USAARL Report No. 2010-12

Preliminary Characterization of the Noise-Immune Stethoscope (NIS) in High Ambient Noise Environment Using a Reverberation Sound Chamber

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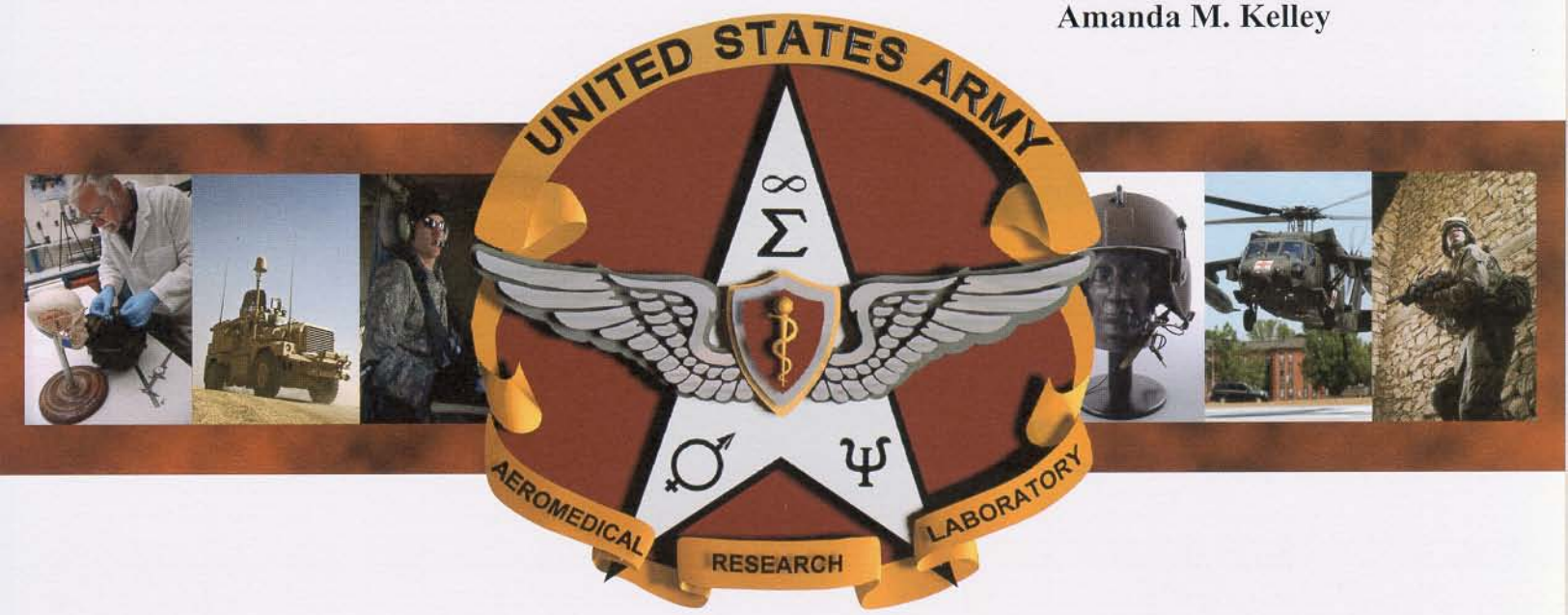

United States Army Aeromedical Research Laboratory
Warfighter Performance and Health Division

February 2010

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REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

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1. REPORT DATE *(DD-MM-YYYY)*
22-02-2010

2. REPORT TYPE
Final

3. DATES COVERED *(From - To)*

4. TITLE AND SUBTITLE
Preliminary Characterization of the Noise-Immune Stethoscope (NIS) in High Ambient Noise Environment Using a Reverberation Sound Chamber

5a. CONTRACT NUMBER

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Steven J. Gaydos
Robert A. Williams
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
U.S. Army Aeromedical Research Laboratory
P.O. Box 620577
Fort Rucker, Alabama 36362-0577

8. PERFORMING ORGANIZATION REPORT NUMBER
USAARL 2010-12

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Material Command
504 Scott Street
Fort Detrick, Maryland 21702

10. SPONSOR/MONITOR'S ACRONYM(S)
USAMRMC

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION/AVAILABILITY STATEMENT
Approved for public release; distribution unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

This report details the preliminary testing of advanced technology development for clinical auscultation in high noise environments. The Noise Immune Stethoscope (NIS) is a hybrid dual function device with electromechanical acoustic and ultrasound Doppler modes. Quantitative evaluation consisted of signal-to-noise ratio (SNR) calculations from 70 to 110 dB ambient noise. The acoustic mode preserved SNR > 0 to 90 dB of ambient noise for heart sounds and 100 dB for breath sounds. The Doppler mode preserved SNR of 20 dB to 110 dB for both heart and breath sounds. Qualitative assessment consisted of representative clinicians evaluating the device at 70, 90, and 110 dB. Clinical usefulness of the signal was determined to be of at least "fair" rating at 70 dB and 90 dB for the acoustic mode and at 70 dB, 90 dB, and 110 dB in the Doppler mode for both heart and breath sounds. Apical position for heart sounds and midaxillary position for breath sounds was found to be preferential. Given this preliminary testing, the NIS represents a viable answer to the need for clinical auscultation in high noise environments across the spectrum of casualty care.

15. SUBJECT TERMS
stethoscope, auscultation

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			Loraine Parish St. Onge, PhD
UNCLAS	UNCLAS	UNCLAS	SAR	38	19b. TELEPHONE NUMBER *(Include area code)* 334-255-6906

Reset

Standard Form 298 (Rev. 8/98)
Prescribed by ANSI Std. Z39.18

Acknowledgements

The authors would like to express their sincere gratitude to the following people for their contributions to this project.

- Arthur Estrada, Ph.D. (Director, Warfighter Performance and Health Division) for his leadership and mentorship.
- Arthur Cook, Keith Bridger, and Dennis Kohlhafer (Active Signal Technologies) for all their support in this endeavor.
- Elizabeth Stokes for assistance with all matters administrative.
- Diana Hemphill (Technical Information Officer), Sharon Fales (Librarian), and Loraine St. Onge (Technical Editor) of the USAARL Science Information Center for their invaluable assistance with literature reviews, manuscript editing, and publication requirements.

