AWARD NUMBER: CDMRPL-22-0-DM210266

TITLE: Effects of Extreme Cold on En Route Care Medical Equipment and Treatment Protocols

PRINCIPAL INVESTIGATOR: Sylvain Cardin, PhD

CONTRACTING ORGANIZATION: Naval Medical Research Unit, San Antonio, TX

REPORT DATE: July 2023

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
July 2023	Annual	01Jun2022-31May2023

4. TITLE AND SUBTITLE

Effects of Extreme Cold on En Route Care Medical Equipment and Treatment Protocols

5a. CONTRACT NUMBER
CDMRPL-22-0-DM210266

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

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5d. PROJECT NUMBER
CDMRPL-22-0-DM210266

5e. TASK NUMBER

5f. WORK UNIT NUMBER
G2204

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Naval Medical Research Unit San Antonio
3650 Chambers Pass
Joint Base San Antonio Fort Sam Houston TX 78234

8. PERFORMING ORGANIZATION REPORT NUMBER

PAO 23-330

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

With the potential for warfighters to be wounded during combat in extremely cold environments, there is the need for renewed medical research revolving around combat casualty care in the Arctic. Current research chiefly involves preventing injuries that are caused by the cold, like frostbite or hypothermia. The objective of this research is to conduct a broad, baseline evaluation of the medical equipment provided to military medical personnel and the standard care protocols that are expected to be performed on patients with traumatic injuries sustained on the battlefield in extreme cold environments.
The goal of this project is to understand and document how the extreme cold affects medical materiel as well as casualty care treatment protocols at the point of injury (POI), during prolonged field care (PFC), and through the en route care (ERC) process. Because little is known regarding the magnitude of both patient and caregiver exposure, the accessibility of even minimal shelter and the availability of transportation, these phases of care will be treated as a continuum rather than clearly divisible elements.
This project concentrates on evaluating the common medical equipment and casualty care assessment and treatment protocols used at the POI, during PFC and throughout ERC. The benefits of this project will be the documentation of current gaps and deficiencies of both medical devices and treatment protocols, illustrating areas of improvement needed in Arctic and extreme cold POI, PFC and ERC medicine. The findings of this study will direct future Arctic research leading to the development of Arctic-capable medical devices and treatment protocols. The benefits of this research will lead to the increase in both warfighter and civilian survivability in Arctic environments.
In the first year of the study, procurement of material exemplars and preparations for testing in cold chambers under controlled conditions was begun. Cold chamber testing is expected to be complete by year two. In the first year, preparations for field testing also occurred including research on the development of a manikin capable of simulating a variety of trauma and the loss of body heat. Preparations for field testing during the ICEX 24 Arctic training exercise focused on preparing the protocol test cards.
After the 4-year Period of Performance, a report will be developed and distributed with the intent of informing decision makers about the results of the evaluations. Ideally, there will be follow-on studies which will further investigate the deficiencies in materiel and procedures and studies dedicated to developing new devices and protocols which are sufficient for use in the extreme cold.
Service members that are injured conducting operations in Arctic regions will receive more effective care by providers using Arctic-capable medical equipment and effective treatment protocols, decreasing mortality and increasing our warfighting capabilities. With increased commercial activity in the Arctic, the probability of non-combat trauma is also increased. Thus the civilian population will also benefit from improved medical equipment and procedures.

15. SUBJECT TERMS

Extreme Cold, Artic, Point of Injury, En Route, Materials Testing, Medical Equipment, Tactical Combat Casualty Care Protocols and Procedures

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRDC
Unclassified	Unclassified	Unclassified	Unclassified	20	19b. TELEPHONE NUMBER *(include area code)*

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

TABLE OF CONTENTS

1. INTRODUCTION:

The goal of this project is to understand how the extreme cold affects medical materials as well as the care providers' performance under these conditions. The objectives are to identify and measure deficiencies in the operational effectiveness of both the medical materiel (equipment and supplies/consumables) currently approved for use, as well as medical procedures and standards of care currently recommended for point of injury (POI), prolonged and en route care (ERC) settings under extreme cold/Arctic conditions.

The start date of this project was 01 JUL 2022. The reporting period for this Year 1 Annual Report is from 01 JUL 2022 through 30 JUN 2023.

2. KEYWORDS: *Provide a brief list of keywords (limit to 20 words).*

Extreme Cold, Arctic, Point of Injury, En Route, Materials Testing, Medical Equipment, Tactical Combat Casualty Care Protocols and Procedures

3. ACCOMPLISHMENTS:

What were the major goals of the project?

