LAWRENCE LIVERMORE NATIONAL LABORATORY

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Non-Invasive Pneumothorax Detector Final Report CRADA No. TC02110.0

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Non-Invasive Pneumothorax Detector

Final Report
CRADA No. TC02110.0
Date Technical Work Ended: April 26, 2013

Date: July 15, 2013 Revision: 2

A. Parties

This project was a relationship between Lawrence Livermore National Laboratory (LLNL) and ElectroSonics Medical Inc. (formerly known as Biomec, Inc.)

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B. Project Scope

This was a collaborative effort between Lawrence Livermore National Security, LLC as manager and operator of Lawrence Livermore National Laboratory (LLNL) and ElectroSonics Medical Inc. (formerly known as BIOMEC, Inc.), to develop a non-invasive pneumothorax detector based upon the micropower impulse radar technology invented at LLNL.

Under a Work for Others Subcontract (L-9248), LLNL and ElectroSonics successfully demonstrated the feasibility of a novel device for non-invasive detection of pneumothorax for emergency and long-term monitoring. The device is based on Micropower Impulse Radar (MIR) Ultra Wideband (UWB) technology. Phase I experimental results were promising, showing that a pneumothorax volume even as small as 30 ml was clearly detectable from the MIR signals.

Phase I results contributed to the award of a National Institute of Health (NIH) SBIR Phase II grant to support further research and development. The Phase II award led to the establishment of a LLNL/ElectroSonics CRADA related to Case No. TC02045.0. Under the subsequent CRADA, LLNL and ElectroSonics successfully demonstrated the feasibility of the pneumothorax detection in human subject research trials.

Under this current CRADA TC02110.0, also referred to as Phase II Type II, the project scope consisted of seven tasks in Project Year 1; five tasks in Project Year 2; and four tasks in Project Year 3. Year 1 tasks were aimed toward the delivery of the pneumothorax detector design package for the pre-production of the miniaturized CompactFlash dockable version of the system. The tasks in Project Years 2 and 3 critically depended upon the accomplishments of Task 1. Since LLNL's task was to provide subject matter expertise and performance verification, much of the timeline of engagement by the LLNL staff depended upon the overall project milestones as determined by the lead organization ElectroSonics. The scope of efforts were subsequently adjusted accordingly to commensurate with funding availability.

The project consisted of the following deliverables:

<u>Deliverables for Project Year 1</u>

1) ElectroSonics will deliver to LLNL technical requirements and necessary ElectroSonics owned hardware and software for technical evaluation for design and integration for the pre-production model no later than two (2) months from beginning of project. (ElectroSonics) (Not completed)
2) ElectroSonics will deliver, with LLNL assistance, a completed board design package to include at least schematic and CompactFlash dockable layout of pneumothorax detector design package Revision 1 due no later than six (6) months from beginning of project. (Tasks 1, 2 and 3) (LLNL) (Not completed)
3) ElectroSonics will deliver prototype miniaturized DAQ electronics for LLNL evaluation no later than nine (9) months from the beginning of project. (ElectroSonics) (Not completed)
4) LLNL will deliver to ElectroSonics the overall project annual report in viewgraph or report format due no later than twelve (12) months from the beginning of project. (Tasks 1 through 7) (LLNL) (Completed, view graphs)
5) LLNL will deliver to ElectroSonics no later than nine (9) months from the beginning of the project all elements of the design package required to document and manufacture the hardware components of a non-invasive pneumothorax detector system. Including but not limited to: antenna design documentation, schematics, BOM, and component specifications. (Partially completed due to lack of funding)

<u>Deliverables for Project Year 2</u>

1) ElectroSonics will deliver to LLNL technical evaluation findings from the prototype pre-production model and additional optimization requirements in preparation for year 2 design and integration for the pre-production model no later than fourteen (14) months from beginning of the project. (ElectroSonics) (Not completed)

2) LLNL will deliver to ElectroSonics recommendations in viewgraph or report format of optimized pneumothorax detector design package no later than eighteen (18) months from beginning of the project. (Tasks 1, 2 and 3) (LLNL) (Not completed, lack of available funding)

3) ElectroSonics will deliver no more than 2 optimized pre-production miniaturized DAQ electronics for LLNL evaluation no later than twenty-one (21) months from the beginning of the project. (ElectroSonics) (Not completed)

4) LLNL annual report to ElectroSonics due no later than twenty-four (24) months from beginning of the project. (Tasks 1 through 5) (LLNL) (Not completed)