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Introduction

The word stethoscope derives its origins from the Greek words *stethos* (chest) and *skopos* (observer). With his new invention in 1816, Rene Laennec noted that intrathoracic organs make specific sounds, and these sounds prove very useful for clinical assessment and diagnosis (Bloch, 1993). Since that time, clinical auscultation by way of a stethoscope has become an essential skill for clinicians. Indeed, it has become fundamental to the assessment of patients: it is rapid, simple, portable, and can be readily repeated to assess patient physiologic status. Meaningful auscultation is compromised, however, in high ambient noise environments.

The asymmetric battlefield of today requires immediate and definitive care of wounded Soldiers, even in conditions of high noise. Such care can include rapid diagnosis, physiologic monitoring, or intervention and stabilization for life-threatening injuries anywhere from the point of injury through evacuation and multiple levels of casualty care. For medical providers delivering this care, auscultation is a vital tool for examination and clinical decision-making. Yet, traditional bell and diaphragm stethoscopes are inadequate for auscultation in high ambient noise environments such as a medical evacuation helicopter (e.g., 110 decibels [dB] in a UH-60 model).

Background

Noise can contaminate the auscultation system of a 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. In conditions of noise, however, the desired signals corresponding to physiologic patient sounds often lie within the spectrum of ambient noise—simple amplification indiscriminately affects both signal and noise, while filtering can interfere with desired physiologic sounds (Ahroon, Houtsma, & Curry, 2007).

There exists a need for a device capable of adequate audible signal discrimination under high noise conditions. Under the provisions of a Small Business Innovative Research (SBIR) award, Active Signals Technology (AST), Inc. of Linthicum Heights, Maryland, in conjunction with the U.S. Army Aeromedical Research Laboratory (USAARL) developed a "noise-immune" stethoscope (NIS) to address this need (Sewell, 2006).

The NIS device consists of a unified hybrid dual-mode design including both an electromechanical acoustic (passive) mode and a 2 to 3 mega Hertz (MHz) Doppler (active) mode (figure 1). The enhanced acoustic mode is similar to an electronic stethoscope, but consists of a directly coupled piezoelectric ceramic stack instead of a simple microphone ensemble. The integrated active mode consists of a Doppler ultrasound (US) transmitter carrier wave with a receiver-transducer integrated into the stethoscope's head. The carrier wave, reflected off of

patient tissue, is modulated by Doppler effect (e.g., when auscultating the heart, if the cardiac wall motion is moving towards the receiver, the wave reflected back to the receiver is at a higher frequency) generating an audible signal return to the clinician. This presents an advantage over ambient noise invasion, since environmental noise should not interfere with sound at such high frequency (i.e., the carrier signal is well above the audible range) (Houtsma, Curry, Sewell, & Bernhard, 2007).

Figure 1. Noise Immune Stethoscope device depicted with Communications Ear Plugs (CEPs) and ultrasound gel.

The NIS device is designed for one-handed operation with the operator controlling the head between the index and middle fingers (figure 2). 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 volt (V), AA-cell batteries located in the stethoscope's headpiece. A circumferential O-ring on the surface of the head shields the sensors from transmitted skin waves. The coaxial cable 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. The Doppler mode requires the use of typical ultrasound contact gel between the stethoscope and the patient's skin to minimize reflections at this boundary layer.

Figure 2. NIS depicted with four-button thumb control. The acoustic mode "on" switch is located at the top, and Doppler mode "on" switch is at the bottom (there is an automatic timed shut-off). Volume increase and decrease switches are located left and right, respectively.

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 (Houtsma, Curry, Sewell, & Bernhard, 2007). Presumably, clinicians can be trained to recognize and interpret these sounds. A finalized product device will contain an educational "push-package" (e.g., in the form of a Compact Disk) accompanying the stethoscope when fielded to clinicians (Brady, 2009). This will include, among other things, sound recordings and information that will train clinicians as to typical or expected sounds corresponding with auscultation of human physiology (e.g., heart and breath sounds) using the Doppler mode.

USAARL preliminary and developmental testing of the advanced prototype NIS device in a reverberant sound chamber demonstrated for cardiac sounds that the acoustic mode functioned (preserved a signal-to-noise ratio > 0) up to an ambient noise environment of approximately 90 dB, whereas the Doppler mode maintained signal-to-noise ratios of approximately 20 dB up to 110 dB of ambient noise (Houtsma, Curry, Sewell, & Bernhard, 2006). Subsequent tests in flight confirmed the ability to auscultate both heart and lung sounds using the Doppler mode in a UH-60 helicopter (Houtsma & Curry, 2007). The NIS has also been tested in a swine model by Ansorge and Bushby (2009, in press). Iatrogenically-induced pneumothorax and simulated (saline) hemothorax were identified with the acoustic mode, but proved difficult to interpret normal from abnormal returns using Doppler. Subsequent improvements in the device were made to improve function (Sewell & Cooke, 2009).

Advanced prototypes have undergone several revisions and technical improvements (Sewell & Cooke, 2009). Performance validation of a production model (versus testing that has been conducted with prototypes) is now required. Specific technical revisions to the advanced prototypes have included the following:

a. The diaphragm's rubberized O-rings were replaced with the addition of a machined ridge.

b. The diaphragm surface was modified from a metal-plastic hybrid to an acrylonitrile butadiene styrene (ABS) plastic "across-the-face" plate.

c. The impedance-matching hardware was replaced with a directly coupled piezoelectric stack.

d. The syntactic foam was removed from the posterior side of the Doppler element.

e. The transmission power of the Doppler was increased.

f. A low-pass 500 Hz 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 high noise environments.

