

Award Number: W81XWH-11-2-00157

TITLE: Burn Resuscitation Decision Support System (BRDSS)

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REPORT DATE: September 2013

TYPE OF REPORT: Annual

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

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REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
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1. REPORT DATE September 2013		2. REPORT TYPE Annual		3. DATES COVERED 20-June-2012 to 19-Aug-2013	
4. TITLE AND SUBTITLE Burn Resuscitation Decision Support System (BRDSS)				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-11-2-0157	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Christopher Meador, MBA, PI E-Mail: chris.meador@arcosmedical.com				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Arcos, Inc. 866 W. 41st St. Houston TX 77018-5308				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel 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 The Burn Resuscitation Decision Support System (BRDSS) is a medical device designed to guide and optimize fluid resuscitation of severely burned patients. The goal of this cooperative agreement is to develop a mobile device that is safe and effective for burn care in the deployed and en route care settings. In this period, we completed Human Factors studies, hardware testing, software design improvements and obtained FDA 510(k) clearance. The device obtained Airmedical Certification. We have completed all major deliverables.					
15. SUBJECT TERMS Fluid resuscitation, burn, decision support					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
U	U	U	UU	15	19b. TELEPHONE NUMBER (include area code)



Burn Resuscitation Decision Support System (BRDSS)

Annual Report

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I. Introduction

The Burn Resuscitation Decision Support System (BRDSS) is medical device software designed to guide and optimize fluid resuscitation of severely burned patients. The goal of this cooperative agreement is to package the software into a mobile device (the *BRDSS-M*, trade name *Burn Navigator™*) with substantial input from caregivers at the USAISR and the IPT, in order to have a safe and effective device for burn care in the deployed and en route care settings.

II. Body

A. Military Significance

Burn injuries are associated with about 10% of casualties from Operations Iraqi and Enduring Freedom. Roughly 20% of those have serious burn injuries, constituting 20% or more of total body surface area (TBSA), which can require 20 to 30 liters of fluid to prevent intravascular volume depletion and circulatory shock. Fluid overloads in the resuscitation phase have led to abdominal compartment syndrome in a number of soldiers, resulting in high mortality rates.

The BRDSS could be used on nearly all soldiers with serious burns requiring fluid resuscitation, starting at Level II / III and being used through Level V in the En Route Care System. By developing and deploying the BRDSS tablet (Burn Navigator™), precise fluid resuscitation can begin on wounded warriors soon after injury and should reduce complications of over- and under-resuscitation, improve outcomes, and reduce total hospital length of stay of seriously burned soldiers.

B. Statement of Work

The Statement of Work describes the project:

The Burn Resuscitation Decision Support System (BRDSS) Tablet project will be broken into four major phases. Throughout the project Arcos will have several meetings with the Decision Support Integrated Product Team (IPT), chaired by Mr. Scott Brady and LTC Serio-Melvin, MS, RN, and the designated U.S. Army Institute of Surgical Research (USAISR) clinical team.

Phase 1 System Requirements and Software Development

Arcos will draft a design plan for IPT or designee review to formalize the device design requirements. Upon design plan approval, Arcos will begin developing the software to the Food and Drug Administration's (FDA's) design controls and creating the design history files. Arcos will present the core software on four (4) tablet hardware candidates to IPT or clinical group for user evaluation. The IPT or clinical group will provide feedback on the features, graphical user interface (GUI), and other design aspects. They will also select up to three (3) tablet

hardware finalists in order of preference. Arcos will develop for each finalist a Special Medical Emergency Evacuation Device (SMEED) bracket and other test platform aspects needed for airworthiness testing. The hardware finalists will be sent to U.S. Army Aeromedical Research Laboratory (USAARL) for critical airworthiness testing.

Phase 2 Refinement, Verification and Validation

Arcos will refine the software based on IPT feedback. Arcos will incorporate robustness improvements, such as data error checking, and begin software unit verification, system level software and hardware verification, and thorough use testing. The final hardware will be chosen based on USAARL critical airworthiness testing results and IPT preference. Arcos will provide three (3) units of the final tablet with software for a second round of user evaluation. One unit of the final tablet will be sent to USAARL for secondary airworthiness testing and another unit will be sent for other electrical, safety, and performance testing as needed. Arcos will develop the attachment mechanism for bed, litter, or SMEED.