Deliverables for Project Year 3

1) ElectroSonics will deliver to LLNL findings in viewgraph or report format of continued system verification and validation throughout the project as indicated on Table 1 (Schedule of Project Phases). The deliverables of such documents shall be on an ad hoc basis, but at least once every six (6) months from the beginning of the project. (ElectroSonics) (Not completed)

2) LLNL will deliver to ElectroSonics subject matter expertise to assist ElectroSonics throughout the verification and validation process as needed with available funding. (LLNL) (Not completed due to lack of funding)

3) LLNL will deliver to ElectroSonics in viewgraph or report format of overall LLNL findings and contributions due no later than thirty-six (36) months from beginning of the project. (LLNL) (Not completed due to lack of funding)

4) Final Report. LLNL and ElectroSonics will submit a final report and abstract due within thirty (30) days of completion or termination of the project, as required under Article XI of the CRADA. (LLNL/ElectroSonics) (Completed)

The CRADA was originally designated as a thirty-six (36) month project. The duration of the project was sixty-nine (69) months. There were four no-cost time extensions for this CRADA due to limitation of available funding.

NCTE #1 was executed on 9/13/10 to allow enough time to complete tasks and deliverables associated with the CRADA Statement of Work. The CRADA was extended for twelve (12) months, to September 4, 2011.

NCTE #2 was executed on 7/24/11 to allow enough time to complete tasks and deliverables associated with the CRADA Statement of Work. The CRADA project was be extended for twelve (12) months, to September 4, 2012.

NCTE #3 was executed on 10/1/12 to allow enough time to prepare and execute Amendment One to the CRADA. The CRADA project was extended for three (3) months, to December 4, 2012.

NCTE #4 was executed on 12/14/12 to allow more time to prepare and execute Amendment One to the CRADA. The CRADA project was extended for six (6) months, to June 4, 2013.

Most of the tasks and deliverables were not completed due to the lack of funding.

C. Technical Accomplishments

The technical accomplishments and overall objective for Phase II Type II were to complete the engineering development required to produce a useful hand-held device that is suitable for continued testing on human subjects as well as to anticipate initial commercial product development. The specific objectives included:

1. Clinical Trials – perform scans on human subjects as necessary to obtain clinical data for analysis optimization. The goal is to use this data to further develop optimized method(s) for processing the scan data to achieve maximum correlation between the MIR/UWB device measure and the observed relative volume of the pneumothorax from standard chest x-rays.
2. Device Development and technology transition– determine the final device parameters and continue development of a dedicated MIR/UWB device for pneumothorax detection in a commercially viable package and form factor.

D. Expected Economic Impact

Traumatic pneumothoraces and hemopneumothoraces are common after blunt and penetrating thoracic trauma. The North American Major Trauma Outcome study investigated the prevalence of pneumothorax and hemopneumothorax in patients sustaining major trauma. Among 15,047 trauma patients with thoracic injuries, a pneumothorax was present in 20 percent of cases, and 25 percent had a hemopneumothorax. Because a pneumothorax is often a life-threatening condition, early and accurate on-site diagnosis and treatment is critical for survival.

Due to the large number of pneumothoraces that result from chest trauma, coupled with the non-portable and costly current forms of diagnosis, a device such as ElectroSonics Medical's represents a significant market need. It is expected that high demand for this device will be in the area of medical air transports, ambulances and other first responders, hospital emergency rooms, and intensive care units. In addition, there is a large veterinary market for this device as x-ray is expensive and can be difficult to perform on animals. The civilian and animal market is expected to create a demand of approximately 75,000 units, thereby creating an attractive commercial market for this device.

Since a portable non-invasive pneumothorax detector is of interest to the military as well, this becomes an additional market for the ElectroSonics Medical device. Data shows that pneumothorax is the third-largest cause of fatality on the battlefield and that many deaths could have been prevented with rapid diagnosis and treatment. The military has a high level of interest in this type of device as they have been funding development of non-invasive pneumothorax detectors for the past 5 to 6 years. ElectroSonics Medical estimates that the military market would need more than 50,000 units just to equip active battlefield medics.

Today, definitive diagnosis of pneumothorax requires a chest x-ray or CT scan, using equipment currently available only in a hospital or clinic. The Noninvasive Pneumothorax Detector provides a portable alternative that can be used in any location—in a hospital or clinical setting, and also in the field by emergency first-responders. The following table shows the potential economic impact to the medical field as a result of introducing the pneumothorax detector.