The long-term goals of this research are to:

1. Provide a baseline of operational performance standards for both materiel and procedures,
2. Identify the highest risk areas that demonstrate deficiencies in the extreme cold, and
3. Gain insights leading to future research and development of both material solutions and improved guidelines for the continuum of POI, prolonged and ERC in the extreme cold.

Specific Aim 1: Test and evaluate the materials and properties of approved-for-use and developmental medical materiel in a controlled, environmental chamber simulating Arctic conditions. (Months 1-18, 15%)

Statement of Work (Revised and Approved June 2023)

TASK	TIME PERIOD (months)	COMPLETE (%)
SPECIFIC AIM 1: TEST & EVALUATE MATERIALS AND PROPERTIES IN A CONTROLLED ENVIRONMENT	1-18	15
Major Task 1.1: Develop testing protocols and acquire items for testing	1-12	60
Subtask 1.1.1: Finalize item list	1-8	100
Subtask 1.1.2: Purchase items for testing	8-12	75
Subtask 1.1.3: Test protocol development	9-12	75
Subtask 1.1.4: Test fixture development	10-12	10

Subtask 1.1.5: Protocol dry runs	10-12	0
MILESTONE 1.1: Test Plan	12	60
Major Task 1.2: Testing in extreme cold	13-18	0
Subtask 1.2.1: Cold chamber testing	13	0
Subtask 1.2.2: Data analysis	13-15	0
Subtask 1.2.3: Reporting	16-18	0
MILESTONE 1.2: Technical Report	18	0
Major Task 1.3: Cyclic exposure to extreme cold (starting 2/24)	13-18	0
Subtask 1.3.1: Cold chamber testing	13	0
Subtask 1.3.2: Data analysis	13-15	0
Subtask 1.3.3: Reporting	16-18	0
MILESTONE 1.3: Technical Report	18	0

Specific Aim 2: Test and evaluate the effectiveness of current materiel, care protocols, and training using POI, prolonged care and ERC trauma scenarios during extreme cold weather training exercises. (Months 2-38, 5%)

Statement of Work (Revised and Approved June 2023)

TASK	TIME PERIOD (months)	COMPLETE (%)
SPECIFIC AIM 2: TEST & EVALUATE EQUIPMENT AND PROTOCOLS IN THE FIELD	2-38	5
Major Task 2.1: Manikin development	6-26	5
Subtask 2.1.1: Literature review & research	6-14	90
Subtask 2.1.2 Prototyping	11-17	0
Subtask 2.1.3 Design Rendering	11-19	0
Subtask 2.1.4 Tooling	17-22	0
Subtask 2.1.5 Manufacturing	21-26	0
MILESTONE 2.1: Manikin	26	5
Major Task 2.2: Protocol assessment cards	2-13	90
Subtask 2.2.1: Protocol development	2-10	80
Subtask 2.2.2: Metrics	6-13	95
MILESTONE 2.2: Protocol Cards	13	90
Major Task 2.3: Pilot testing	12-23	0
Subtask 2.3.1: IRB submission	14-16	0
Subtask 2.3.2: IRB approval	17-18	0
MILESTONE 2.3.1: IRB Protocol	18	0
Subtask 2.3.3: Materials acquisition	12-14	0
Subtask 2.3.4: Recruitment	19-20	0
Subtask 2.3.5: Pilot testing	19-20	0
Subtask 2.3.6: Data analysis	21-22	0
Subtask 2.3.7: Reporting	22-23	0

MILESTONE 2.3.2: Technical Report	23	0
Major Task 2.4: Final testing	13-38	0
Subtask 2.4.1: IRB submission	25-26	0
Subtask 2.4.2: IRB approval	27-29	0
Subtask 2.4.3: Materials acquisition	24-26	0
MILESTONE 2.4.1: IRB Protocol	29	0
Subtask 2.4.4: Recruitment	30-32	0
Subtask 2.4.5: Final testing	30-32	0
Subtask 2.4.6: Data analysis	33-35	0
Subtask 2.4.7: Reporting	35-38	0
MILESTONE 2.4.: Technical Report	38	0

What was accomplished under these goals?