Phase 3 Packaging, Labeling, Certifications and Regulatory Preparations

Arcos will develop the device packaging and shipping materials and will ensure completion of all safety, effectiveness, performance, shipping, and environmental test certifications. Arcos will write the FDA 510(k) regulatory clearance application, including predicate device analysis, safety and effectiveness results, risk management, and draft labeling. The IPT will validate the pre-release device to ensure it meets all clinical needs and other Army requirements.

Phase 4 Complete Clinical Studies (if needed) and Obtain Regulatory Clearance

The FDA may require clinical studies to demonstrate safety and effectiveness of the BRDSS Tablet. Arcos will work with the Brooke Army Medical Center (BAMC) and U.S. Army Institute of Surgical Research (USAISR) for clinical studies to be performed on their premises. Arcos will submit the 510(k) application along with any new clinical study results to FDA. Arcos will finalize the user manual, labeling, serviceability plan and a set of PowerPoint slides for product training. The IPT or designated clinical group will assess the training materials and all labeling for adequacy. Arcos will receive 510(k) clearance on the BRDSS Tablet.

C. Progress towards Statement of Work

Phase 1 – System Requirements and Software Development

Phase 1 was completed in the first year of the project.

Phase 2 – Refinement, Verification and Validation

Most of the refinement, verification and validation was conducted in the first year of the project. The 510(k) application submitted to FDA in May 2012 included verification records and validation reports. However, FDA requested a human factors validation study to ensure the device was safe and usable as designed. We found that three aspects of the software needed to be changed, so we had to make those changes, verify those changes, and conduct a follow-on human factors validation study to ensure that those changes were sufficient.

Significantly more time and energy was given to the human factors validation studies than expected. This includes significant time from Maria Serio-Melvin, MS, RN, at USAISR, as well as Ada Garcia, both study coordinators for the human factors validation studies.

The human factors validation study is described in “Conducting a FDA Human Factors Study on a Burn Resuscitation Decision Support System”, by Maria L. Serio-Melvin, RN, MSN, Chris Meador, MBA, and Ada Garcia, RN, a poster presented at MHSRS 2013. (See Appendix B.)

FDA accepted the final human factors report.

We also conducted hardware based testing, such as electromagnetic compatibility (EMC) and radio-frequency identification (RFID) compatibility testing. These reports, along with the human factors validation report, were submitted to FDA in Q1, 2013. We obtained FDA 510(k) clearance in April 2013.

We also worked with engineers at USAARL for aeromedical certification. On 08-Aug-2013, Arcos' Burn Navigator obtained Aeromedical Certification for H-60 Blackhawk helicopters from the U.S. Army, based on airworthiness testing performed by the U.S. Army Aeromedical Research Laboratory (USAARL).

This certification means the Burn Navigator is approved for patient care use during flight on these aircraft and allows the Burn Navigator to be used in military en-route care, provided that aircrew and medical personnel are familiar with the instructions and guidance in the certification documents.

Helicopter certification requires one of the most rigorous sets of tests, including hard acceleration in multiple directions, lifetime vibration testing and rigorous electromagnetic compatibility testing.

Obtaining aeromedical certification completes Phase 2 of the Statement of Work. However, USAARL is evaluating the test data towards Lakota aeromedical certification in addition to Blackhawk aeromedical certification.

Phase 3 – Packaging, Labeling, Certifications and Regulatory Preparations

Device packaging and shipping materials were chosen in the first year of the study and provided to USAISR with the BRDSS prototypes. Environmental test certifications (primarily: EMC and RFID testing) was completed in Q1 2013.

Labeling includes labeling directly on the device as well as the User's Manual. All copies of the labeling were included in the 510(k) application. The User's Manual was also subject to human factors validation study feedback from 15 participants in Dec 2012. We made improvements to the User's Manual based on that feedback. Those improvements were evaluated in the Feb 2013 follow-on human factors validation study.

The initial 510(k) regulatory application was completed and sent to FDA in May 2012.