As mentioned previously, the audible returns for the Doppler mode, while defeating extreme ambient noise environments, are distinctly different than that of a traditional bell and diaphragm stethoscope. Whereas clinicians would require some "retraining" for interpretation of this signal, it may also represent a unique bedside diagnostic opportunity. The Doppler signal does carry ultrasound returns unobtainable by a traditional stethoscope, perhaps containing novel clinical information (Houtsma, Curry, Sewell, & Bernhard, 2007). Therefore, Doppler acoustic images may be of use to internists, intensivists, or cardiologists even in quiet conditions provided these unique returns are correlated to specific abnormal physiology. This represents a second important application for the NIS device.

Military significance

Examination, clinical decision making, and patient management using auscultation is a vital tool for clinicians. Bedside auscultation has numerous advantages—quick, simple, portable, and repeatable. The military environment is austere and noisy, however, and conventional diagnostic tools are often not appropriate or sufficient for combat casualty care in such operational settings.

Clinical auscultation is a challenge at best, often impossible, in high-noise environments (e.g., a medical evacuation helicopter); and there exists a need for a device capable of adequate signal-to-noise ratios (e.g., > 0) and sound discrimination in such conditions (Houtsma, Curry, Sewell, & Bernhard, 2006). In the military, these high-noise environments can present anywhere from the point-of-injury through medical evacuation, levels of care in theater, and fixed-wing air evacuation. This might include scenarios such as engagement on a noisy battlefield, enroute care aboard a UH-60 medical evacuation helicopter, or inter-theater transport on an Air Force C-17 aircraft.

Furthermore, acoustic returns from the integrated ultrasound Doppler are unobtainable by traditional stethoscopes and may represent novel clinical information. This may prove to be of value augmenting military clinicians in austere military conditions whereby a traditional ultrasound machine is unavailable or impracticable.

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 defeat noise and permit and enhance clinical auscultation yielding better diagnostic capability and improved casualty care.

Study objectives

This test plan was conceived with two primary objectives.

a. Conduct a quantitative evaluation of the performance of the production model NIS in a high-noise environment using the natural cardiopulmonary signal of a human test subject inside a reverberation sound chamber. This entailed computation of signal-to-noise ratios for ambient noise ranging from 70 to 110 dB.

b. Conduct a preliminary qualitative assessment of the production model NIS at different levels of ambient noise using the cardiopulmonary signal of a human test subject. Assessment was conducted by a convenience sample of representative "end-user" clinicians (e.g., physicians and medics). This qualitative assessment will serve to direct near-future large-scale testing of the device, as well as contribute to the design of an educational "push package" to be fielded with the NIS device.

Methods

Description of test activity

According to the objectives, the test plan was completed in two phases, each lasting one day. Two production model NIS devices were transported to USAARL by supporting Active Signal Technologies (AST) engineers. Both devices were tested with the same human physiologic

cardiopulmonary signal source.

Phase I testing

The NIS signal output was routed via coaxial cable into a signal splitter for simultaneous digital recording on a Dell Latitude X300 laptop computer using Graphical Interactive Processing of Speech (GIPOS) (ver. 2.3) software, as well as signal output to the HGU-56/P helmet with CEPs for auscultation purposes. Ambient noise (representative of a UH-60 Blackhawk helicopter) was escalated from 70 dB to 110 dB in stepwise 5 dB increments (C-weighted equivalent sound pressure level re 20 micro Pascals). The ambient noise levels were verified using a Brüel and Kjær type 2260 Investigator Sound Level Meter. Recordings were made at a rate of 8000 samples per second for a duration of 10 seconds. A hearing-protected test volunteer with normal cardiopulmonary function served as the physiologic signal source.

Digital recordings were made in acoustic and Doppler modes for heart sounds (apical region) and breath sounds (right mid-axillary lung field). From each 10-second recording, a block of samples were chosen that contained the desired signal (e.g., a heartbeat). This block was chosen by the investigator clinician operating the stethoscope, and was identified as the portion of the recording that contained the most clinically useful acoustic signal. This block was defined as desired signal plus noise. An additional block of samples was chosen that contained none of the desired signal (the time between heartbeats, for example). This block was defined as only noise.

Phase II testing

A convenience sample of five representative "end-user" clinicians served to evaluate the device from a clinical auscultation perspective by way of qualitative questionnaire (appendix A). During testing, a hearing-protected research volunteer with normal cardiopulmonary function served as the physiologic signal source. Auscultation was performed at three ambient noise levels: 70 dB, 90 dB, and 110 dB in both acoustic and Doppler modes. In each mode and at each sound level, auscultation consisted of five anatomic positions (two cardiac, three pulmonary):

a. Cardiac	Left/Right para-sternal
	Apical
b. Pulmonary	Left/Right posterior, mid-lung field
	Left/Right mid-axillary
	Left/Right mid-clavicular

In addition to qualitative assessment at the different levels, observations, comments, and recommendations were recorded (appendix A) with the intention of directing near-future large-scale testing of the device, as well as contributing to the design of educational material that will accompany the production device when fielded.

Testing equipment and materials

Testing equipment and materials included the acoustic reverberation chamber, ambient noise driving amplifier with four-speaker system, a sound level meter, and laptop computer running signal processing software (figure 3).

Figure 3. Acoustic reverberation chamber with set-up of test equipment.

Reverberation acoustic chamber

The acoustic reverberation chamber was operated by the Acoustics Branch of the Sensory Research Division of the USAARL. The chamber is approximately 5.6 by 7.1 by 4.6 meters (m) (L by W by H) and contains a large rotating diffuser to prevent the formation of acoustic standing waves.

Sound amplification and associated measuring equipment

An Altec 9440A amplifier driving four large speakers provided the necessary background noise. Frequency section of noise was selected to be representative of a UH-60 helicopter. Noise

level (Sound Level dB C) was escalated in a stepwise fashion from 70 to 110 dB. Prior to each point of data collection, ambient noise level was verified via measurement using a Brüel and Kjær type 2260 Investigator Sound Level Meter.

Software and digital recording

Noise was shaped using a General Radio one-third octave graphic equalizer, as necessary. Digital recordings for each data point were made and analyzed using a Dell laptop computer operating GIPOS (ver. 2.3) software.