Specific Aim 1
Major Task 1: (in process, 60% complete)

Subtask 1 – Finalize device and equipment list (100% complete – see Appendix 9.1)
- Researched national source numbers (NSNs) for test items for identification and AMAL list agreement
- Reviewed list with collaborators

Subtask 2 – Material Acquisition (in process, 75% complete – see Appendix 9.2)
- Generated purchase request orders for purchases
- Purchasing from the ECAT medical equipment and supply system is not available for NAMRU San Antonio requiring GSA purchases resulting in longer lead times and, in some cases, increased pricing

Subtask 3 – Test protocol development (in process, 75% complete – see Appendices 9.3 & 9.4)
- Designed test protocols for each item on the device and equipment list
- Developed and researched established protocols for test list items
- Planned with CRREL engineers regarding extreme cold testing

Subtask 4 – Test fixture development (in process, 10% complete – see Appendix 9.5)
- Designed test fixtures for specific items due to their unique specifications and operations

Subtask 5 – Test protocol dry runs (not started, 0% complete)

Specific Aim 2

Major Task 1 (in process, 5% complete)

Subtask 1 – Literature review & research (in process, 90% complete)
- Requirements set with SME input (in order of priority):
  - Core and peripheral body temperature simulation
  - Massive hemorrhage simulation
  - Airway management simulation
  - Needle decompression simulation

- An extensive literature review has been conducted including physiological and anatomical features as well as cold injuries, response to trauma, and evaluation procedures
- Research in test design of skeletal frame and circulatory pump; prototype development is ready for the pump
- Development of a design requirement matrix and corresponding technical specification sheet for manikin design including anatomical and physiological features

Major Task 2 (in process, 90% complete)

Subtask 1 – Protocol Development (80% complete – see Appendix 9.6)

- Protocol assessment card feedback from SMEs at ICEX22
- Protocol task list finalized
- Materials purchase list generated and materials purchased
- Test plan drafted

Subtask 2 – Metrics (95% complete)

- Metrics revised and finalized

What opportunities for training and professional development has the project provided?

- The project provided opportunities for project engineers to learn about the effects of extreme cold on both casualties and care providers in the field, during casualty transport, and at Role 1 care facilities (medical support which is integral or allocated to a small unit, and will include the capabilities for providing first aid, immediate lifesaving measures, and triage**). In addition to personnel effects, the project engineers learned of the effects of extreme cold on authorized medical equipment issued to military units.
- The cold chamber test planning provided opportunities for project engineers to expand their knowledge of established test standards, e.g., ASTM test protocols for adhesives and rigid bodies.
- The PI and test lead attended the HFM-RSY-349 Symposium: Human Performance and Medical Treatment and Support During Cold Weather Operations (17-19 OCT 2022). This meeting gave the opportunity to discuss the project with international experts in the field.
- The PI attended the Below Zero Medicine (BZM) conference (9-12 May, 2023) sponsored by Alaska Command's Surgeon General office and the 673d Medical Group. The PI presented the status of the Polar Medicine working group including details on this project. This conference provided an opportunity to discuss the project with U.S military experts in the field.
- An Oak Ridge Institute for Science and Education Fellow was brought onto the project for the summer to work on the literature review and research for the cold weather test manikin. He is a Penn State University undergraduate student.

** NATO Logistics Handbook, (1997), 3rd Ed., Ch. 16, https://www.nato.int/docu/logi-en/1997/lo-1610.htm, Accessed August 21, 2023.

How were the results disseminated to communities of interest?

In addition to the two briefings mentioned above, the project was briefed to the International Cooperative Engagement Program for Polar Research Human Performance Working Group and has become a major element of the Cognition Performance and Instrumentation Sub-working group under the Materials and Training Aids & Test Platforms Task Areas.

What do you plan to do during the next reporting period to accomplish the goals?

Complete Specific Aim 1, Major Task 1

- Purchase remaining test items and fixture components
- Continue protocol development for cold climate testing for each item
- Continue scheduled meetings with CRREL engineers
- Schedule testing at CRREL

Complete Specific Aim 1, Major Tasks 2 & 3

- Test items in extreme cold conditions at CRREL and report the results.

Continue work on Specific Aim 2, Major Task 1

- Set manikin design
- Build and test prototypes

Continue work on Specific Aim 2, Major Task 2

- Obtain IRB approval for pilot testing
- Pilot test protocol assessment card deck with SMEs at ICEX 24

4. **IMPACT:**

Nothing to Report.

What was the impact on other disciplines?

Nothing to Report.

What was the impact on technology transfer?

Nothing to Report.

What was the impact on society beyond science and technology?

Nothing to Report.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

Nothing to Report.

