround time.

II. GENERAL PROJECT INFORMATION

	Description	
Project Name	***Rapid and Secure Deployment of Medical Devices and Instrumentation - Ventilator Case***	
Project Description	*Rapidly Manufacture Disposable Ventilator Parts During COVID-19*	
Technology Developed	*Concept demonstration:* ▪ *Digital Methodology Framework in medical device development.* ▪ *IoT-enabled connected care* ▪ *Executable digital twin to monitor system status and provide real-time insights for control*	*Program: Research & Development* *Thrust Area: Design Future Factory*
Project Lead	*Siemens Corporation, Technology*	*Principal Investigators: Gaurav Ameta, Elaine Tang* *Technical Representative: Elena Arvanitis* *Contract Representative: Terri Held*
Other Project Participants	*Fast Radius* *Siemens Industry Software*	*MxD Program Manager: Daniel Reed*
Project Funding	*N/A*	*Project Start Date: 01/27/2021* *Project End Date: 12/30/2022*
Technology Readiness Level	*TRL 6 Technology demonstrated in relevant environment.* *All demonstrations conducted with commercially available software.*	

a. Project Background

MxD-20-17 Project Call Title	
Project Call Release Date	*August 2020*
Project Call Goal	*In 2020, MxD was awarded 15 million in funding from the DoD via the CARES Act to address critical public health and infrastructure needs and to support manufacturing, as it mobilized in response to the COVID-19 pandemic.* *MxD created three programs that focused on supply chain resiliency and transparency, rapid and secure medical device deployment, and pharmaceutical industry production optimization.*

b. Project Goal Statement

The COVID-19 pandemic exposed critical vulnerabilities in the global health care supply chain. To overcome those vulnerabilities, we speed the design, and production of improved medical devices by leveraging the benefits of digital methodology framework (DMF) combined with device prototyping using additive manufacturing (AM), product simulation and generative design technologies. This effort seeks to create digital frameworks for processes that are executed repeatedly in designing, manufacturing, and validating medical devices in order to expedite their development and approval.

c. Specific Industry Problem or Challenge being addressed by the Project

Medical devices are highly regulated, and during production they undergo multiple checks and verifications to ensure that they function safely and as designed. However, in emergencies, rapid redesigns are often necessary, and delays can cost lives. For example, at the height of the COVID-19 pandemic, some physicians made decisions to put two patients on one ventilator because ventilators were in short supply, even though it was not an approved use. In emergencies such as these, it is necessary to rapidly compare new designs to existing, proven design models to determine which tests, simulations, and checks need to be re-evaluated. All these procedures take time, which can translate to increased patient suffering and loss of life.

d. How was the Problem addressed

In this project, the team led by Siemens, sought to address two critical questions physicians faced in the ventilator case (two patients with similar lung conditions connected to a single ventilator):

1. *How can the ventilator lines be split effectively?*
2. *How could they determine if a single ventilator could support two patients with similar lung conditions?*

To address the first question, the team designed a disposable assembly, consisting of a splitter and two one-way valves to limit patient-to-patient backflow, for use during shared ventilation of two patients in emergencies. The disposable assembly was designed such that it could be manufactured additively to enable rapid prototyping iterations. Design features and assembly performance were verified using computational fluid dynamics simulations as well as structural and durability analyses. Digital Methodology Framework (DMF) was implemented throughout design development and verification to analyze and track requirements for the dual patient use case and demonstrate rapid and compliant engineering design and prototyping.

To address the second question, the team modeled the 'ventilator-to-two patients' system and simulated its operation, and then built the "Lungs-in-the-Loop" (LiL) physical testbed (exact system match) to demonstrate further the benefit of having the system simulation model serve as a baseline to monitor system status and provide real-time insights for control (executable Digital Twin concept). The LiL testbed is IoT-enabled to collect sensor data from the patient lines and analyze operational trends in the cloud (IoT-enabled connected care concept).

e. Summary of Project Outcomes

Project MxD 20-17-01 was successful in:

- *meeting the program's objective of demonstrating rapid and secure medical device deployment through a) digital design development and engineering analysis using simulation, of a disposable assembly, consisting of a splitter and two one-way valves, for use during shared ventilation, and b) Digital Methodology Framework to analyze and track requirements for the ventilator case and demonstrate rapid and compliant engineering design and prototyping.*
- *answering both critical questions set forth in the ventilator case and demonstrating the benefits of virtual engineering design and simulation in the development and validation of medical devices.*
- *disseminating to the MxD membership relevant industry experience in implementing Digital Methodology Framework and showcasing its application to the development of medical devices.*
- *deploying the Lungs-in-the-Loop testbed at the MxD Factory Floor and thereby providing to MxD membership and visitors the opportunity to experience this test bench for a medical device and IoT-enabled architecture for connected care.*
- *meeting project schedule and budget.*

f. Final Project Deliverables

The following project deliverables have been produced and are available:

- *Technical Report*
  - *Technical overview of digital design development and verification of the disposable assembly, 1D system simulation model development and implementation of Digital Methodology Framework.*
  - *MxD 20-17-01_Ventilator Case_Tech Report_1.0 (available in pdf and docx formats)*
- *Presentations*
  - *Overview of Digital Methodology Framework, MxD Tech Call, November 18, 2021 (pdf and recording available)*
  - *Overview of Digital Design development and Engineering Analyses, MxD Tech Call, May 19, 2022 (pdf and recording available)*
  - *Final project presentation, February 23, 2023 (pdf and recording available)*
- *Workshops*
  - *Overview of industry trends and challenges in applying digital engineering methods at group and enterprise level, useful techniques and methods to address these challenges, and state-of-the-art tools and approaches to realize DMF.*
  - *Introduction to DMF, July 12, 2022 (pdf and recording available through YouTube)*
  - *Forward Methodology and application to MxD 20-17-01 project, July 19, 2022 (pdf and recording available through YouTube)*
  - *Reverse Methodology and benefits of a DMF implementation, July 25, 2022 (pdf and recording available through YouTube)*
- *Demonstration*
  - *Overview of the LiL Testbed*
  - *MxD 20-17-01 LiL Workshop_12_19_2022 (pptx and recording available)*
  - *Procedure to power up/down and troubleshoot the testbed*
  - *MxD_LungsinTheLoop_Startup_Shutdown.pptx*
- *Video*
  - *Marketing video available through YouTube*

III. KPI's + METRICS

No KPIs were defined and tracked for this project.

Metric	Baseline	Goal	Results	Validation Method
Enter Metric	Enter Baseline	Enter Goal	Enter Results	Enter Validation Method

IV. INDUSTRY IMPACT + POTENTIAL

a. Impact to the specific market the project was addressing and size of that market

The program's objective was to demonstrate the rapid and secure deployment of medical by creating and demonstrating the benefits of digital frameworks for processes that are executed repeatedly in designing, manufacturing, and validating medical devices in order to expedite their development and approval.

Medical devices are regulated by the U.S. FDA and undergo a lengthy approval process before market launch. Developing increasingly complex medical devices requires increasingly capable tools for simulation and testing that can enable medical device manufacturers to generate digital evidence of device performance throughout the product life cycle. Simulation is playing an increasingly significant role in the development of medical devices, saving development costs by optimizing device performance and reliability, reducing benchtop tests and clinical trials, and helping to speed the regulatory approval process.

The project sought to address medical device manufacturers and regulators by demonstrating the benefits of simulation in product development and testing, and showing how simulation can be used to answer two critical questions posed in the ventilator case in which the ventilator's operation had never been tested and approved for.

b. How this could be used in other industries

Simulation is widely adopted in industries such as automotive, aerospace, tooling, electronics, in product development and testing.

c. Next Steps based on other use potential

V. ACCESSING THE TECHNOLOGY

a. Background Intellectual Property

Siemens commercial software was used for:

- *Digital design development and comprehensive engineering analysis*
  - *Siemens NX MACH 3 Product Design (CAD software for product design), Simcenter STAR-CCM+ (software for CFD simulation and topology optimization), Simcenter 3D (software for structural and durability analysis), Simcenter Amesim (1D system simulation)*
- *Digital Methodology Framework*
  - *Polarion® ALM™ (software to streamline, automate, and optimize development processes across multiple projects and lifecycles)*
- *Lungs-in-the-Loop testbed*
  - *Industrial Edge Management License (for each Edge Device SIMATIC box PC), LiveTwin app (software to import 1D simulation models to Edge Devices SIMATIC box PC)*

b. Technical and System Requirements

The Lungs-in-the-Loop testbed is IoT-enabled and runs on a Siemens automation stack consisting of a PLC and Industrial Edge device that connects to Siemens Mindsphere (cloud solution and application ecosystem for data analysis and visualization).
The 1D simulation model of the 'ventilator-to-two patients' system developed in Simcenter Amesim is exported as a FMU and unpacked on the Industrial Edge for execution at runtime.

VI. ADDITIONAL COLLABORATION OPPORTUNITIES

The Principal Investigator is interested in further collaborating with MxD members in the following ways:
Opportunity to showcase to medical device manufacturers and regulators the value of system simulation in testing virtually the ventilator in an unforeseen scenario and having the system simulation model serve as a baseline to monitor system status and provide real-time insights for control (executable Digital Twin concept).
☐ Case studies to further test technology
☐ Further develop technology outcomes (advance TRL)
☐ Utilize MxD Partner Innovation Projects platform
☐ Commercialization partner
☐ Venture funding
☐ Other