Auscultation and hearing protection

The NIS device was interfaced with the U.S. Army's HGU-56/P Aircrew Integrated Helmet System with CEPs for both hearing protection and auscultation.

Test subject

A single hearing-protected, consented volunteer (male, 26 years of age, body mass index [BMI] 23.0 kilograms per meter squared [kg/m^2]) with normal cardiopulmonary function served as the physiologic signal source for all testing.

Test evaluators

Testing evaluators consisted of a convenience sample of five representative "end-user" clinicians (three Flight Surgeons, one Aeromedical Physician Assistant (APA), and one Flight Medic) from USAARL and the U.S. Army School of Aviation Medicine (USASAM). All evaluators were on flight duty status, as such, required to pass annual audiograms. On the day of testing, each received a brief orientation to the device with instruction provided by an AST engineer and an opportunity to "practice" under quiet ambient noise conditions (approximately one hour) before evaluation.

Clinician questionnaire

Each clinician evaluator completed a questionnaire (appendix A) during the testing sequence. In both acoustic and Doppler modes, they were asked to evaluate the NIS signal for quality and clinical usefulness of the audible signal with an overall impression of excellent, good, fair, poor, or simply noise.

Clinician comments

Clinician evaluators were also asked to submit comments regarding their experience with the device. These comments were directed at ease of use, recommendations for training, best anatomic sites for auscultation in different modes, correlation of Doppler returns with physiologic sounds, potential applications, and improvements (appendix B).

Results

There were two main areas of analysis corresponding to the two test objectives: quantitative evaluation in ambient noise environment (Phase I testing) and a preliminary qualitative assessment of clinical performance at three representative ambient noise levels (Phase II testing). Statistical analysis was performed using SPSS® (ver. 13.0) software with significance set at $\alpha = 0.05$.

Phase I testing

Incoherence of desired signal and noise was assumed. Given incoherence, the mean square value of the summation (desired signal plus noise) was calculated as the sum of the mean square value of the desired signal and the mean square value of the noise (Pierce, 1989). The mean square value of each block of samples was calculated. The mean square value of the noise alone was subtracted from the mean square value of the desired signal plus noise to determine the mean square value of the desired signal. Finally, the signal to noise ratio was calculated as 10 times the logarithm base 10 (Log_{10}) of the mean square value of the desired signal divided by the mean square value of the noise.

Samples of digital recordings for the physiologic signal in ambient noise conditions are shown in figures 4 through 11.

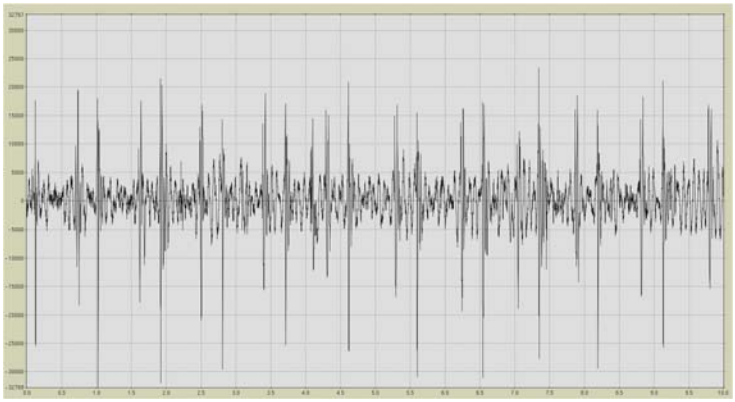

Figure 4. Heart sounds, acoustic mode, 70 dB.

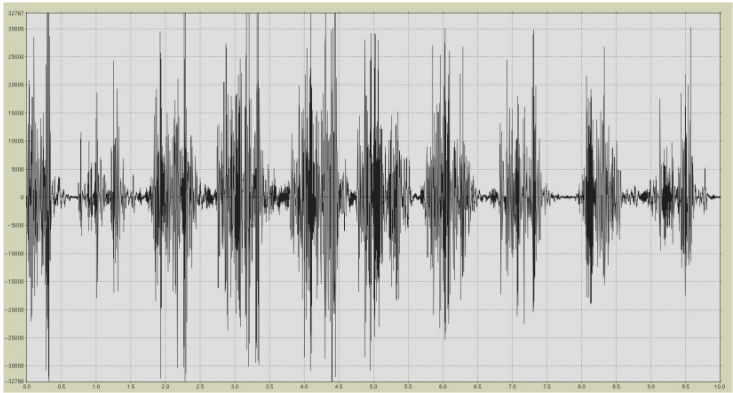

Figure 5. Heart sounds, Doppler mode, 70 dB.

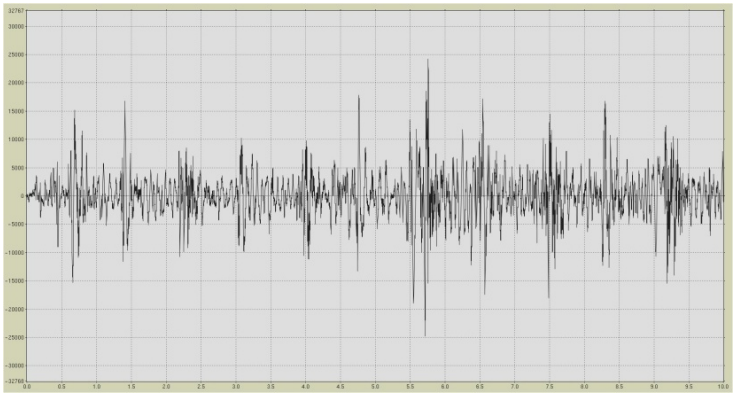

Figure 6. Breath sounds, acoustic mode, 70 dB.