Actual or anticipated problems or delays and actions or plans to resolve them

Regarding Specific Aim 1, funding for testing at CRREL was delayed to Y2 of the project. CRREL and NAMRU San Antonio funding are off by a Fiscal Year making it difficult to align the effort. Thus, some preliminary work with CRREL was accomplished, but scheduling use of the cold testing facilities was not possible. When funding is actually available to CRREL, the timeline will be revised.
Regarding Specific Aim 2, the timeline was revised (June 2023) to reflect the proposed versus actual start date for the period of performance, the delayed availability of funding and the forecasted execution of the contract with SynDaver.

Changes that had a significant impact on expenditures

The inability to make purchases using the ECAT system have impacted the acquisition of some equipment and supplies for testing due to availability and/or pricing.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Significant changes in use or care of human subjects

Nothing to Report.

Significant changes in use or care of vertebrate animals

Nothing to Report.

Significant changes in use of biohazards and/or select agents

Nothing to Report.

6. PRODUCTS:

- **Publications, conference papers, and presentations**

Journal publications.

Nothing to Report.

Books or other non-periodical, one-time publications.

Nothing to Report

Other publications, conference papers and presentations

The PI attended the Below Zero Medicine (BZM) conference (9-12 May, 2023) sponsored by Alaska Command's Surgeon General office and the 673d Medical Group and presented the status of the Polar Medicine working group including details on this project.

- **Website(s) or other Internet site(s)**

Nothing to Report.

- **Technologies or techniques**

Nothing to Report.

- **Inventions, patent applications, and/or licenses**

Nothing to Report.

- **Other Products**

Nothing to Report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	Sylvain Cardin, PhD
Project Role:	PI
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	4
Contribution to Project:	Dr. Cardin has performed overall project management and has represented the effort at several conferences and working groups.
Funding Support:	N/A
Name:	William D'Angelo, PhD
Project Role:	NAMRU-SA Test Lead
Researcher Identifier (e.g. ORCID ID):	0000-0001-5738-6571
Nearest person month worked:	6

Contribution to Project:	Dr. D'Angelo has performed project management and planning and contributed to the development of the protocol cards, compiling the equipment list, procuring equipment, test fixture development, manikin development and protocol development.
Funding Support:	N/A
Name:	Justin Bequette
Project Role:	Research Engineer II
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	3
Contribution to Project:	Mr. Bequette is responsible for developing the protocol test cards.
Funding Support:	N/A
Name:	Jack Harris
Project Role:	Research Engineer II
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	8
Contribution to Project:	Mr. Harris is responsible for compiling the equipment list, procuring equipment, test fixture development, and protocol development.
Funding Support:	N/A
Name:	Nadine Baez
Project Role:	Manikin Development
Researcher Identifier (e.g., ORCID ID):	N/A
Nearest person month worked:	3
Contribution to Project:	Ms. Baez is the lead at SynDaver Laboratories.
Funding Support:	N/A
Name:	Kathryn Trubac
Project Role:	Research General Engineer
Researcher Identifier (e.g., ORCID ID):	N/A
Nearest person month worked:	1
Contribution to Project:	Ms. Trubac is responsible for coordinating and overseeing the test efforts at CRREL for this project.
Funding Support:	N/A

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to Report

What other organizations were involved as partners?

Nothing to Report

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: N/A

QUAD CHARTS: Attached

9. APPENDICES:

Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

9.1 Final Test Equipment List

Below is the final equipment list showing the equipment description, authorized medical allowance list (AMAL), material concerns resulting from exposure to extreme cold, national stock number (NSN, if available), and quantity for testing and control.

EQUIPMENT	AMAL	MATERIAL CONCERNS	NSN	QUANTITY
Airway Supraglottic	645, 647, 648	Liquids, Patient Interface, Plastic	6515-01-618-8278	2
Bag Valve Mask (BVM), Laerdal Silicone Resuscitator	631, 633, 645, 647, 648	Liquids, Mechanicals, Patient Interface, Plastics	6515-01-295-8152	6
Bag Valve Mask (BVM), Micro BVM, Pocket BVM Silicone Resuscitator	N/A	Liquids, Mechanicals, Patient Interface, Plastics	6515-01-590-8909;	6
AdSafe CPR Pocket Resuscitator Kit w/Pair of Nitrile Gloves & Alcohol Wipe	N/A	Liquids, Mechanicals, Patient Interface, Plastics	6515-01-215-4177;	6
Mask Oronasal Univ Size C/O Head Strap Coupling; Pre-inflate Cushion	N/A	Liquids, Mechanicals, Patient Interface, Plastics	6515-01-276-1417	6

