

Development and Assessment of a Dual-Mode, Noise-Immune Stethoscope for Combat Environments

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ABSTRACT

Future NATO operations will continue to take place in remote and austere environments far from fixed medical facilities. Not only is access to advanced medical technology lacking in such operational environments, but the use of certain basic medical devices can also be severely inhibited. The common acoustic stethoscope is rendered useless when ambient noise levels exceed 80-85 dBA. Noise cancelling electronic stethoscopes with mechanical impedance-matched transducer designs can extend the useful range up to 90 dBA. Unfortunately many operational environments exceed this threshold. The noise level in an air ambulance can reach 120 dBA, rendering even advanced electronic stethoscopes unusable.

A need exists for a stethoscope that can detect heart and lung auscultation in the presence of fixed- and rotary-wing aircraft, as well as in ambulances and other operational environments where the ambient noise level precludes auscultation with a standard stethoscope. Possessing this capability can help prevent unnecessary loss of life by allowing combat medics to identify pneumothoraces and loss of intubation integrity – conditions that would otherwise go undetected. This is basic medical care available in medical fixed facilities everywhere, but currently not available to our deployed medical personnel operating in high noise environments.

The U.S. Army has partnered with Active Signal Technologies to develop a dual-mode noise-immune stethoscope (NIS) capable of operating in a standard electro-mechanical (acoustic) mode, or a unique Doppler mode. The Doppler mode allows auscultation in high-noise environments. Because even modern military vehicles do not produce acoustic energy at the ultrasound carrier frequencies of 2-3 MHz, the use of an ultrasound transmitter/receiver provides an essentially noise-free auscultation channel for the NIS. However, the physiological information and the manner in which it is acoustically conveyed, shows fundamental differences between conventional and ultrasound-based stethoscopes.

Multiple studies have been completed on the NIS. The U.S. Army Institute of Surgical Research (USAISR) evaluated the ability of the stethoscope to detect iatrogenically induced pneumo- and simulated (saline) hemothorax in swine. These were correctly identified with the acoustic mode, but proved difficult to interpret normal from abnormal returns using Doppler. In addition to evaluating the clinical effectiveness of the NIS, the U.S. Army Aeromedical Research Laboratory (USAARL) performed multiple tests to

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14. ABSTRACT

Future NATO operations will continue to take place in remote and austere environments far from fixed medical facilities. Not only is access to advanced medical technology lacking in such operational environments, but the use of certain basic medical devices can also be severely inhibited. The common acoustic stethoscope is rendered useless when ambient noise levels exceed 80-85 dBA. Noise cancelling electronic stethoscopes with mechanical impedance-matched transducer designs can extend the useful range up to 90 dBA. Unfortunately many operational environments exceed this threshold. The noise level in an air ambulance can reach 120 dBA, rendering even advanced electronic stethoscopes unusable. A need exists for a stethoscope that can detect heart and lung auscultation in the presence of fixed- and rotary-wing aircraft, as well as in ambulances and other operational environments where the ambient noise level precludes auscultation with a standard stethoscope. Possessing this capability can help prevent unnecessary loss of life by allowing combat medics to identify pneumothoraces and loss of intubation integrity conditions that would otherwise go undetected. This is basic medical care available in medical fixed facilities everywhere, but currently not available to our deployed medical personnel operating in high noise environments. The U.S. Army has partnered with Active Signal Technologies to develop a dual-mode noise-immune stethoscope (NIS) capable of operating in a standard electro-mechanical (acoustic) mode, or a unique Doppler mode. The Doppler mode allows auscultation in high-noise environments. Because even modern military vehicles do not produce acoustic energy at the ultrasound carrier frequencies of 2-3 MHz, the use of an ultrasound transmitter/receiver provides an essentially noise-free auscultation channel for the NIS. However, the physiological information and the manner in which it is acoustically conveyed, shows fundamental differences between conventional and ultrasound-based stethoscopes.

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determine the stethoscope's effectiveness in high-noise environments. Using a sound chamber to compare the NIS to other stethoscopes, it was found that while the signal-to-noise ratio of conventional stethoscopes declined with increasing noise levels; the NIS not only maintained a constant signal-to-noise ratio in Doppler mode, but was also superior to conventional modes at all levels from 70-120 dBA.