Phase 4 – Complete Clinical Studies (if needed) and Obtain Regulatory Clearance

FDA reviewed the 510(k) application in summer 2012. The Agency requested data demonstrating that the device was effective in the patient population. USAISR provided data collected from 207 patients resuscitated with aid of the BRDSS algorithms. FDA accepted this data and did not ask for additional clinical studies.

We obtained FDA 510(k) clearance in Apr 2013. (See Appendix A, 510(k) certification letter.) The device training slides were not part of the 510(k), but were part of the human factors validation study and part of the roll-out plan. The training slides were completed in Dec 2012 and are updated periodically to keep up with software versions and to improve the training session.

D. Future Work

1. Burn Navigator improvements

The software is a start, but clinical users at USAISR have made requests for improvements to the software. These improvements should also be applicable for the deployed and en route care setting, so we expect a better device by continuing the cooperative agreement.

2. Data Tool

We are developing a Data Tool that will allow users and researchers to transform the encrypted patient file into a PDF report and a text CSV file. The PDF report could be used for after action reviews, quality improvement and possibly rounds. The text CSV file will contain the numerical hourly data and checklist information. These data can be imported into Excel for graphing and data analysis or uploaded to another data repository. We expect that easy numerical exportation of these data will aid researchers in improving fluid resuscitation and burn care.

E. Progress towards Deliverables

Deliverables and status:

1. Four (4) different hardware tablet candidates with core software for Phase 1 User Evaluations. *Done. USAISR caregivers provided feedback in the first year of the project.*
2. Six (6) units of the final hardware tablet with complete software for Phase 2 User Evaluations. *Done. Phase 2 User Evaluations were conducted at USAISR, also with AMEDD; additionally we did two Human Factors validation studies.*
3. A pre-release product incorporating one unit of the above final hardware tablets, the latest software, the attachment mechanism (for patient bed, litter, or SMEED), draft user manual, and training materials. *We completed the attachment mechanisms; USAISR has two attachment mechanism units. A draft user manual and training slides were completed in the first year of the project; both were refined during the human factors validation studies. USAISR has at least one copy of the user's manual and the training slides.*
4. A Confidential electronic copy (.PDF) of the 510(k) application submitted to FDA. *Completed in the first year of the project, May 2012, shortly after the application was submitted to the FDA.*
5. A Confidential, Proprietary Technical Data Package (.PDF), which will include: System Requirements, Software Requirements Specification, Hardware Requirements Specification, Attachment Mechanism Design, Risk Management Summary, and Program Executable File (.EXE) at time of 510(k) submission. *The technical data package was also provided to USAISR at the time of 510(k) submission.*
6. A PDF copy of the FDA 510(k) clearance letter. *A copy of this letter was forwarded to USAISR and MRMC in April 2013. It is also included as Appendix A below.*

Note: not all of the units for deliverables 1 and 2 above are at USAISR yet. The outstanding devices are being used for testing new software versions and for pending aeromedical clearance.

III. Key Research Accomplishments

Development accomplishments for this period include:

- **Human factors validation studies passed**
- Electromagnetic compatibility testing passed
- Radio-frequency identification compatibility testing passed
- **Obtained FDA 510(k) clearance!**
- **Milestone C decision!**
- **Blackhawk aeromedical certification**

IV. Reportable Outcomes

Reportable outcomes include:

- **FDA clearance of a new medical device**
- **FDA human factors study poster**
- **Milestone C decision**
- **Blackhawk aeromedical certification**
- **Commercialization partner (Arcos) in place**
- **Manufacturing facility (Arcos) registered with FDA and producing**
- **Adoption of technology in civilian Burn ICUs**

V. Conclusion

This cooperative agreement has successfully resulted in bringing a new medical device to market. This device utilizes sophisticated algorithms developed by burn care experts to guide and optimize fluid resuscitation for severely burned patients. The device has received 510(k) clearance, aeromedical certification, and Milestone C decision. The device is now commercially available for deployment and en route care and is now being used in civilian Burn ICUs.

VI. References

Serio-Melvin, ML et al, "Conducting a FDA Human Factors Study on a Burn Resuscitation Decision Support System", Poster, MHSRS 2013.