Equipment	Size	Weight	Power Requirements	Time for Diagnosis	Suitable Location	Price
Portable Noninvasive Pneumothorax Detector	2.5” x 5”	Less than 1 lb	3.7 VDC (Note: battery powered)	15 seconds	In clinic, hospital, or in the field	About $1000
X-ray equipment*	About 3 ft^3 and larger	96 lb and up	100-260 VAC	Depends on availability of diagnostician (minutes to hours)	In clinic or hospital	About $15,000 and up
CT-scanner equipment^	About 5 ft^3 and larger	740 lb and up	260 VAC	Depends on availability of diagnostician	In clinic or hospital	About $250,000 and up

* http://www.med1online.com/p-5777-minxray-hf12060hppwv-powerplus-portable-x-ray.aspx
^ http://www.neurologica.com/CereTom.aspx (this small form factor is currently used only for head imaging)

D.1 Specific Benefits

<u>Benefits to DOE</u>

The CRADA supported the efforts of the Physics and Life Sciences Directorate and the Engineering Directorate at LLNL in improving their capabilities in the field of diagnostic medicine. This project and collaborations led to be selected as a recipient of the 2007 R&D 100 Award.

<u>Benefits to Industry</u>

The CRADA enabled ElectroSonics Medical to continue development of the pneumothorax detector, a device that would be extremely valuable for emergency care and triage of injured personnel.

E. Participant Contribution

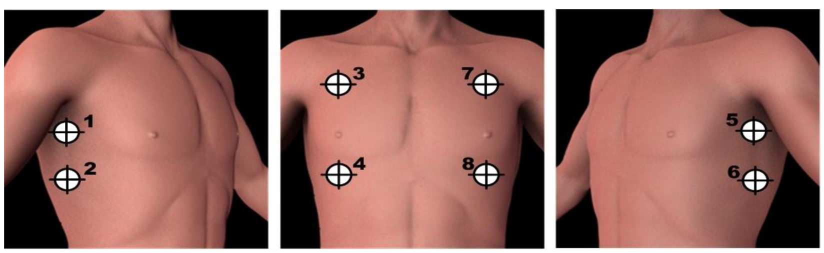
ElectroSonics Medical has developed two novel devices for non-invasive detection of pneumothorax utilizing the Micropower Impulse Radar (MIR) Ultra Wideband (UWB) technology. One device, the PneumoScan is detecting pneumothoraces in the pre-hospital and trauma markets and the second device, Fynd, is detecting and monitoring pneumothoraces in the clinical setting during certain venous access procedures.

PneumoScan is a portable device that can rapidly and reliably detect the presence of a pneumothorax at the point-of-care.

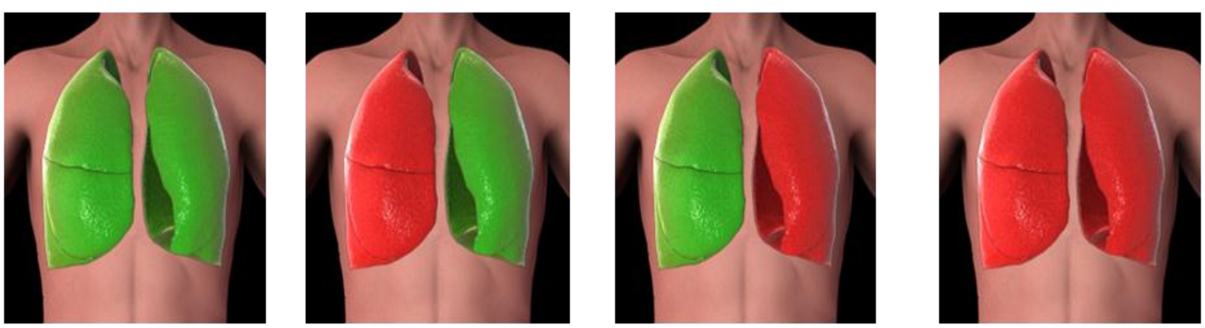
PneumoScan

The PneumoScan, shown at left, can integrate into any laptop, notebook, or hand-held computing platform running at least Windows CE Mobile 6.0 or Windows XP ("Host") through a standard USB interface. The system draws all power from the Host, and provides indicator lights for scan feedback and diagnosis. Positioning assistance and scan results are provided to the user through the Host display (which can be automatically saved into a database).

The PneumoScan has distinct advantages over existing technologies used for pneumothorax diagnosis. The device is portable and rugged making it suitable for use in any setting. Effective use requires only limited training and no advanced medical knowledge. After scanning the patient at the 8 pre-defined locations (Fig. 1 below),



PneumoScan utilizes proprietary software to provide an immediate interpretation indicating whether a pneumothorax is present and its location (left or right side) if detected (Fig. 2 below).