The NIS has demonstrated not only its utility for heart and lung auscultation in a quiet setting, but also its usefulness in high noise environments when used in the unique Doppler mode. However, because the sounds produced by the acoustic and ultrasound modes are fundamentally different, it is recommended that further studies be conducted to fully characterize the sounds produced by a Doppler stethoscope in more clinical scenarios.

1.0 BACKGROUND AND LITERATURE REVIEW

Auscultation of heart and lung sounds is a constant component of casualty triage and ongoing care. It is a tool used to identify pathophysiology and determine the appropriate course of treatment. Current triage algorithms utilize the patient's physiologic status to give a medical care provider a "snapshot" of the patient's stability [4,5,6,7,12,17,20]. The absence or inability to obtain physiological measurements, especially in a military environment, necessitates pre-hospital providers to make rapid decisions about priority of care, application of interventions and transport destinations based upon isolated physiological data points (i.e., arterial pressure, arterial oxygen saturation, heart rate, and respiratory rate) without the benefit of observing dynamic trends intrinsic to trauma physiology. As such, it is inherently important that military medical care providers have the tools available to identify physiological parameters that may be indicative of developing complications and potential cardiovascular collapse.

Clinical examination by auscultation is fundamental to the assessment of patients; it is rapid, simple, portable, and can be readily repeated to continually assess patient physiologic status. However, meaningful auscultation is compromised in high ambient noise environments [3,8,9,10]. Aeromedical evacuation presents challenges for en-route patient care; the most notable is the inability for effective auscultation during helicopter flight.

During aeromedical evacuation, a wounded soldier with an undiagnosed and untreated pneumothorax has an increased risk of respiratory and cardiovascular collapse due to the decreased atmospheric pressure experienced during flight which will lead to expansion of the trapped intra-thoracic air. The inability of medics or flight surgeons to hear heart and lung sounds or to detect the development or progression of either a pneumothorax or hemothorax greatly compromises their ability to manage airways and provide appropriate life saving interventions.

The asymmetric battlefield of today requires immediate and definitive care of wounded Soldiers. This care can include rapid diagnosis, monitoring, and intervention for life-threatening injuries anywhere from the point of injury to evacuation and through multiple levels of care. For medical providers delivering this care, examination and clinical decision-making using auscultation is a vital tool. Yet, traditional bell and diaphragm stethoscopes prove inadequate for auscultation in high ambient noise environments such as a medical evacuation helicopter. Ambient noise levels can get as high as 120 dBA in a UH-60 Black Hawk [8].

Noise can contaminate the auscultation system of a traditional bell stethoscope through several routes: via transmitted surface waves across the patient's skin; transmission through the housing of the head of the device or rubber tubing; or penetrating the interface of the earpiece and external ear canal. Recent solutions to improve clarity and subsequent diagnostic yield of stethoscopes in conditions of noise have included the electronic stethoscope, whereby a microphone in the headpiece converts sound waves into electrical energy negating the need for rubber tubing. These devices can also serve to amplify the signal and, in some cases, include digital signal processing. However, in many high-noise environments the

desired signals – those corresponding to physiologic patient sounds - often lie within the spectrum of ambient noise [1].

1.1 Introduction to the NIS

Because the frequency of ambient sound and the desired physiologic sounds overlap, filtering can interfere with obtaining the desired signal, while simple amplification will indiscriminately affect both signal and noise [1]. For that reason, electronic stethoscopes still do not allow for auscultation in environments where ambient noise exceeds 90 dBA. There exists a need for a device with an adequate signal-to-noise ratio capable of sound discrimination under austere noise conditions. To address this need, Active Signal Technologies, Inc. (AST) of Linthicum Heights, Maryland worked to develop their dual-mode noise-immune stethoscope in conjunction with the U.S. Army Aeromedical Research Laboratory under the provisions of a Small Business Innovate Research (SBIR) award [15].



Figure 1: Photograph of the dual-mode, noise-immune stethoscope.

The NIS device is a unified hybrid dual-mode stethoscope that includes both an electromechanical acoustic (passive) mode and a 2-3 MHz Doppler (active) mode. The enhanced acoustic mode functions similarly to an electronic stethoscope, but contains a directly coupled piezoelectric ceramic stack instead of a simple microphone ensemble. A Doppler ultrasound transmitter together with a receiver-transducer integrated into the stethoscope's head provides the active operation. The carrier wave generated by the ultrasound transmitter is reflected back off of patient tissue. When tissue such as the heart moves, the wave is modulated by the Doppler effect and the stethoscope decodes the information contained in the carrier wave to generate an audible signal to return to the clinician. The advantage of this technology is its near immunity to ambient noise invasion; environmental noise does not interfere with sound at such high frequency [11].

