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Award Number: W81XWH-10-2-0145

TITLE: Self-Contained Video Laryngoscope

PRINCIPAL INVESTIGATOR: Dr. Anthony Plunkett

CONTRACTING ORGANIZATION: Henry M. Jackson Foundation for the Advancement of
Military Medicine
Rockville, MD 20852

REPORT DATE: October 2011

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 (DD-MM-YYYY) XXXXXX 01-10-2011		2. REPORT TYPE Annual		3. DATES COVERED (From - To) 27 Sep 2010 - 26 Sep 2011	
4. TITLE AND SUBTITLE Self-Contained Video Laryngoscope				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-10-2-0145	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Dr. Anthony Plunkett E-Mail: Anthony.Plunkett@amedd.army.mil				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Henry M. Jackson Foundation for the Advancement of Military Medicine Rockville, MD 20852				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 Abstract on next page.					
15. SUBJECT TERMS Subject terms on next page.					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT UU	18. NUMBER OF PAGES 7	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			19b. TELEPHONE NUMBER (include area code)

14. ABSTRACT

Perseus Medical, Inc. proposes to build and test a cost effective self-contained video laryngoscope (SVL) providing visualization of trachea and vocal chords during emergent situations at the point of care. The SVL will fulfill currently unmet needs by providing a completely self-contained portable endoscopic system that can be used at bedside without the need for external power sources and/or instrumentation. The annual report fully details that strides that have been made to the SVL sub-systems: optical, mechanical, electronics, and software.

15. SUBJECT TERMS

Self-contained video larynogoscope

16. SECURITY CLASSIFICATION OF:

17. LIMITATION

18. NUMBER

19. NAME OF RESPONSIBLE PERSON

Concept Description

Henry M. Jackson Foundation processed a sub award to UCLA for Perseus Medical, Inc. to work on designing a self-contained video laryngoscope (SVL). Perseus Medical, Inc. proposes to build and test a cost effective SVL providing visualization of trachea and vocal chords during emergent situations at the point of care. Our SVL will fulfill currently unmet needs by providing a completely self-contained portable endoscopic system that can be used at bedside without the need for external power sources and/or instrumentation. Perseus is a company founded and run by a dedicated team of UCLA MBA, Medical and Engineering Ph.D. students and alumni. This team was awarded highly prestigious first place in the 2009 Knapp Venture Competition at the UCLA Anderson School of Management, judged by dozens of entrepreneurs, venture capitalists and angel investors, faculty, and advisors.

The Perseus SVL novelty is in its unique integration of various state of the art components. The combination of these new optical, electronic, and mechanical elements now permits construction of an entirely self-contained video laryngoscope. The Perseus laryngoscope features a 4.0mm (preliminary data) outer diameter probe without fiber-optic bundles. The elimination of fiber optics reduces costs, weight and potential damage while improving robustness, portability, mechanical bending, and steering capabilities. Mechanical controls in Perseus SVL permit 2-way deflection with bending radii lesser and angles greater than current endoscopes. The use of removable, rechargeable high-capacity lithium ion batteries permits at least 1.5 hours of continuous operation before a rapid battery exchange or recharge. Video capture achieves at least a QVGA resolution often seen in handheld devices. It has a minimum video frame rate of 24fps achieving a balance between image clarity and battery life while exceeding both the 23.976fps NTSC and 24fps PAL/SECAM standard. The endoscope will use a solid state image sensor with an objective lens which provides an 80° field of view. A bright white LED light source provides both general and stroboscopic illumination, which is synchronized with the video capture system. The Perseus SVL system will deliver efficient information management, significant cost-savings, and video-laryngostroboscopy capability in an ultra-portable and user friendly package.

Technical Accomplishments

Achievements/Results:

The funds for this project became available through UCLA on July 1, 2011. Since then, we have started working on main sections of the system in parallel. The following describes updates for each of the SVL sub-systems: optical, mechanical, electronics, and software.

Optical

Accomplishments to Date

1. Determined the size and optical parameters for distal end lens.
2. Placed the order for the initial set of lenses from the John Tesar and Associates (JT&A).
3. We have determined the bset testing methods and end points for optimization of the optical system.

Next Steps

Once we receive the optical cells form JT&A, we will conduct tests with the image sensor and electronics image acquisition circuitry to verify the optical properties of the lens assembly.