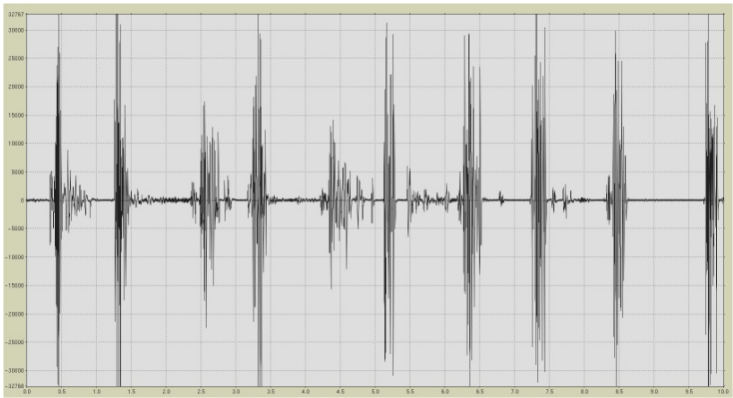

Figure 7. Breath sounds, Doppler mode, 70 dB.

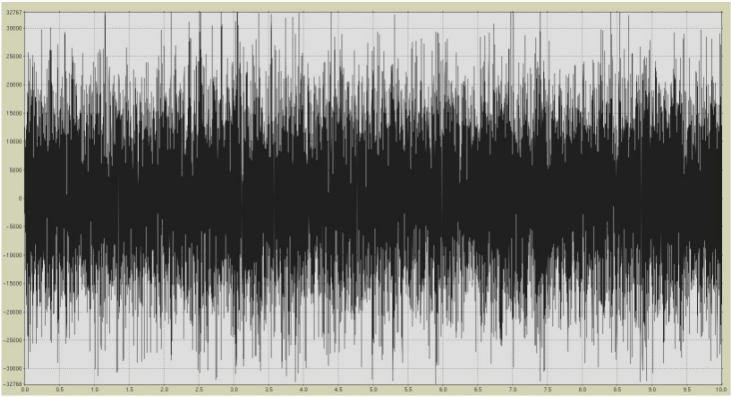

Figure 8. Heart sounds, acoustic mode, 110 dB.

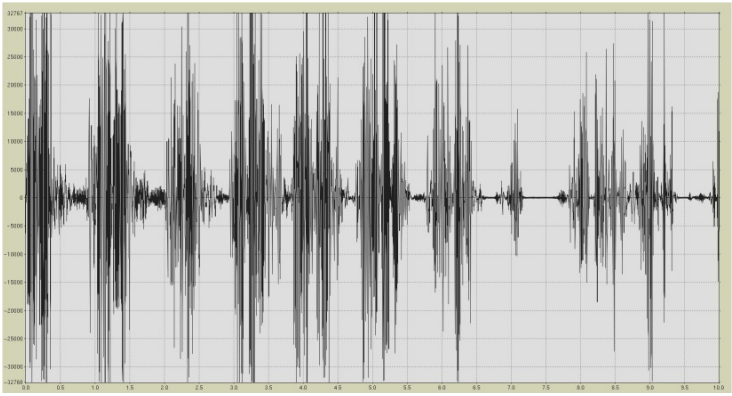

Figure 9. Heart sounds, Doppler mode, 110 dB.

Figure 10. Breath sounds, acoustic mode, 110 dB.

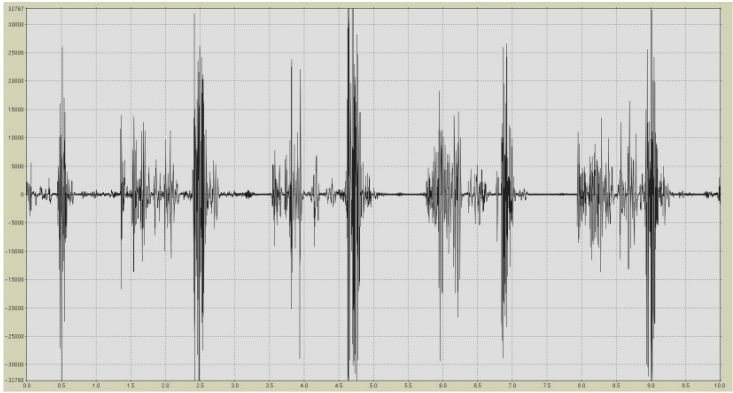

Figure 11. Breath sounds, Doppler mode, 110 dB.

Signal-to-noise ratio calculations, performed using MATLAB® (ver. R2009b) software, are depicted in figures 12 and 13 for heart and breath sounds, respectively.