North American Rescue, Cyclone Pocket BVM Kit	N/A	Liquids, Mechanicals, Patient Interface, Plastics	6515-01-568-0193	6
Dressing Wound, Chest Seal, Hyfin, 3-Channel Pressure Relief Vents 7.5 in. X 7.5 in.	N/A	Adhesives, Liquids, Mechanicals, Plastics	6510-01-624-0840	12
Chest Wound Occlusive Seal 8 in. X 6 in.	647, 648	Adhesives, Liquids, Mechanicals, Plastics	6510-01-573-0300	12
Cricothyrotomy Set Field Pack	647, 648	Plastics	6515-01-573-0692	6
Gloves, 5-mil, Green, Neoprene, L, Condor	N/A	Plastics	N/A	6
Gloves, 5-mil, Powder-Free, Latex-Free, Blue, L, AbilityOne Better Touch	N/A	Plastics	N/A	6
Gloves, Chemical Resistant, 16-miI, L, Honeywell North	N/A	Plastics	N/A	25
Gloves, Cold Protection, L, Condor	N/A	Plastics	N/A	25
Gloves, D1619, Cryogenic, Elbow, L, National Safety Apparel	N/A	Plastics	N/A	25
Gloves, Polyethylene, Powder-Free, L	N/A	Plastics	N/A	6
Gloves, Pro-Guard, Purple, Vinyl, L, Impact Products	N/A	Plastics	N/A	6
Gloves, Purple Trilites 994, Tri-Polymer, L, MAPA Professional	N/A	Plastics	N/A	6
Gloves, PVC and Nitrile-Coated, L, Honeywell	N/A	Plastics	N/A	6
Infusion Pump, Multitherapy, Large Volume, Single Channel, Wireless, B. Braun	633, 647	Batteries/Power Generation, LCD, Liquids, Mechanicals, Plastics, Sensors, circuitry, material interactions	6515-01-676-0320	6

Intraosseous Injection Gun, Teleflex	631, 645, 647	Batteries/Power Generation, Liquids, Mechanicals, Patient Interface, Plastics, Sensors	6515-01-571-3152	6
IV Tubing, Administration Set	647, 648	Plastics	6515-01-652-5203	1
IV Tubing, Administration Set	N/A	Plastics	6515-01-676-8390	1
IV Tubing, Administration Set	N/A	Plastics	6515-01-676-8354	6
NaCl bag, 3%, 1,000 ml	N/A	Plastics	6505-01-291-0333	40
IV Warmer, Buddy Lite, Belmont	631, 633, 645, 647, 685	Batteries/Power Generation, Heating/Insulation, LCD, Liquids, Plastics, Sensors	6515-01-598-8290	6
IV Warmer, Ranger, 3M	N/A	Batteries/Power Generation, Heating/Insulation, LCD, Liquids, Plastics, Sensors	6515-01-479-2437	6
Monitor, Blood Pressure Kit, North American Rescue Products	631, 633, 635, 645	Batteries/Power Generation, LCD, Mechanicals, Patient Interface, Plastics, Sensors	6515-01-542-7723	6
Oximeter Rad-57, Co-Oximeter, Masimo Set, Handheld, Base Model Only, W/Oxygen Saturation (Spo2), Pulse Rate (PR) And Perfusion Index (PI)	631, 633	Batteries/Power Generation, LCD, Liquids, Mechanicals, Plastics, Sensors, circuitry, material interactions	6515-01-572-7224	6
Monitor, Finger Pulse Oximeter, MightySAT, Masimo Corp	635, 645, 647, 648	Batteries/Power Generation, LCD, Patient Interface, Plastics, Sensors	6515-01-655-9412	6
Airway, Nasopharyngeal, 32F, Medline Industries, Box Of 5	647	Liquids, Patient Interface, Plastics	6515-01-467-6695	6
Decompression Needle Device, Tension Pneumothorax, 14 Gage by 3.25 in., Needle Catheter	647, 648	Liquids, Patient Interface, Plastics	6515-01-541-0635	6
Catheter, IV, Introcan, Safety , 16 Gage by 1.25 in., 200S	645	Liquids, Patient Interface, Plastics	6515-01-488-4971	2