To make use of the unique Doppler mode requires the use of ultrasound contact gel between the stethoscope and the patient's skin to minimize reflections at this boundary layer. It should be noted that the audible returns of the Doppler mode are distinctly different from that of a traditional stethoscope by which clinicians are trained to hear. For example, Doppler heartbeat sounds have been described as a "ta-dá-da" three-part rhythm pattern versus the "lub-dub" of a traditional stethoscope [8,11]. Yet, clinicians can be trained to recognize and interpret these sounds. The finalized NIS package will contain educational media to accompany the stethoscope when purchased. This media will include sound recordings and information that will serve to re-train health care providers' ears to the unique auscultation sounds provided by the Doppler stethoscope.

This NIS device is designed for one-handed operation (including a gloved hand with aviation Nomex) with the operator controlling the head between the index and middle fingers. It is operated via a four-button thumb control: acoustic mode and Doppler mode “on” switches, as well as volume increase/decrease switches. There is an automatic timed shut-off. The NIS is powered by two 1.5 V AA-cell batteries located in the stethoscope’s headpiece. The coaxial cable output electrical output of the device can be configured for use with headset ear phones or to be compatible with the Army’s HGU-56/P Aircrew Integrated Helmet System with Communications Ear Plugs (CEPs) for both hearing protection and auscultation.

1.2 Completed Studies

Preliminary and developmental testing of the advanced prototype NIS device in a reverberant sound chamber at USAARL demonstrated that the acoustic mode functioned (preserved a signal-to-noise ratio > 0) up to an ambient noise environment of approximately 90 dBA, whereas the Doppler mode maintained higher signal-to-noise ratios and could be function in environments with up to 110 dBA of ambient noise [9]. Subsequent tests in flight confirmed the ability to auscultate both heart and lung sounds in the Doppler mode in a UH-60 helicopter [10]. Further studies at USAARL showed the NIS could provide auscultation in high-noise environments up to 120 Dba [8,11]. The NIS has also been tested in swine models whereby iatrogenically induced pneumo- and simulated (saline) hemothorax were identified with the acoustic mode, but proved difficult to interpret normal from abnormal returns using Doppler [2]. Subsequent improvements in the device are thought to improve function [16].

The advanced prototypes used in the completed studies have since undergone several revisions and technical improvements [16]. Specific technical revisions to the advanced prototypes have included the following:

- 1) The diaphragm’s rubberized O-rings were replaced with the addition of a machined ridge.
- 2) The diaphragm surface was modified from a metal-plastic hybrid to an acrylonitrile butadiene styrene (ABS) plastic “across-the-face” plate.
- 3) The impedance-matching hardware was replaced with a directly coupled piezoelectric stack.
- 4) The syntactic foam was removed from the posterior side of the Doppler element.
- 5) The transmission power of the Doppler was increased.
- 6) A 500 Hz low-pass filter for the acoustic mode was added.

Clearly, the NIS has potential applications for clinical auscultation in moderate to severe noise conditions including such diverse applications as patient evacuation in a helicopter, a busy emergency department, or even at a sporting event with loud stadium noise. This advanced technology development can address the need for auscultation in such austere noise environments. Furthermore, the Doppler function may even provide novel acoustic information to clinicians as well.

Although the audible returns for the Doppler mode overcome high ambient noise, they are distinctly different from the sounds produced by a traditional bell and diaphragm stethoscope. While clinicians would require some retraining for interpretation of this signal, these new physiologic sounds may also represent a unique diagnostic opportunity. The Doppler signal carries ultrasound returns unobtainable by a traditional stethoscope and may contain novel clinical information [8,11]. If these unique returns are correlated to specific abnormal physiology, then Doppler acoustic images may be of use to internists, intensivists, or cardiologists even in quiet conditions provided. This represents a separate important potential application for the NIS device.

2.0 SUITABILITY TO COMBAT ENVIRONMENTS

Many devices can be useful in a protected hospital setting, but prove to be ineffective in a combat environment. The noise-immune stethoscope was developed specifically to overcome the noise encountered on evacuation platforms such as the UH-60 Black Hawk helicopter. However, noise is only one factor differentiating a combat medicine from a hospital setting. To be useful to combat medics, the equipment brought to the battlefield must also be ruggedized to withstand rough handling and extreme environments.