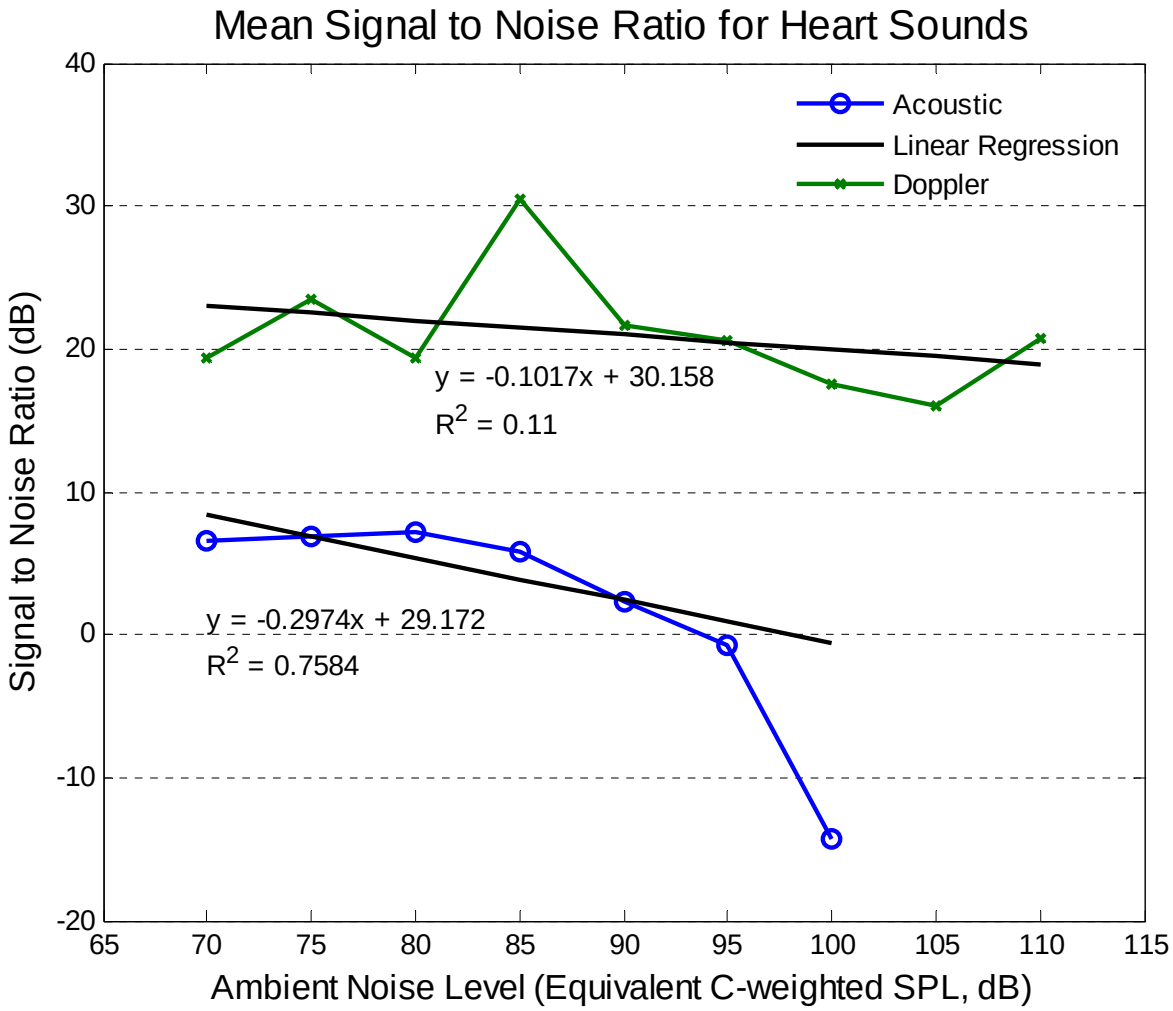

Figure 12. Mean signal-to-noise ratio versus ambient noise level (C-weighted dB SPL) for heart sounds. Note: Heartbeat signals were not audibly discernable at or above 100 dB in the acoustic mode.

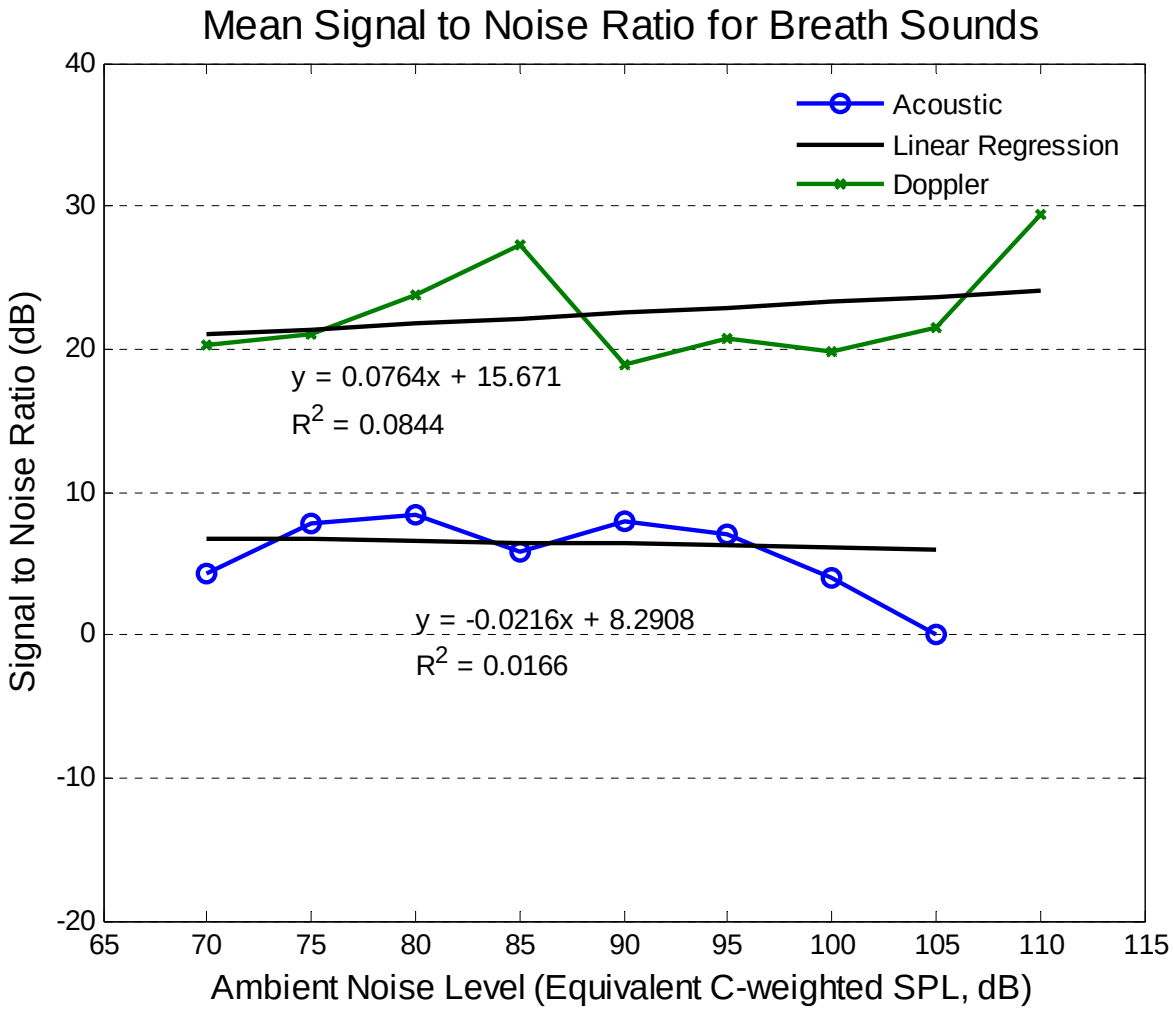

Figure 13. Mean signal-to-noise ratio versus ambient noise level (C-weighted dB SPL) for breath sounds. Note: Breath sound signals were not audibly discernable at or above 105 dB in the acoustic mode.

