AFRL-RH-WP-TR-2023-0010

Multi-Channel Infusion Pump (MCIP)

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711 HPW/RHBAM

JANUARY 2023
Final Report

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AFRL-RH-WP-TR-2023-0010 HAS BEEN REVIEWED AND IS APPROVED FOR PUBLICATION IN ACCORDANCE WITH ASSIGNED DISTRIBUTION STATEMENT.

LYONS.HEATHER.L.1538957999 Digitally signed by LYONS.HEATHER.L.1538957999 Date: 2023.05.23 08:38:11 -04'00'

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This report is published in the interest of scientific and technical information exchange, and its publication does not constitute the Government's approval or disapproval of its ideas or findings

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE *(DD-MM-YY)*
05-01-23

2. REPORT TYPE
Final Report

3. DATES COVERED *(From - To)*
September 2020 – December 2022

4. TITLE AND SUBTITLE
Multi-Channel Infusion Pump (MCIP)

5a. CONTRACT NUMBER
FA8650-20-C-6240

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER
Legacy

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
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8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)
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Air Force Research Laboratory
711th Human Performance Wing
Airman Systems Directorate
Airman Biosciences Division
Product Development Branch
En Route Care Section
Wright-Patterson AFB, OH 45433

AFRL
2510 North 5th St
Fairborn, OH 45324

10. SPONSORING/MONITORING AGENCY ACRONYM(S)
711 HPW/RHBA

11. SPONSORING/MONITORING AGENCY REPORT NUMBER(S)
AFRL-RH-WP-TR-2023-0010

12. DISTRIBUTION/AVAILABILITY STATEMENT
Distribution Statement A: Approved for public release. Distribution unlimited.

13. SUPPLEMENTARY NOTES
AFRL-2023-1650, cleared 10 April 2023

14. ABSTRACT
The En Route Care (ERC) section within the Air Force Research Labs (AFRL) collaborated on a Phase II Small Business Innovation Research (SBIR) to develop a multi-channel infusion pump (MCIP), the TRIAD-MP, that would eventually replace the MedSystem III multi-channel pump. The technical involvement of ERC did not begin until Lynntech had a physical prototype. The Lynntech team delivered 2 Beta prototypes after component level testing was completed. The ERC team began testing to identify performance and usability limits. The testing included testing relevant flow rates, fluid viscosities, and altitudes to encompass any scenario the device may be in during patient transport. Feedback from these tests were shared with Lynntech and changes were then implemented into the Gamma level prototypes.

15. SUBJECT TERMS
Lynntech, infusion pump, infusion device

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT:**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON** (Monitor)
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**			Heather Lyons
Unclassified	Unclassified	Unclassified	SAR	14	**19b. TELEPHONE NUMBER** *(Include Area Code)*

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1.0 SUMMARY

The En Route Care (ERC) section within the Air Force Research Labs (AFRL) collaborated on a Phase II Small Business Innovation Research (SBIR) to develop a multi-channel infusion pump (MCIP), the TRIAD-MP, that would eventually replace the MedSystem III multi-channel pump. The technical involvement of ERC did not begin until Lynntech had a physical prototype. The Lynntech team delivered 2 Beta prototypes after component level testing was completed. The ERC team began testing to identify performance and usability limits. The testing included testing relevant flow rates, fluid viscosities, and altitudes to encompass any scenario the device may be in during patient transport. Feedback from these tests were shared with Lynntech and changes were then implemented into the Gamma level prototypes.

Five Gamma level prototypes were delivered to ERC. Testing of these prototypes included testing relevant flow rates and fluid viscosities. Testing only occurred at ground level altitude due to performance limitations, testing at altitude was only deemed necessary if the device functioned as intended at ground level. Feedback from these tests were shared with Lynntech and the Lynntech team began work on further improvements. The improvements were focused on patient safety features and failure modes of the device. ERC supported any further testing that was required and provided input regarding any technical work.

2.0 INTRODUCTION

2.1 Background

There is an unmet need for a multi-channel infusion pump (MCIP) across various service branches. The pump must be US Food and Drug Administration (FDA) approved, reliable, and able to perform as intended in rugged, military environments. The pump is used throughout patient transport from first response to return to stateside and is used by multiple critical care teams. This means the pump must be user friendly and be able to infuse various fluids such as medications and/or blood products.