Catheter, Intravenous, D9, 20 Gage, Plastic Poly Rd, 1", 200S	645	Liquids, Patient Interface, Plastics	6515-01-488-5454	2
Catheter & Needle Unit, D13, IV, 22 Gage, Catheter, 24 Gage X 1 in. Needle, Blue Striped, 50S	645	Liquids, Patient Interface, Plastics	6515-01-210-7838	3
POC Whole Blood Analyzer, I-STAT Blood Analyzer	631	Batteries/Power Generation, screen, Liquids (consumables), Mechanicals, Plastics, Sensors, circuitry, material interactions	6630-01-526-7377	6
Tape, Medical/Surgical, 2 in., North American Rescue Products	N/A	Adhesives	6510-00-926-8883	6
Tubing, Corrugated, Breathing, Aerosol	N/A	Liquids, Plastics	6515-01-542-3720	6
Tubing, Corrugated, Breathing, Aerosol, AutoMedx SAVe II	N/A	Liquids, Mechanicals, Plastics	6515-01-580-0768	6
Patient Warming System, Bair Hugger, Model 775	631, 633, 645	Batteries/Power Generation, Heating/Insulation, Mechanicals, Patient Interface, Plastics, Sensors	6530-01-645-3959	6
Cassette, Blood-Fluid Warmer System	685	Liquids	6515-01-542-4545	12
Heat Pack, Instant	685	Heating/Insulation, Patient Interface	6515-01-504-6096	6
Thermometer, Digital, Hypothermia	685	Batteries/Power Generation, Patient Interface, Plastics, Sensors	6515-01-540-9946	6
Adhesive Tape, Surgical, 3M Durapore, 3 in. x 360 in.	647, 648	Adhesives	6510-00-926-8884	6
Adhesive Tape, Surgical, 3M Durapore 1 in. x 360 in.	647	Adhesives	6510-00-926-8882	3
Bag, Individual Equipment, Carrier, Pouch Hand Warmer, 500D, AOR-1	N/A	Patient Interface, Heating/Insulation	8465-01-574-5428	6
Duct tape	645, 647, 648	Adhesives	5640-01-462-0102	6

9.2 Purchased Test Equipment

PR DATE	SHORT DESCRIPTION	QUANTITY	UNIT
6/9/2023	3M Ranger Blood/Fluid Warming Unit, Model 245, 120V-ENG-E; 1 Each	6	EA
6/9/2023	3M Ranger Fluid Warming Set. PN #24200, Standard Flow; 10 Each/Case	9	CS
6/14/2023	Belmont Buddy Lite, Fluid Warming Unit, PN #905-00017; 1 Each	4	EA
6/14/2023	Belmont Buddy Lite Fluid Warming Set, PN #905-00010; 24 Each/Case	3	CS
6/14/2023	Belmont Buddy Lite Fluid Warming Set, PN #905-00010; 24 Each/Case	3	CS
6/15/2023	North American Rescue, Analog Blood Pressure/Stethoscope Combination Kit; 1 Each	6	EA
6/29/2023	Intraosseous Injection Gun, EZ-IO System Training Kit; TeleFlex; 1 Each	6	EA
6/15/2023	Masimo RAD-57, Handheld Pulse Oximeter; 1 Each	6	EA
6/15/2023	Masimo MightySAT, Fingertip Pulse Oximeter; 1 Each	6	EA
6/26/2023	B. Braun Infusomat Space Infusion Pump, Single Channel; 1 Each	4	EA
6/26/2023	Power Supply for B. Braun Infusomat Space Infusion Pump; 1 Each	4	EA
6/26/2023	Pole Clamp for B. Braun Infusomat Space Infusion Pump; 1 Each	4	EA
6/26/2023	Combi-Lead for B. Braun Infusomat Space Infusion Pump; 1 Each	1	EA
6/26/2023	Universal, 15 Drop Pump Set for B. Braun Infusomat Space Infusion Pump; 24 Each/Case	4	CS
6/21/2023	Wound Seal, X-Stat Training Kit; 1 Each	1	EA
6/21/2023	FingrSim, Pulse Oximeter Simulator; 1 Each	1	EA
6/22/2023	Pocket Bag Valve Mask; 1 Each	6	EA
6/23/2023	Laerdal Bag Valve Mask Kit in Compact Case; 1 Each	6	EA
6/26/2023	Oronasal Pocket Mask; 1 Each	9	EA
6/26/2023	Dressing, Chest Wound, Hyfin, Vented; 6 in X 6 in; 1 Each	15	EA
6/26/2023	Dressing, Chest Wound, Occlusive; 6 in X 6 in; 1 Each	15	EA
6/26/2023	Dressing, Chest Wound, Hyfin, Vented; 6 in X 6 in; 2 Each/Pack	5	PK
6/27/2023	Cricothyrotomy Set, Field Pack; 1 Each	6	EA

9.3 Sample Test Protocol Using Thermal Chamber

Each piece of equipment is uniquely tested after exposure to different temperatures:

- Phase 1: Test article at -40 ℃ (Test article(s) may be moved to lab environment for testing thus allowing their temperature to warm somewhat),
- Phase 2 Test article at 0-15 ℃ (Test article(s) may be moved to lab environment for testing thus allowing their temperature to warm somewhat), and
- Cyclic (back and forth from Phase 1 to lab temperature, 25-28 ℃).