Phase II testing

Qualitative NIS evaluators consisted of a convenience sample of clinicians from USAARL and USASAM (figure 14).

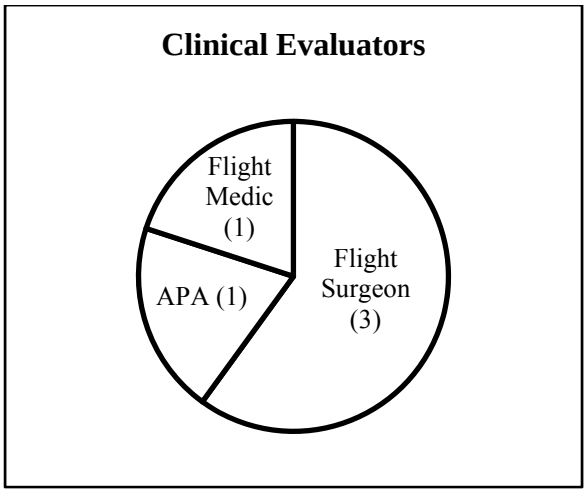

Figure 14. Clinical evaluators.

Interrater reliability (e.g., homogeneity) was determined to establish the degree of concurrence among the evaluators. This was assessed using a two-way random effects model for consistency with single measure reliability (Shrout, 1979). The analysis yielded an intraclass correlation of 0.601 (CI 0.44-0.751) that suggests relatively good consistency among raters. However, a global assessment of the overall ratings provided suggests that Rater 1 applied a stricter criterion to his subjective ratings than the other four raters (table 1).

Table 1.
Rater means and standard deviations of the means for 30 observations for each rater. Ratings correspond to excellent (4), good (3), fair (2), poor (1), or simply noise (0).

	Mean	Std. Deviation	# Observations
Rater 1	1.4333	1.16511	30
Rater 2	3.0000	1.36458	30
Rater 3	3.1333	1.25212	30
Rater 4	3.1333	.77608	30
Rater 5	2.8000	1.21485	30

Note: Rater means and standard deviations used for determination of interrater reliability.

Mean ratings for each mode, each noise level, and at each anatomic position are depicted in figures 15 and 16. In the acoustic mode, mean ratings at all anatomic positions were of at least "fair" quality and clinical usefulness at 70 dB and 90 dB for both heart and breath sounds. In the Doppler mode, mean ratings at all anatomic positions were of at least "fair" quality and clinical usefulness at 70 dB, 90 dB, and 110 dB for both heart and breath sounds. Refer to table 2 for specific mean ratings and standard errors of the mean. Standard errors of the mean ranged from 0.00 to 0.33.