The MedSystem III MCIP was discontinued prior to 2011—Est. End of life for Air Force Mobility Command (AMC) is 2025. AMC & Air Combat Command (ACC) are spending approx. $1.4 million/month purchasing stop gap single-channel pumps. The stop gap pumps have critical space and function limitations. (e.g. cannot stack higher than 2). The 711th Human Performance Wing (711HPW) has a Phase III with Lynntech, Inc. for the development of a new MCIP. This effort addresses ACC & AMC R&D Priority #1 (2019) and AFMS Expeditionary Medicine Gap #21. There is an ACC-sponsored Capability Development Document (CDD) that was signed in September of 2015.

Lynntech delivered two integrated Beta prototypes to 711HPW in September 2021 for testing at AFRL. Five Gamma prototypes were delivered in March 2022 for testing. Ground level testing was completed, and data was sent to Lynntech for review. Upon review, Lynntech began work to improve volumetric outputs and other technical features. AFRL has supported Lynntech's effort by testing the technical updates and sending data.

In parallel to AFRL testing efforts, Lynntech also completed component and device level testing. The testing was focused on three main objectives: 1) advance the Technical Readiness Level (TRL) of the system by making improvements to key performance attributes, 2) demonstrate functionality in extreme environments that are relevant to the military, and 3) address any questions from the FDA relevant to the above considerations.

2.2 Objectives and Aims

The ERC Section in the Airman Biosciences Division at the 711th Human Performance Wing was tasked with testing the performance of the Beta and Gamma prototypes. A test protocol was written that listed two main objectives and five aims, which are listed below. The purpose of these objectives and aims is to find a replacement for the MedSystem III MCIP and to push the new prototype to a higher TRL.

> **Objective #1** - Obtain the services of a consulting firm with experience developing acquisition, regulatory and commercialization strategy for military medical devices to build a plan for the MCIP moving forward.
>
> **Objective #2** - Conduct an independent verification and validation test, including examining the effects of a variety of clinical and environmental conditions, as well as

trapped gas or “air in the line”, power regulation performance, and preliminary safe-to-fly testing to assess the battery and pump systems. The legacy MedSystem III MCIP will be used as a comparison system for prototype performance testing.

Aim #1 - Determine the effect of fluid rate and density, containers, hypobarism, simultaneous multi-channel use, secondary infusion, and fluid container and pump orientation on the operating characteristics of the MCIP prototype (Triad) versus the current MedSystem III MCIP.

Aim #2 – Determine the types of device alarms and their frequency for both the MedSystem III and prototype MCIP (Triad) devices.

Aim #3 - Evaluate the MCIP prototype (Triad) against the current MedSystem III MCIP fluid delivery accuracy at various degrees of battery charge at Ground Level (GL) (820 Ft, WPAFB, OH).

Aim #4 – Evaluate the effect on blood hemolysis for the MCIP prototype (Triad) versus the current MedSystem III device at GL (820 Ft, WPAFB, OH). (See the MCIP Hemolysis Testing Protocol for details).

Aim #5 - Perform preliminary non-destructive tests from MIL-STD-810G/JECETS for the battery and hydrogen-gas pump systems of the MCIP prototype.

3.0 METHOD, ASSUMPTION AND PROCEDURES

3.1 Test Methods

Aim 1 testing was completed at AFRL and included several variables to represent different scenarios the pumps would be exposed to. These variables include different flow rates and densities of fluids to represent medications or blood that may be infused. The variables also included several positions and orientations of the pump and fluids. Table 1 shows each of the testing scenarios. The Beta devices were tested at ground level and at three different altitudes, while the Gamma devices were tested at ground level only. Battery tests were also completed on the Beta and Gamma level devices to test the life of the batteries installed in the devices. Per the CDD the battery life must be at least 8 hours.

The test setup included the use of a saline IV drip bag, IV lines that are connected to a scientific burette, and the MCIP device and cassette. Figure 1 shows the test setup. After setup was complete, the test ran for two hours at the specified flow rate and altitude. Volumetric measurements were recorded every fifteen minutes from the burette and the device’s expected output was also recorded. Any alarms that occurred during the test was also recorded with any notes about the device’s operation and functionality.

