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Award Number: W81XWH-12-2-0111

TITLE: Deployment Ready Airway Management System (DRAMS)

PRINCIPAL INVESTIGATOR: Richard B. Schwartz, MD

CONTRACTING ORGANIZATION: AI Medical Devices, Inc.
Evans, GA 30809-5471

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14. ABSTRACT Overall the project has progressed with excellent results. Alpha one and two prototypes have been developed and the initial Beta one prototype device manufactured. Civilian and Military airway experts have evaluated the B-1 prototype with excellent feedback. Minor modifications are being integrated into the prototype for completion of environmental and electrical safety testing. The B-1 Prototype will be utilized for initial clinical trials utilizing airway simulators in a difficult airway model.					
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AI Medical Devices

Annual Report

Award Number:	W81XWH-12-2-0111
Proposal Number:	11160001
Title:	Deployment Ready Airway Management System (DRAMS)
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Report Date:	10-24-13
Report Period:	Sept. 2012 – Oct. 2013
Contracting or Grants Officer's Representative:	Maribel Fratina

Project Summary:

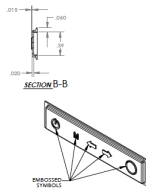
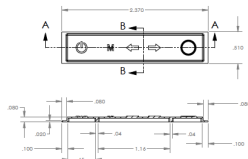
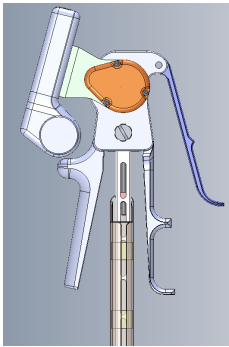
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Project Accomplishments:

The following milestones have been completed as listed in the proposal:

1. Handle and Monitor Housing Development: The project has gone through the use of multiple evolutions of 3D models and the use of rapid prototyping culminating in the B-1 prototype that has meet with excellent feedback from airway experts.

The figure consists of three photographs of a prosthetic arm. The left image shows a side view of the arm, highlighting the white upper arm and the black lower arm. The middle image shows a top-down view of the arm, revealing the internal components and the red and green segments. The right image shows a front view of the arm, showing the black upper arm and the white lower arm.



A hand is holding a blue manual sphygmomanometer. The device has a blue plastic body with a silver metal cuff and a clear plastic tube. The hand is positioned to show the side of the device, with the thumb and index finger visible. The background is a plain, light-colored surface.

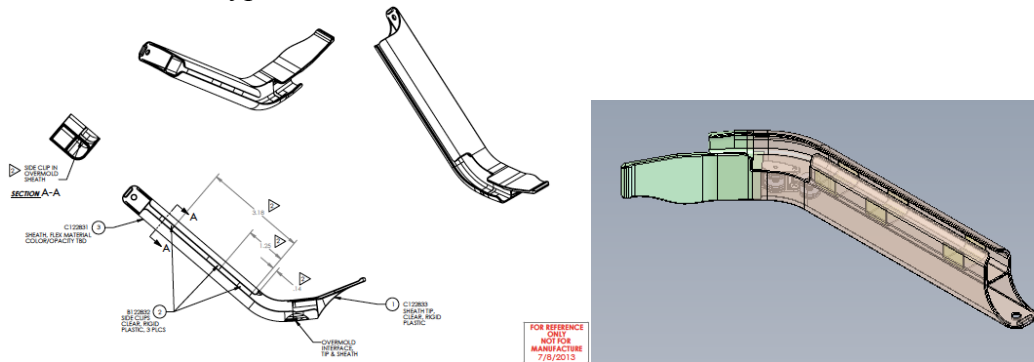
Disposable sheath prototype development.

Multiple versions of disposable sheath prototypes have been developed culminating in the B-1 prototype with excellent video transmission and functional results.

Alpha 1 and Alpha 2 prototypes



3D Models of B-1 Prototype



B-1 Disposable Sheath



Video Image Through the Disposable Sheath



FlexBlade Working Length Development:

Several versions of the working length have been developed along with rapid prototypes. The results have been excellent and DMLS Alpha one and two prototypes have been developed resulting in a B-1 prototype. Several evolutions of waterproof contacts have been developed with a B-1 prototype developed.

SLA of Electrical Contact Model



DMLS FlexBlade Reusable Module B-1 Prototype



Completed B-1 Prototypes:

B-1 Articulated with ET Tube

B-1 Relaxed with ET Tube





Relaxed in Simulator

Flexed in Simulator

Tube Advanced

Clinical Studies: The B-1 prototypes have meet all required feedback from airway experts and the device is ready to begin trials in Cadavers and the initial clinical trial in simulators. Protocols should be submitted to the IRB in Nov. 2013.

Project Progress: The project has made substantial progress and has resulted in an excellent B-1 prototype that will be used in clinical trials. The final environmental testing and electrical safety testing should be completed in the next quarter.

Barriers Encountered: The project experienced some upfront delay as all original quotes from the proposal had expired before final funding had been procured. Substantial delays in reimbursement for the project has lead to frequent delays in the project. Despite these barriers we should be able to complete the project on time.

Budget/Financial Report:

	Cumulative
Personnel	\$61,999.04
Fringe Benefits	0
Travel	\$1,537.72
Equipment	0
Supplies	\$7,511.70
Other	0
Subaward - Organization	\$214,656.56
Subtotal	\$285,705.02
Indirect Costs	0
Fees	0
TOTAL	\$285,705.02