The preliminary production model NIS was put through a series of tests as stipulated by MIL-STD-810G to help ensure its suitability for deployed use. The following table summarizes all tests performed.

Table 1: Environmental and Field Test Results of the NIS [13].

Test	Result
1. High Temperature, Storage (unpackaged) 160°F (71°C) for 2 hours	Successfully completed validation
2. High Temperature, Operational (unpackaged) 120°F (49°C) for 2 hours	Successfully completed validation
3. Low Temperature, Storage (unpackaged) 0°F (-20°C) for 2 hours	Successfully completed validation
4. Low Temperature, Operational (unpackaged) 40°F (4°C) for 2 hours	Successfully completed validation
5. High Temperature/High Humidity, Storage (unpackaged) 160°F (71°C) and 95% RH for 2 hours	Successfully completed validation
6. High Temperature/High Humidity, Operational (unpackaged) 120°F (49°C) and 95% RH for 2 hours	Successfully completed validation
7. Temperature Shock, Storage (unpackaged) 32°F (0°C) for 1 hour, then 160°F (71°C) for 1 hour	Successfully completed validation
8. Vibration, Non-Operational (packaged) (cumulative 3-hour test) vertical axis – 1 hour at 2.2 GRMS transverse axis – 1 hour at 1.5 GRMS longitudinal axis 1 hour at 1.9 GRMS	Successfully completed validation
9. Loose Cargo Transportation (packaged) 300 RPM and 1-inch amplitude for 1 hour	Successfully completed validation
10. Transit Drop (unpackaged) dropped three times from 4 feet onto dirt surface	Failed validation. Damage prevented stethoscope from emitting sound.

The NIS successfully passed 9 of the 10 tests and Active Signal Technologies is currently working to better protect the stethoscope when it is dropped.

3.0 FUTURE STUDIES

Testing and evaluation of the NIS prototype devices have verified the ability to function (preserve signal-to-noise ratio) in high ambient noise conditions, as well as in the austere conditions encountered during

combat casualty care. However, clinical testing has only included small numbers of research clinicians and small numbers of human and swine test subjects. What remains unknown is the diagnostic potential of the NIS under conditions of human pathology. Future evaluation strategy and research must include a large-scale qualitative diagnostic assessment of effectiveness with a clinician cohort representative of future end-user clinicians (e.g., trauma physicians, physician assistants, nurses, medics, flight surgeons and flight medics, internists, etc.) under conditions of human pathophysiology, including pneumo- and hemothorax, thoracic trauma, pneumonia, arrhythmias, valvulopathy, heart failure, endotracheal tube misplacement, and more.

3.1 USAISR Study

The U.S. Army Institute of Surgical Research has a study planned during 2010 to evaluate the NIS. The purpose of this study is to determine if a patient with a pneumothorax or hemothorax can be detected using either sound waves or radio waves. The study will evaluate the effectiveness the NIS as well as a separate device that uses radio waves to look into the chest in a manner similar to the way radar is used to look at clouds and weather formations. Both of these tools are small, lightweight, and battery powered making them ideal for use by combat medics. The ability to accurately diagnose a pneumothorax or hemothorax by combat medics under field conditions would lead to early lifesaving interventions and increased survival of combat casualties. The protocol objective is to develop a swine model with which to evaluate the NIS. This study will also look at an Ultra-wideband Medical Radar (UWBMR).

The protocol will test the NIS in its ability to identify differences in heart and lung sounds in normal animals compared to those with either improper (i.e., defined as placement in the esophagus) endotracheal tube placement, hemothorax, pneumothorax, and tension pneumothorax. The UWBMR system will be evaluated simultaneously as a method to differentiate between normal thoracic anatomy, pneumothorax, hemothorax, and tension pneumothorax.

3.1.1 Methods

3.1.1.1 Model Development

Before the main study, normal swine will be used to develop the auscultation, recording and injury techniques in a reproducible model. This model development time will also facilitate team integration, NIS and UWBMR familiarization, and validation of reproducible NIS heart and lung sound data and UWBMR data recording with each injury perturbation.