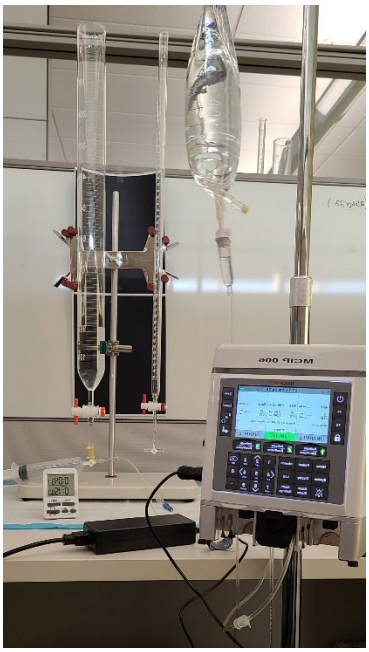

Figure 1: MCIP Test Setup

The analysis of the data compared the expected volumetric output to the actual volumetric output. A percent error was calculated to quantify the performance of the device. Per the CDD for the MCIP and FDA regulations, there is a requirement for the percent error of the volumetric output to be between +5 percent (%) and -5%. This was considered during the analysis.

Aim 2 testing occurred in parallel with Aim 1 testing. Any alarms that occurred during testing were recorded in an electronic data sheet. This allowed for easy analysis of each alarm type and the occurrence rate.

Aim 3 testing involved running all the tests from Aim 1 and 2 with a MedSystem III device to compare performance metrics.

Aim 4 testing was completed on the Beta level prototype only. The test involved pumping human blood products through the prototype using the same setup as in Aim 1.

Aim 5 testing was not complete due to time constraints with completing Aim 1 – 4 testing.

Lynntech completed several tests and gathered much data on a component level and a device level. All the test methods and data are described in the final report written by Lynntech. The objective of component level testing was to test the functionality of the cassettes and actuators at different altitudes and temperatures. The device level testing included a beta level and a gamma level. The beta level testing included evaluation of core functionality and usability components such as the three independent infusion channels, a pushbutton user-interface, system alarms, and prototype cassettes. The gamma level testing included evaluation of a prioritized list of development issues that was put together by Lynntech and AFRL. The list can be found in the final report by Lynntech.

Table 1. MCIP Beta and Gamma Test Scenarios

Test Type	Flow Rates Tested (mL/hr)	Fluid Types Tested	Altitudes Tested
Single Channel	6 18 240 600 960	Distilled Water Isopropyl Alcohol Glycerin	Ground 5,000 ft 8,000 ft 16,000 ft
Multiple Channel	18 96 240	Distilled Water Isopropyl Alcohol Glycerin	Ground 5,000 ft 8,000 ft 16,000 ft
Secondary Infusion	250	Distilled Water	Ground
Fluid Container	125	Distilled Water	Ground
Pump Orientation	125	Distilled Water	Ground

4.0 RESULTS AND DISCUSSIONS

4.1 Beta Results

In all, there were forty-three single channel tests, six multiple channel tests run, and thirty-seven other tests run (including orientation of the pump, location of the fluid bag, and battery tests). Percent error was calculated for each category. The results are summarized in Table 2 with all 'Other' tests included in 'Single Channel' summary. There was a total of 83 alarms during testing of the Beta prototypes. The alarms consisted of above pump air-in-line, below pump air-in-line, and actuator alarms.

Table 2. Beta MCIP Data Analysis Summary

Test Type	Percent Error Occurrences									
	(<-20)	(-19.99, -15)	(-14.99, -10)	(-9.99, -5)	(-4.99, 0)	(0, 4.99)	(5, 9.99)	(10, 14.99)	(15, 19.99)	(>20)
Single Channel	8	5	10	22	87	146	154	81	14	39
Multi-Channel	10	1	5	5	13	27	18	15	17	14
Total	18	6	15	27	100	173	172	96	31	53

Battery tests lasted on average 162 minutes (2.7 hours) with 5 tests being run. The range of time the batteries last is 135 minutes up to 225 minutes.

4.2 Gamma Results

There were two iterations of testing. Iteration one included seventy-five single channel tests, five multiple channel tests, and sixty other tests (including orientation of the pump, location of the fluid bag, and battery tests). Percent error was calculated for each category. The results are summarized in Table 3 with all 'Other' tests included in 'Single Channel' summary. Iteration two tested software and mechanical changes to the Gamma prototypes and included fourteen single channel tests. Percent error was calculated, and the results are also summarized in Table 3. There was a total of 93 alarms during testing of the Gamma prototypes. The alarms consisted of above pump air-in-line, below pump air-in-line, actuator, and occulusion alarms.