Phase	Temperature (℃)		Humidity (est.)	Environment
1	T1	-40	0	POI
2	T2	0 - 15	80	Transport Facility
Cyclic	T3	25 - 28	50	Test Lab

Temperature T1: Point of Injury, cold soak (prolonged cold exposure); -40 °C; 0% humidity; Phase 1 Testing
Temperature T2: Transport/Procedure Facility; 0 to 15 °C; 80% humidity; Phase 2 Testing
Temperature T3: Test Laboratory Ambient; 25 to 28 degrees C; 75% humidity; Cyclic Testing

Generic Test Protocol:

1) Cold soak test article(s) in the thermal chamber (TC) at T1 for a minimum of 12 hours.
2) Prepare equipment test fixture if Phase 1 testing.
3) Remove test article(s) from TC and run specific Phase 1 test.
4) Return test article(s) to TC and set temperature to T2.
5) Prepare test fixture if Phase 2 testing.
6) Remove test article(s) from TC and run specific Phase 2 test.
7) Return test article(s) to TC and set temperature to T3.
8) Prepare test fixture if Cyclic testing.
9) Remove test article(s) from TC and run specific Cyclic test.
10) Return test article(s) to TC and set temperature back to T1 for another cold soak.

9.4 Specific Test Protocol for Blood/Fluid Warmers Using Thermal Chamber

The Belmont Buddy Lite is tested at Phase 2 temperature only. The reasons being that:

- The equipment is not suitable for use in the field at the POI. This eliminates testing at T1
- When used in a transport vehicle or care facility at T2, by design, it warms up above temperature T3. This removes the possibility for cyclic testing.

1) The first cycle of the test begins with the Buddy Lite cold soaked in the TC at T1 for in-excess of 12 hours. During this time, prepare the test fixture for use.
2) Then the TC is warmed to T2.
3) Remove the Buddy Lite from the TC.

4) Insert a new standard tubing set into the Buddy Lite for fitment check (qualitative).
5) Place Buddy Lite in the test fixture and attach input/output (I/O) tubing to standard set.
6) Place a fully charged battery into the Buddy Lite.
7) Prime the standard set and purge system air. Empty the output fluid reservoir.
8) Run Buddy Lite, checking for warning signals, and read the I/O fluid and Buddy Lite temperatures. Record time, temperatures, and any observations.
9) Check until there is agreement between designed output fluid and measured temperature. Turn off Buddy Lite and stop the test.
10) Remove the battery and return it to its charger.
11) Return the Buddy Lite to the TC and set the TC to begin its next cycle back at T1.
12) Measure the output fluid reservoir volume for flow rate calculation and prepare the test fixture for the next cycle.

9.5 Sample Test Fixture Details for Equipment Using Fluids (Blood/Fluid Warmers and Infusion Pumps)

Belmont Buddy Lite Fluid/Blood Warmer

The Buddy Lite test fixture requires:

- IV pole on wheels to facilitate moving between thermal chambers (If possible)
- IV pole mounting bracket or moveable cart/table available for warmer
- Saline bag(s) on IV pole (at a predetermined, consistent height)
- Fully charged battery for warmer
- Unused Luer lock tubing set with clamps to attach between saline bag and warmer
- Warmer, battery, and power supply (if available)
- Unused Luer lock tubing set with clamps to attach to warmer output
- Calibrated bucket to catch output and measure fluid output (tare-able scale might replace)
- Stopwatch to measure time in operation for flow rate calculation
- Thermal imager to measure (I/O) fluid and warmer temperatures throughout test
- Digital camera/video for archives
- Equipment ID system (bar code) for test items and equipment used
- Calibration sheets for all test equipment

9.6 Sample Protocol Assessment Card With Updated Metrics

Task: Airway – NPA and EGA Ambient Temp (C): Blood Simulant:		Location: Point of Injury			Participant ID:		
Time	**Steps:**	**Provider**	**Casualty**	**Procedure**	**Hands Warmed**	**Hand Temp (c)**	**Comments Recorded**
Start Timer	1. Take body substance isolation (BSI)						
	2. Assess the patient's airway						
	a. Open patient's airway using the head tilt chin lift or jaw thrust maneuver						
	b. Determine if the airway is patent. Look, listen and feel for respirations						
	3. Insert a nasopharyngeal airway (NPA)						
	a. Ensure the casualty is supine with the head in a neutral position						
	b. Assess nasal passages for apparent obstruction **Find no obstruction**						
	c. Select the appropriately sized adjunct by measuring the NPA from the tip of the nose to the bottom of the earlobe						
	d. Lubricate the tube with a water-based lubricant						
	e. Insert the NPA						
	f. Secure the NPA						
	5. Reassess the patient **Patient needs EGA**						
Reset Timer	6. Insert an i-gel extraglottic airway (EGA)						
	a. Remove I gel from aidbag						
8/22							**(1 of 4)**