3.1.1.2 Experimental Set

Using the smallest number of subjects possible [12,14], the animals (n=8) will be divided into two groups. Group A (n=4), which will consist of animals undergoing control/ ET tube misplacement, progressive pneumothorax, followed by a subsequent simulated pneumothorax and hemothorax. The second group, group B (n=4), will consist of animals undergoing control/ ET tube misplacement, progressive pneumothorax and a tension pneumothorax. Animals will be anesthetized throughout the procedure. Animals in both group A and group B will then receive a decompressive needle thoracocentesis to reduce the pneumothorax with a subsequent re-evaluation with the NIS and UWBMR.

Animals from both groups A and B will serve as the control for subsequent experiments. In the control setting, the ET tube will be placed properly in the trachea. Heart and lungs sounds will be recorded in the intact right and left chest. After the control heart and lung sounds recordings are made, the ET tube will then be placed improperly into the esophagus. The pig will be taken off of the ventilator to respire spontaneously and heart and lung sounds will be recorded. To attenuate the stomach from filling with air and potentially altering the effectiveness of auscultation, a stomach tube will be passed to attenuate the

accumulation of stomach gases. The purpose is to determine if the NIS can detect the changes in lung sounds or other relevant sounds that would indicate improper ET placement.

After control recordings are made, animals in group A will receive a progressive pneumothorax. With the animals in the dorsal recumbent position, local anesthesia (Lidocaine 0.5 mg) will be injected subcutaneously in the subzyphoid region and a 5mm thoroscope will be inserted from the subzyphoid region into the left hemithorax. This will allow access to create both a pneumothorax and a simulated hemothorax via the insufflation port on the thoroscope trochar. Additionally, through the thoroscope the left hemithorax can be directly visualized to quantify the size of both the pneumothorax, simulated hemothorax and to directly evaluate the efficacy of the decompressive needle thoracentesis. Compressed carbon dioxide gas (CO₂) will be insufflated into the left hemithorax to create a pneumothorax. NIS auscultation and UWBMER evaluation with subsequent recording will be made through the left chest wall to evaluate the left hemithorax/left pneumothorax. Measurements will be made with an estimated pneumothorax of 10%, 25%, 50%, 75%, and 100%. At each percent change in the degree of the pneumothorax, evaluation of the right chest wall/right hemithorax will be conducted to act as a control.

Afterward, these animals will receive a simulated hemothorax by infusing saline through the insufflation port of the thoroscope trochar into the left pleural cavity until approximately 50% of the left hemithorax volume is filled with saline. The left lung will remain collapsed from the previous pneumothorax. Again, NIS auscultation and UWBMER recordings will be made of the left chest hemithorax wall, as well as the intact right hemithorax. Next the animals will receive a decompressive needle thoracentesis to reduce the pneumothorax with a subsequent re-evaluation with the NIS and UWBMER.

After control recordings are made, animals in group B will receive a progressive pneumothorax ending with a tension pneumothorax. CO₂ will be insufflated into the left hemithorax to create a pneumothorax. NIS auscultation and UWBMER evaluation with subsequent recording will be made through the left chest wall to evaluate the left hemithorax/left pneumothorax. Measurements will be made with an estimated pneumothorax of 10%, 25%, 50%, 75%, and 100%. At each percent change in the degree of the pneumothorax, evaluation of the right chest wall/right hemithorax will be conducted to act as a control. To create a tension pneumothorax, the pressure in the left hemithorax will be slowly increased to ensure complete lung collapse on the left. Maximum left hemithorax pressure will be determined during model development by monitoring for a significant decrease in cardiac output. NIS auscultation and UWBMER recordings will be made of the injured left chest wall, as well as the intact right chest wall. The animals will then receive a decompressive needle thoracentesis to reduce the pneumothorax with a subsequent re-evaluation with the NIS and UWBMER.

3.1.2 Data Analysis

Heart and lungs sounds measured with the noise immune stethoscope will be collected by recording the auscultation signals coming from the electrical output of the stethoscope. These electrical signals are transmitted via simple coax cable system to the microphone input of a Dell Latitude-300X laptop computer and captured in a digital format using Microsoft WAV software. The data analysis will consist of a determination of signal to noise (S/N) ratios between the various conditions (normal heart/lung sounds, properly/improperly placed endotracheal tube, pneumo-/hemo-thorax, and normal/ tension pneumothorax) and the background noise associated with auscultation at the same stethoscope volume at an acoustically non-productive tissue, for example a large muscle mass (6). This S/N ratio will be processed through proprietary software producing a numeric value as the ratio plus an absolute value in dBA. The minimum absolute difference in signal to noise to provide for intelligibility has been shown to be 3 dBA, and this will be the first benchmark for the device. The S/N ratios will then be analyzed by repeated measures ANOVA to assess the overall performance of the device. Similarly the reflections collected from the control run and each of the defect runs using the UWBMER will be processed and evaluated to determine the feasibility of detecting pleural defects caused by either the induced pneumothorax or simulated hemothorax.