Table 3. Gamma MCIP Data Analysis Summary

Test Type	Percent Error Occurrences									
	(<-20)	(-19.99, -15)	(-14.99, -10)	(-9.99, -5)	(-4.99, 0)	(0, 4.99)	(5, 9.99)	(10, 14.99)	(15, 19.99)	(>20)
Single Channel	106	2	3	35	61	108	198	389	166	97
Multi-Channel	24	0	0	2	15	2	2	2	0	90
Total	136	4	5	47	100	192	372	708	324	194
Gamma Iteration 2	3	3	7	2	25	35	14	1	0	0

Battery tests lasted on average 309 minutes (5.5 hours) with 5 tests being run. The range of time the batteries last is 250 minutes up to 330 minutes.

4.3 MedSystem III Results

In all, there were one hundred and thirty-four single channel and other tests (including orientation of the pump, location of the fluid bag, and battery tests) and seventy-two multiple channel tests run. Percent error was calculated for each category. The results are summarized in Table 4 with all 'Other' tests included in 'Single Channel' summary. There was a total of 134 alarms during testing of the Gamma prototypes. The alarms consisted of above pump air-in-line, below pump air-in-line, actuator, and battery alarms.

Table 4. MedSystem III MCIP Data Analysis Summary

Test Type	Percent Error Occurrences									
	(<-20)	(-19.99, -15)	(-14.99, -10)	(-9.99, -5)	(-4.99, 0)	(0, 4.99)	(5, 9.99)	(10, 14.99)	(15, 19.99)	(>20)
Single Channel	0	0	0	1	24	116	19	4	1	2
Multi-Channel	7	0	1	1	6	156	22	3	1	0
Total	7	0	1	2	30	272	41	7	2	2

4.4 Discussion

Based on the requirements listed in the CDD of the MCIP and the objectives listed in the testing protocol, no prototypes meet volumetric output accuracy requirements. Although, the modified Gamma prototype has 67% of points within its limits, while the Beta and Gamma prototypes have 41% and 14% within the limits, respectively. For a prototype to move forward with the product development process, the volumetric output accuracy needs to be 100% within the limits defined in the CDD and by the FDA. This for the safety of the patient and to ensure a reliable device is produced.

The number of alarms is also an issue for the prototypes. The alarms occurred multiple times during tests and impeded the delivery of the fluids. The alarms were sometimes unable to be cleared or had no visible cause. This is another safety concern for patients in need of fluids or medications.

Battery life also does not meet the requirement defined in the CDD. The requirement calls for a battery life of 8 hours. The longest battery life in the current prototypes is 5.5 hours. This is an issue for patient transport and safety.

It is understood that this product is still a prototype and is not a final product. This means there will be challenges with the performance and functionality as the development team continues advancement of the device. The development team has shown their ability to find solutions to problems in the last iteration of the Gamma device by improving the volumetric output accuracy significantly. The team has also made improvements to the actuator reliability and patient safety features in the device. The changes include hardware and software to allow for better control of the volumetric output, power efficiency throughout the device (to extend battery life), and overall performance improvement.

Next steps should include continuing development and refinement of device components that allow the device to meet performance requirements. In parallel, the development should prepare for verification and validation testing. This testing is important for FDA approval and JCETS approval.

5.0 CONCLUSION

The 711th Human Performance Wing entered a Phase II SBIR with Lynntech, Inc to create a MCIP. The purpose of the SBIR is to replace the obsolete MedSystem III pump which is quickly becoming unavailable for use within the DoD. The new pump was developed to have increased functionality, usability, performance, and reliability. There was 2 Beta and 5 Gamma prototypes delivered to the ERC team. Testing was conducted by the ERC Team at the 711HPW and by Lynntech. The tests included using the pump in different environments with high and low altitude and temperature, and the tests included using the pump at different flow rates with different fluids to represent the different scenarios it would go through.

Although, there were many performance challenges throughout the duration of the device development, there were also improvements made with each iteration of the prototype. Although,

there were significant improvements made to the prototypes after the initial round of Gamma testing was complete. The ERC team and Lynntech worked together to improve patient safety measures, including volumetric output accuracy. Other improvements include device battery life, cassette reliability and durability, and actuator reliability. Specifics of these improvements are discussed in the Lynntech, Inc final report.

REFERENCES

Lynntech, Inc Final Report

AFRL Testing Protocol

LIST OF SYMBOLS, ABBREVIATIONS AND ACRONYMS

711th Human Performance Wing (711HPW)
Air Combat Command (ACC)
Air Force Mobility Command (AMC)
Air Force Research Labs (AFRL)
Capability Development Document (CDD)
En Route Care (ERC)
Food and Drug Administration (FDA)
Ground Level (GL)
Multi-Channel Infusion Pump (MCIP)
Percent (%)
Small Business Innovation Research (SBIR)
Technical Readiness Level (TRL)