No Pneumothorax Detected	Pneumothorax on the right side	Pneumothorax on the left side	Pneumothorax on both sides

Data Acquisition System and Antenna

Fynd is comprised of two components, a small data acquisition system and a disposable antenna. The data acquisition system integrates into any laptop, notebook, or hand-held computing platform through a standard USB interface. The system draws all power from the host computer. The software interface provides the user with antenna positioning assistance, access to patient records, and real-time scan results.

The sterile antenna emits and receives the radar signals. It is approximately 2” x 2” in size, low profile, and adheres to a patient’s chest in the same fashion as an EKG lead. The antenna is disposable and intended for one-time use.

The Fynd system has distinct advantages over existing technologies used for pneumothorax diagnosis. The device is portable, uses low levels of non-ionizing radiation and is suitable for use in any setting. Effective use requires only limited training and can be easily interpreted thereby eliminating the need for a confirmatory x-ray specifically for pneumothorax detection. Once placed on the patient, the system can continuously monitor the patient providing the clinician with real-time updated patient information.

F. Documents/Reference List

Reports

No formal reports were generated.

Copyright Activity

There were no software, drawings, or data developed for this project.

Subject Inventions

None

Background Intellectual Property

LLNL disclosed the following Background Intellectual Property (BIP) for this CRADA project:

Invention Disclosure Number	*U.S. Patent Number*	*Title*	*Inventors*	*Issue Date*
IL-9091A	5,345,471	Ultra-Wideband Receiver	Thomas E. McEwan	9/6/94
IL-9091B	5,523,760	Ultra-Wideband Receiver	Thomas E. McEwan	6/4/96
IL-9092 Expired 4/12/2013	B1 5,361,070	Ultra-Wideband Radar Motion Sensor Reexamination Certification for: Patent No. 5,361,070 Issued: 11/1/94 Appl. No. 08/044,717 Filed: 4/12/93	Thomas E. McEwan	5/16/00
IL-9197	5,457,394	Impulse Radar Stud Finder	Thomas E. McEwan	10/10/95 Expired 4/12/2013
IL-9318	5,465,094	Two Terminal Micropower Radar Sensors	Thomas E. McEwan	11/7/95
IL-9340A	5,573,012	Body Monitoring and Apparatus and Method	Thomas E. McEwan	11/12/96
IL-9340B	5,766,208	Monitoring and Imaging Apparatus and Method	Thomas E. McEwan	6/16/98
IL-9426	5,512,834	Homodyne Impulse Hidden Object Locator	Thomas E. McEwan	4/30/96
IL-9514A	5,521,600	Range-Gated Field Disturbance Sensor with Range-Sensitivity Compensation	Thomas E. McEwan	5/28/96
IL-9514B	5,682,164	Pulse Homodyne Field Disturbance Sensor	Thomas E. McEwan	10/28/97
IL-9515	5,630,216	Micropower RF Transponder with Super regenerative Receiver and RF Receiver with Sampling Mixer	Thomas E. McEwan	5/13/97
IL-9516A	5,510,800	Time-of-Flight Radio Location System	Thomas E. McEwan	4/23/96
IL-9516B	5,661,490	Time-of-Flight Radio Location System	Thomas E. McEwan	8/26/97
IL-9547	5,609,059	Electronic Multi-Purpose Material Level Sensor	Thomas E. McEwan	3/11/97
IL-9567B	5,774,091	Short Range, Micro-Power Impulse Radar with High Resolution Swept Range Gate with Damped Transmit and Receive Cavities	Thomas E. McEwan	6/30/98
IL-9567C	5,757,320	Short Range, Ultra-Wideband Radar with High Resolution Swept Range Gate	Thomas E. McEwan	12/17/96
IL-9595	5,581,256	Range Gated Strip Proximity Sensor	Thomas E. McEwan	6/6/95
IL-9613	5,832,772	Micropower RF Material Proximity Sensor	Thomas E. McEwan	1/27/97