3.2 USAARL Study

In addition to the study conducted by USAISR, the U.S. Army has a single center, prospective, non-randomized survey assessment proposed by the U.S. Army Aeromedical Research Laboratory to evaluate the qualitative diagnostic performance potential of the NIS in human patients with normal versus pathologic cardiopulmonary physiology. This study has three primary objectives:

- 1) Assess the ability of the NIS to detect clinically relevant hemothorax and/or pneumothorax.
- 2) Assess the ability of the NIS to verify or refute correct ET tube placement.
- 3) Assess the ability to clinically map novel audible Doppler returns of the NIS to known cardiopulmonary pathology (valvulopathy, arrhythmia, pneumonia, heart failure, reactive airways, or other adventitious clinical sounds).

3.2.1 Methods

Data collection will be conducted at a large tertiary military medical center (MEDCEN) with large trauma and inpatient patient volume. Objectives 1 and 2 will be accomplished in the emergency department (ED) and among emergency medical services (EMS), while objective 3 will be accomplished with the inpatient population on the general medical ward and medical or surgical intensive care units (ICU). As this device is still considered investigational, the NIS will not be used to diagnose or direct medical intervention on any patient. Patient diagnosis and medical treatment will not be delayed or otherwise compromised in anyway by data collection. Data collection for objectives 1 and 2 will be timed for peak trauma presentation rates based on historical MEDCEN census data. Data collection will be in the form of clinician survey following patient auscultation with the NIS.

3.2.2 Training

Twenty-five clinicians (15 from the ED and EMS services and 10 from the inpatient medical services including wards and/or ICU) will receive training on the NIS by an experienced USAARL researcher and an AST engineer familiar with the NIS. Clinicians will be a representative cohort of clinical end-users (physicians, physician assistants, nurses, medics, etc.). Training will consist of study overview, data collection procedures, and familiarization with the NIS device.

3.2.3 Study Population

Study population will consist of nonrandomized, non-sequential, consenting adults presenting to the MEDCEN hospital for care. Minimum number of subjects will include 10 per specific pathologic condition under consideration with no upper limit of enrollment. There will be no active recruitment of subjects outside the MEDCEN. The two study subsets will consist of:

- Patients presenting to the ED or through EMS services with suspected or known hemothorax or pneumothorax and/or patients requiring endotracheal intubation. The focus of this subset will be to evaluate the performance characteristics of the NIS for application in the austere military operational setting.
- Patients admitted to the inpatient service (general ward or ICU) with existing cardiopulmonary pathology established by cardiac echocardiogram, cardiac catheterization, computerized tomography (CT) scan, x-ray radiograph, or other radiologic study. The focus of this subset will be to map novel audible Doppler returns with known cardiopulmonary abnormalities.

3.2.4 Inclusion/Exclusion Criteria

3.2.4.1 Inclusion Criteria

- Consenting adult male and female patients presenting to the MEDCEN ED or EMS services with known or suspected hemothorax, pneumothorax, or requiring endotracheal airway
- Consenting adult male and female MEDCEN in-patients with known diagnosed cardiopulmonary pathology

3.2.4.2 Exclusion Criteria

- Minors

3.2.5 Screening

There are no screening evaluations prior to enrollment other than reasonable clinical suspicion that patient meets the subject inclusion criteria.

3.2.6 Data Management

Nonparametric data will be obtained in the form of clinician survey response following intervention (auscultation) with the NIS. Survey information will be completed by the participating clinicians regarding the ability to distinguish normal and abnormal pathology by auscultation (equivalence parameters compared to traditional stethoscope) in both acoustic (passive) and Doppler (active) modes and/or mapping novel audible Doppler returns to known cardiopulmonary pathophysiology. The comprehensive questionnaire will also address relevant questions, including: sound clarity, quality, familiarity, diagnostic value, ease-of-use, and field utility.