VII. Appendices

A. Appendix A – FDA 510(k) Clearance Letter

Arcos

K121659
P 1/2

Burn Resuscitation Decision Support System 510(k) Summary

APR 18 2013

Submitted by: Arcos, Inc.
866 W. 41st St.
Houston, TX 77018

Contact: Chris Meador
713-397-3030

Date Prepared: May 25, 2012

Product Trade Name: Burn Resuscitation Decision Support System (BRDSS)

Common Name: Drug Calculator

Classification: Class II

Classification Name: 21 CFR 868.1890, *Predictive Pulmonary-function value calculator*. Product Code: PDT

Predicate Device: K011571, TRxF Intelligent Dosing System™

Device Description: The BRDSS is a fluid calculator for use in the care of seriously burned patients. It is used to calculate the next dose of fluid for patients.

Indications For Use

The Burn Resuscitation Decision Support System (BRDSS) is indicated for use in the care of adult patients with 20% or more Total Body Surface Area (TBSA) burned as a fluid resuscitation calculator for hourly fluid recommendations. The BRDSS is intended to be initiated within 24 hours of the burn.

Substantial Equivalence

A. Predicate Device Comparison

	Predicate Device K011571 TRxF Intelligent Dosing System™	Applicant Burn Resuscitation Decision Support System (BRDSS)
Device Description	The IDS™ is a next-dose calculator for any drug that can be used by physicians to calculate the next dose for patients.	The BRDSS is a fluid calculator for use in the care of seriously burned patients. It is used to calculate the next dose of fluid for patients.

Arcos

K121659
P2/2

Intended Use	The IDS is a software-based drug-dosing calculator designed for use by the physician to calculate the next dose of any drug to achieve a desired target.	The Burn Resuscitation Decision Support System (BRDSS) is indicated for use in the care of adult patients with 20% or more Total Body Surface Area (TBSA) burned, as a fluid resuscitation calculator for hourly fluid recommendations. The BRDSS is intended to be initiated within 24 hours of the burn incident and ending by 72 hours post burn.
Intended User	Healthcare professional	Healthcare professional
Intended Use Environment	Health care facility	Hospital critical-care environment
Human Factors	Physician enters patient's glucose values and amounts of insulin. Warnings are presented when values are out of range and /or insulin doses are greater than or less than 20% of the most recent dose.	Physician or nurse enters patient weight, % of body surface area burned and time of burn. Warnings are presented when the primary fluid rate recommendation is +/- 25% (and +/- 200mL/hr) from the current primary fluid rate dose. In addition, graphs are included to show patient's cumulative volume of fluids received and hourly fluids in and urine out.
Software-Based	Yes	Yes
Dose Calculation	Yes	Yes

B. Non-Clinical Data

The BRDSS adheres to hardware requirements, such as form factor and power requirements, as well as software requirements, such as data input validation, user warnings, alerts and messages, user interface requirements, functional requirements and error handling requirements. The BRDSS includes many human factors best practices for the software user interface.

The BRDSS has passed product verification as well as clinical user validation.

Substantial Equivalence

The BRDSS and the predicate device, the TRxF Intelligent Dosing System, are both portable software-based systems that allow the healthcare professional to calculate dosages of either medicines or fluids to a patient. Both devices provide dose calculations based on relevant patient clinical data. The indications for use are very similar, and the technological and human factors features are essentially identical.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

April 18, 2013

Arcos, Incorporated
% Mr. Chris Meador
866 West 41st Street
Houston, Texas 77018

Re: K121659

Trade/Device Name: Burn Resuscitation Decision Support Software (BRDSS)
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive pulmonary-function value calculator
Regulatory Class: Class II
Product Code: PDT
Dated: February 28, 2013
Received: March 04, 2013

Dear Mr. Meador:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours, FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121659

Device Name: Burn Resuscitation Decision Support System (BRDSS)

Indications for Use:

The Burn Resuscitation Decision Support System (BRDSS) is indicated for use in the care of adult patients with 20% or more Total Body Surface Area (TBSA) burned, as a fluid resuscitation calculator for hourly fluid recommendations. The BRDSS is intended to be initiated within 24 hours of the burn incident and ending by 72 hours post burn.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S

(Division Sign-Off)

Division of Surgical Devices

510(k) Number: K121659

B. Appendix B – “Conducting a FDA Human Factors Study on a Burn Resuscitation Decision Support System” Poster