Invention Disclosure Number	***U.S. Patent Number***	***Title***	***Inventors***	***Issue Date***
IL-9648	5,519,400	Phase-Coded, Micro-Power Impulse Radar Motion Sensor	Thomas E. McEwan	6/6/95
IL-9649	5,767,953	Light Beam Range Finder	Thomas E. McEwan	6/6/95
IL-9650	5,576,627	Narrow Field Electromagnetic Sensor System and Method	Thomas E. McEwan	3/17/95
IL-9727	5,589,838	Short Range Radio Locator System	Thomas E. McEwan	8/3/95
IL-9772	5,563,605	Precision Digital Pulse Phase Generator	Thomas E. McEwan	8/2/95
IL-9779	5,661,385	Window-Closing Safety System	Thomas E. McEwan	8/3/95
IL-9797	5,517,198	Ultra-Wideband Directional Sampler	Thomas E. McEwan	8/3/95
IL-9798	5,610,611	High Accuracy Electronic Materials Level Sensor	Thomas E. McEwan	8/3/95
IL-9812	5,883,591	Ultra-Wideband Impedence Sensor	Thomas E. McEwan	3/16/99
IL-9842	5,805,110	Impulse Radar with Swept Range Gate	Thomas E. McEwan	9/8/98
IL-9992	5,754,144	Ultra-Wideband Horn Antenna With Abrupt Radiator	Thomas E. McEwan	5/19/98

ElectroSonics executed LLNL License TL02055-0.0 on 3/27/06, and LLNL License TL02282 on 2/17/12 for the BIP listed for different fields of use.

ElectroSonics Medical disclosed the following BIP for this CRADA project:

Invention Disclosure Number	***U.S. Patent Number***	***Title***	***Inventors***	***Disclosure Date***
ESM 110	n/a	Method for Processing of Signals for Pneumothorax Detection	Steven E. Wilder	April 2005

G. Acknowledgement

Industrial Participant's signature of the final report indicates the following:

1) The Participant has reviewed the final report and concurs with the statements made therein.
2) The Participant agrees that any modifications or changes from the initial proposal were discussed and agreed to during the term of the project.
3) The Participant certifies that all reports either completed or in process are listed and all subject inventions and the associated intellectual property protection measures generated by his/her respective company and attributable to the project have been disclosed and included in Section E or are included on a list attached to this report.
4) The Participant certifies that if tangible personal property was exchanged during the agreement, all has either been returned to the initial custodian or transferred permanently.
5) The Participant certifies that proprietary information has been returned or destroyed by LLNL.

7-19-1

Robert "Bob" Purcell, President and Chief Operating Officer — Date
ElectroSonics Medical Inc.

7/31/13

John Chang, ~~LLNL Principal~~ Investigator — Date
Lawrence Livermore National Laboratory

8/13/2013

Veronica ~~Lanier, Acting Technology Commercialization Manager~~ — Date
Lawrence Livermore National Laboratory
Richard Rankin, Director, Industrial Partnerships Office

Attachment I – Final Abstract

Non-Invasive Pneumothorax Detector

Final Abstract (Attachment I)
CRADA No. TC02110.0
Date Technical Work Ended: April 26, 2013

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B. Purpose and Description

This was a collaborative effort between Lawrence Livermore National Security, LLC as manager and operator of Lawrence Livermore National Laboratory (LLNL) and ElectroSonics Medical Inc. (formerly known as BIOMEC, Inc.), to develop a non-invasive pneumothorax detector based upon the micropower impulse radar technology invented at LLNL.

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Due to the large number of pneumothoraces that result from chest trauma, coupled with the non-portable and costly current forms of diagnosis, a device such as ElectroSonics Medical's represents a significant market need. It is expected that high demand for this device will be in the area of medical air transports, ambulances and other first responders, hospital emergency rooms, and intensive care units. In addition, there is a large veterinary market for this device as x-ray is expensive and can be difficult to perform on animals. The civilian and animal market is expected to create a demand of approximately 75,000 units, thereby creating an attractive commercial market for this device.

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The overall objective for this CRADA was to complete the engineering development required to produce a useful hand-held device that is suitable for continued testing on human subjects as well as to anticipate initial commercial product development.

C. Benefit to Industry

The CRADA enabled ElectroSonics Medical to continue its development of the pneumothorax detector, a device that would be extremely valuable for emergency care and triage of injured personnel.

Today, definitive diagnosis of pneumothorax requires a chest x ray or CT scan, using equipment currently available only in a hospital or clinic. The Noninvasive Pneumothorax Detector provides a portable alternative that can be used in any location—in a hospital or clinical setting, and also in the field by emergency first-responders.

D. Benefit to DOE/LLNL

The CRADA supported the efforts of the Physics and Life Sciences Directorate and the Engineering Directorate at LLNL in improving their capabilities in the field of diagnostic medicine. This project and collaborations led to be selected as a recipient of the 2007 R&D 100 Award.

E. Project Dates

September 4, 2007 through April 26, 2013