Effects of Extreme Cold on En Route Care Medical Equipment and Treatment Protocols
DM210266
CDMRPL-22-0-DM210266

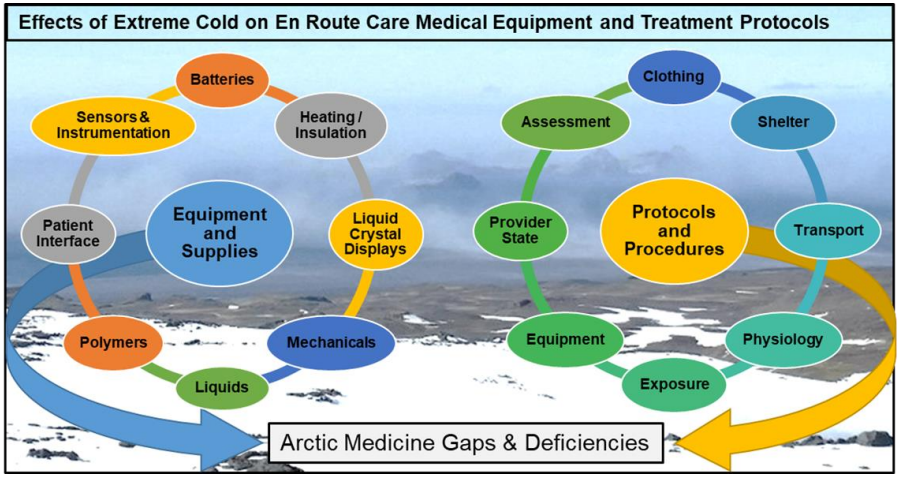
PI: Sylvain Cardin, PhD **Org:** Naval Medical Research Unit San Antonio **Award Amount:** $1,201,000.00

Study/Product Aim(s)

- Specific Aim 1: Test & evaluation of materials and properties in a controlled environment (cold chamber)
  - Task 1.1: Develop testing protocols and acquire approved items
  - Task 1.2: Testing materials in the extreme cold chamber
  - Task 1.3: Cyclic exposure to extreme cold, testing at tent temp.
- Specific Aim 2: Test & evaluation of protocols in the field (extreme cold)
  - Task 2.1: Development of trauma manikin for extreme cold
  - Task 2.2: Development of protocol assessment cards
  - Task 2.3: Pilot testing
  - Task 2.4: Final testing

Approach

The central hypothesis is that current biomedical equipment combined with compromised treatment protocols degrade combat casualty care in Arctic conditions. The objectives are to identify and measure deficiencies in the operational effectiveness of materiel and medical procedures.



Accomplishment: All equipment and supplies have been acquired based on the approved equipment list. Test protocols are underway for the cold chamber testing. Procedure evaluation planning and cold weather manikin development are underway.

Timeline and Cost

Activities CY	22	23	24	25
1.1: Test plan & purchases				
1.2 & 1.3: Technical Reports				
2.1: Manikin development				
2.2: Protocol Cards				
2.3: Pilot Testing				
2.3: Final Testing				
Estimated Budget ($K)	**$117**	**$772**	**$240**	**$72**

Updated: 18 August 2023

Goals/Milestones

CY22 Goal – Kickoff
☑ Funding received, kickoff with partners
CY23 Goals – Test preparation
☑ Finalize equipment list
☐ Develop test platforms and protocols for chamber testing
☑ Set requirements for extreme cold evaluation manikin
CY24 Goals – Chamber and pilot testing
☐ Chamber test at CRREL (May-Jun, 2024)
☐ Pilot test at ICEX (Feb-Mar, 2024)
CY25 Goal – Final testing
☐ Field test with extreme cold manikin (Feb-Mar, 2025)

Comments/Challenges/Issues/Concerns

- Timeline changing due to funding delays
- Spending on track

Budget Expenditure to Date

Projected Expenditure: FY21: $117k; FY22: $394k
Actual Expenditure: FY21: $117k; FY22: $119k