Potential Issues: If the image quality and optical characteristics of the optical cell assembly and image sensor are not satisfactory, we will reorder new set of lenses. This may delay completion of the system.

Mechanical

Insertion Tubing

Background

The mechanical, optical, and electronic components need to be incased in an outer shell composed of the handle and tubing. The tubing component plays the critical role in determining the flexibility of endoscope. It needs to be stiff enough to not buckle under a specified bend radius, while being flexible enough to travel through the nasal passage as required.

Accomplishments to Date

1. Determined required specifications for insertion tubing.
2. Communication with tubing manufacturers to attain quotes and available specifications.

Next Steps

Once the specifications are approved by the necessary parties, the insertion tubing will be ordered with a 4-6 week lead time. Once the distal subassembly is finished, we will begin to decide on the best method for attachment to the insertion tubing. These methods include the use of heat-shrink wrap tubing, glues, and mechanical devices to lock components in place.

Potential Issues: If we decide that the insertion tubing does not meet specifications, we may need to re-order and have to wait another 4-6 weeks.

Potential Issues: None.

Distal Subassembly

Background

The main function of the distal subassembly is to contain the distal components (LED, image sensor, and their respective optical components) in the correct orientation and distance in respects to one another. A secondary function of the subassembly is to properly isolate light and heat from the LED to the image sensor.

Accomplishments to Date

1. Initial CAD model for the distal subassembly in respect to current knowledge of the optical components.
2. Determined material used for initial prototyping to be aluminum for machinability, thermal properties, and strength.
3. Communicated with UCLA machine shop to ensure the machinability of the initial design. *Current*

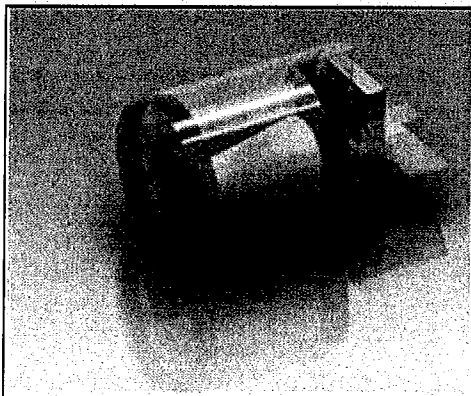


Figure 1: CAD rendering of distal end assembly design

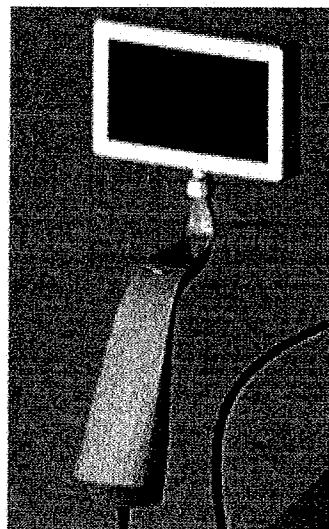


Figure 2: Engineering rendering of SVL proximal end design

Next Steps

Update distal subassembly with updated specifications of distal components. There will be changes in regards to component dimensions which we will need to take into consideration. At this point, we expect to have a distal subassembly built by a machine shop to be tested. Next, we will test the imaging capabilities of the distal subassembly with the LED and image sensor combined. The testing will also

include a study of the thermal and light isolation capabilities of the distal subassembly.

Potential Issues: If the thermal isolation between the LED and the image sensor is inadequate, the design may need to be restructured or a different material may have to be used.

Electronics

Background

The electronic subsystem consists of the image sensor, LED, the LCD screen, connecting wires, and information storage. The subsystem provides drivers to enable software interfacing with the control board, LEDs, and electronics. Wiring assembly in the distal end needs to fit in the available space with the endoscopes.

Accomplishments to Date

The electronic subsystem uses OMAP based processor board with a Linux operating system. The processor has native support for camera, screen, and storage, which we have tested to work. We have tested this system and it operates as designed. In addition, we have also completed the design for the LED board with strobe capability.