4.0 TRANSITION PLAN

These studies will provide important information regarding the qualitative diagnostic potential of the NIS along with valuable clinician assessment and feedback. Such knowledge, coupled with the known quantitative acoustical characteristics of the NIS in extreme ambient noise, is necessary to support large scale fielding efforts for the designed military end-user clinician.

The Ancillary Care Division of the Program Management Office, Medical Devices (PMO MD) of the U.S. Army Medical Materiel Agency (USAMMA) is currently developing an Acquisition Support Strategy for the NIS in conjunction with the NIS Integrated Product Team (IPT). The NIS will be a non-stocked, centrally procured durable item projected for the Air Ambulance Medical Equipment Set (MES) (444 total), Ground Ambulance MES (2,582 total), and Trauma Field MES (724 total) [18,19].

The NIS has a life expectancy of 7 years and the cost of an individual package containing the NIS and all required consumables and supplies is \$1,700 [18,19]. Intended end-users will include the Health Care Specialist (MOS 68W), Flight Surgeon (MOS 61N), Emergency Medicine Physician (MOS 62A), Field Surgeon (MOS 62D), Physician Assistant (MOS 65D), and Medical Surgical Nurse (MOS 66H). The NIS will also be placed on the Common Table of Allowance 8-100 Army Medical Department Durable and Expendable Items for availability to other end user clinicians or departments choosing to procure and use [18,19].

5.0 CONCLUSION

Examination, clinical decision making, and patient management using auscultation is a vital tool for clinicians. It has numerous advantages—quick, simple, portable, and repeatable. However, the military environment is often noisy and traditional clinical auscultation devices are not appropriate or sufficient for casualty care in such austere operational settings. A need exists for a capability to surmount the extreme noise encountered throughout combat casualty care and preserve this vital clinical tool.

The NIS, developed by a partnership between the U.S. Army and Active Signal Technologies, is a device with both electromechanical acoustic (passive) and ultrasound Doppler (active) modes. It is designed specifically to overcome ambient noise while preserving signal-to-noise ratios. This design permits clinical auscultation in moderate to severe noise environments, resulting in improved ability to diagnose and subsequently provide medical intervention across the spectrum of care from point of injury through evacuation and levels of care. Preliminary testing has validated the preservation of adequate signal-to-noise ratios in Doppler mode in austere noise conditions up to 110 dB and in flight on a UH-60 Black Hawk helicopter. Future studies are planned to better characterize the unique physiologic sounds produced by the NIS. This device represents a viable answer to the need for clinical auscultation in high noise combat environments.

Additionally, the novel integrated Doppler carrier wave design may present unique diagnostic information to clinicians not readily available through a traditional stethoscope. This may prove to be of value augmenting military clinicians in austere military conditions where traditional ultrasound devices are unavailable or impracticable.

The ability to clearly and definitively auscultate and differentiate physiologic parameters in high noise environments represents a significant step forward for military medicine. This would impact many phases of patient care including clinical diagnosis, physiologic detection, and monitoring, and treatment intervention. Improving the military caregiver's ability for clinical auscultation in any environment enhances ability to diagnose, monitor patient physiologic parameters, and provide rapid medical treatment for lifesaving interventions across the continuum of battlefield care. The tenets and tools of combat casualty care are continuously evolving, and the NIS represents a viable solution to overcome ambient noise to allow and enhance clinical auscultation, thereby yielding better diagnostic capability and improved casualty care.

6.0 ACRONYMS, ABBREVIATIONS, AND SYMBOL DEFINITIONS

ABS	Acrylonitrile Butadiene Styrene
AST	Active Signals Technologies, Inc., Linthicum Heights, MD
CEP	Communications Ear Plug
dB	Decibel
dba	Decibel, A-Weighted
CT	Computerized Tomography
ED	Emergency Department
EMS	Emergency Medical Services
ET	Endotracheal
Hz	Hertz
ICU	Intensive Care Unit
IPT	Integrated Product Team
MEDCEN	Medical Center
MES	Medical Equipment Set
MOS	Military Occupational Specialty

NIS	Noise Immune Stethoscope
PMO MD	Program Management Office, Medical Devices
SBIR	Small Business Innovate Research
S/N	Signal to Noise
USAARL	U.S. Army Aeromedical Research Laboratory
USAISR	U.S. Army Institute of Surgical Research
USAMMA	U.S. Army Medical Materiel Agency
UWBMR	Ultra-wideband Medical Radar
V	Volts

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