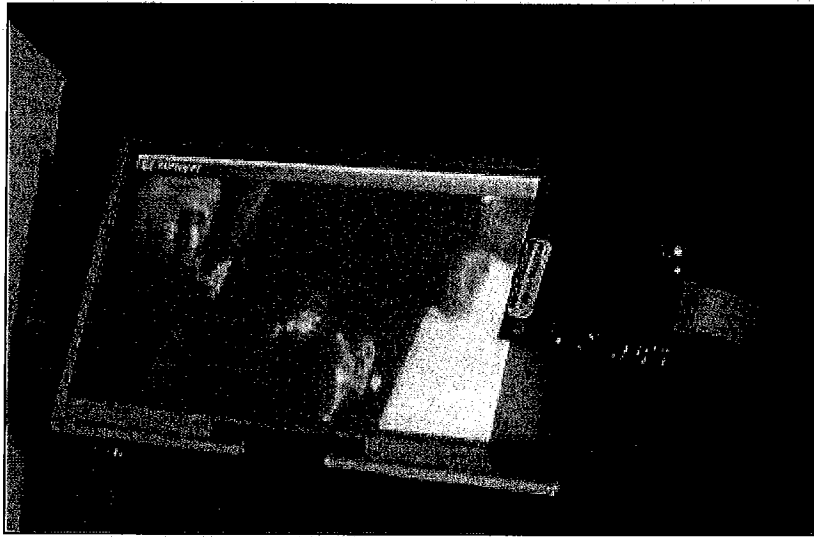


Figure 3: Gumstix™ board (under LCD screen) with LCD screen and OEM camera displaying real-time image/video

Next Steps

Incorporate a functional video driver adjusted from an existing generic driver and confirm its functionality using a live video stream. Complete the design for LED board and its drivers and test their functionality.

Potential Issues: LED board might need adjustment if desired results are not achieved.

Software / Graphical User Interface (GUI)

Background

The Graphical User Interface (GUI) subsystem channels the video feed from the camera to the screen, and allow user to control the brightness, contrast, and perform function selections.

Accomplishments to Date

The GUI software platform has been defined using Java and tested to work with standard video feed. The interface currently contains brightness and contrast control. The function selection development will be deferred until the LED board is developed.

Next Steps

Perform feasibility test for GUI software platform and select the most stable version. Develop the GUI which will display video feed from the camera to the screen and implement the user control for image brightness and contrast. Design user controls for various stroboscopic functions.

Potential Issues: LED board might need adjustment if the desired result cannot be achieved.

Programmatic

Perseus Team

During the last period of performance, our team met several times to discuss project responsibilities, details, issues, and other considerations. The following is a list of our team members, their background, and project responsibilities:

- Jules Huang, M.D, M.B.A., Founder, President, and Chairman of Board. Dr. Huang is currently an Anesthesiology and Critical Care Medicine Resident Physician at Johns Hopkins. She will support the group with testing of prototypes and business development efforts.
- Boris Vulovic, Ph.D., Engineer. Responsibilities will include electronic parts acquisition, PCB assembly, CCD camera acquisition and testing, basic electronic development for testing of LEDs and CCD options, driver development for the image sensor, optimization of the electronics system, and battery charger PCB assembly.
- Andreas Ali, Ph.D., Engineer. Responsibilities will focus on components for electronics, LED, and FPGA, FPGA board design, distal tip subassembly development, electronic system assembly, battery testing PCB assembly, and battery lifetime testing.
- Ali Ayazi, Ph.D., Engineer. Responsibilities will focus on optical system parts acquisition, optical system jig development, CCD and lens component testing, CCD Lens development and assisting on the distal tip subassembly development.
- Kirby Chiang, M.S., Engineer. Responsibilities will include mechanical development, distal tip packaging development, insertion tube material selection and testing, machining, handle subassembly construction and testing, and final device assembly.
- Marko Kostic, Ph.D. student, Engineer. With over eight years of experience in medical device research, development, testing, and product development, Mr. Kostic will focus on electrical and optical system integration as well as regulatory testing compliance and prototype testing.
- Pushkar Gejji, M.S. student, Engineer. Responsibilities will focus on electrical circuit design for analog and digital sections of the system, power supply design. Mr. Gejji will be assisting Dr. Ali with any other electrical system integration tasks.
- Prof. Warren S. Grundfest, MD, FACS - overall project supervisor, sub-contract PI.

Schedule

The project has initially been delayed due to UCLA funding issues earlier this year. However, since then, we have started work on multiple sections in parallel and anticipate on-time project completion by the end of no-cost extension period.