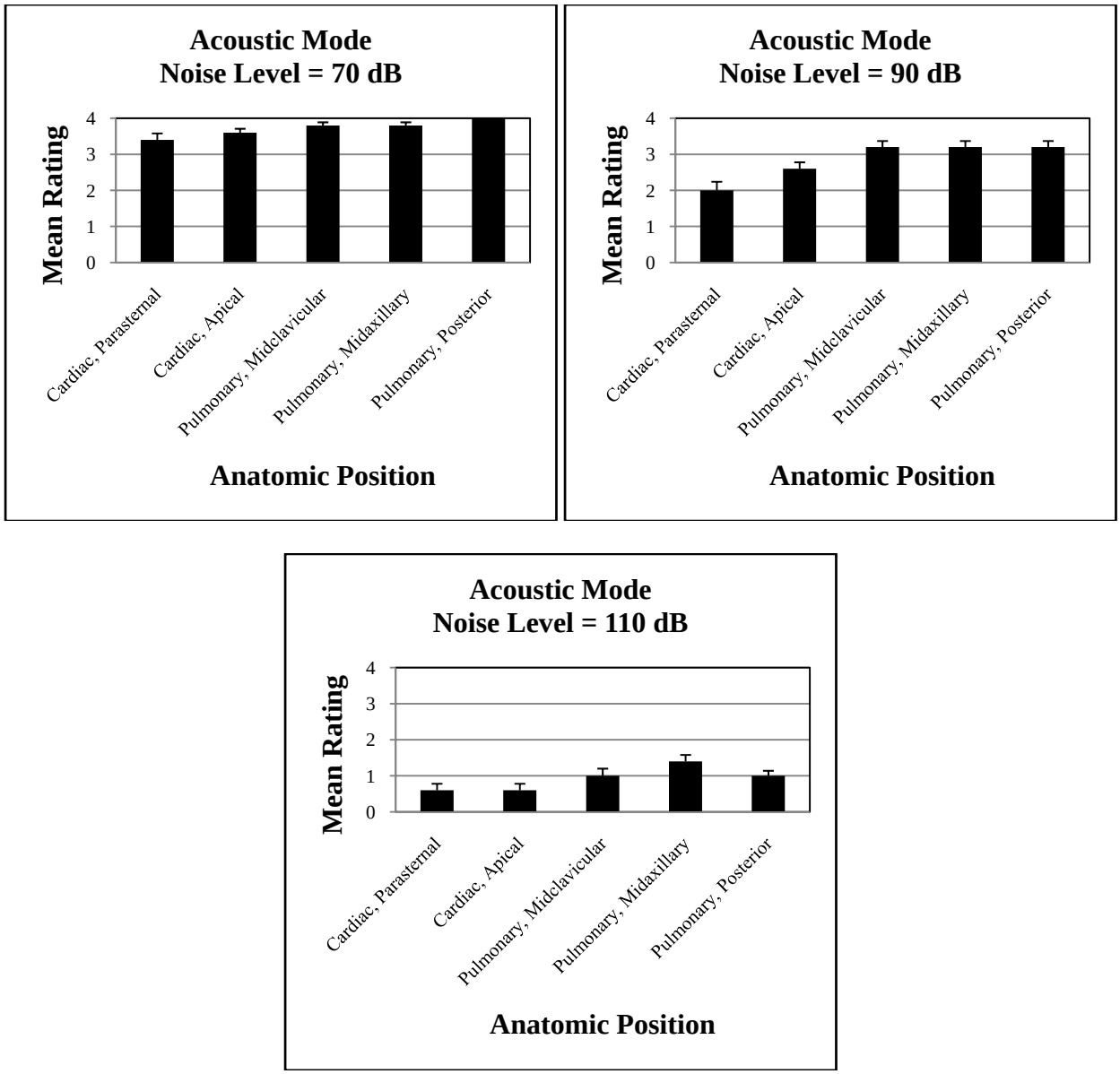

Figure 15. Mean ratings for each position at each noise level in the acoustic mode. Error bars represent standard error of the mean. Ratings correspond to excellent (4), good (3), fair (2), poor (1), or simply noise (0).

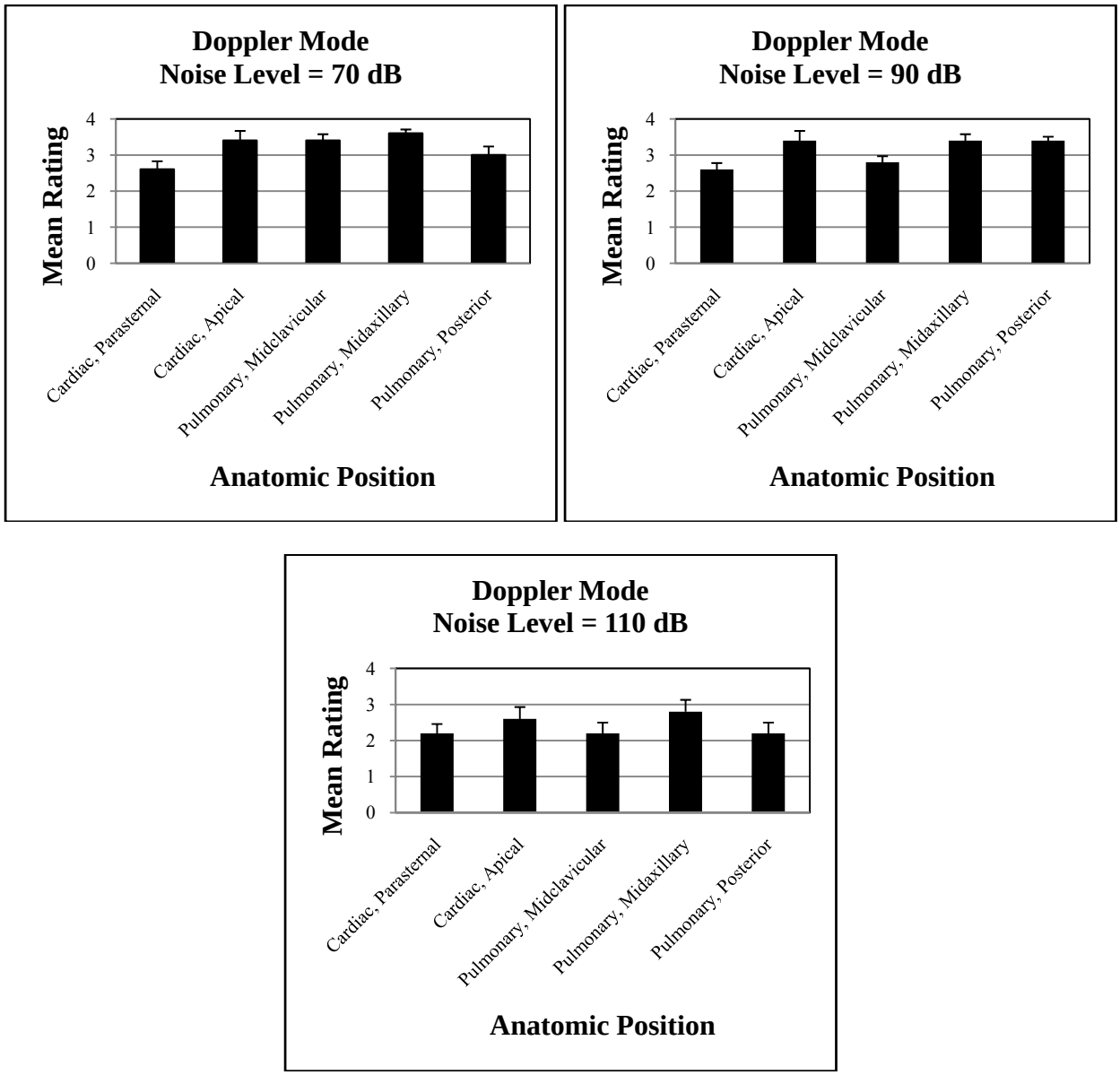

Figure 16. Mean ratings for each position at each noise level in the Doppler mode. Error bars represent standard error of the mean. Ratings correspond to excellent (4), good (3), fair (2), poor (1), or simply noise (0).

Table 2.

Mean ratings and standard errors of the mean for each mode, noise level, and at each anatomic position. Ratings correspond to excellent (4), good (3), fair (2), poor (1), or simply noise (0).

Acoustic Mode

	Anatomic Position	Mean Rating	SE
70 dB	Cardiac, Parasternal	3.4	0.18
	Cardiac, Apical	3.6	0.11
	Pulmonary, Midclavicular	3.8	0.09
	Pulmonary, Midaxillary	3.8	0.09
	Pulmonary, Posterior	4.0	0.00
90 dB	Cardiac, Parasternal	2.0	0.24
	Cardiac, Apical	2.6	0.18
	Pulmonary, Midclavicular	3.2	0.17
	Pulmonary, Midaxillary	3.2	0.17
	Pulmonary, Posterior	3.2	0.17
110 dB	Cardiac, Parasternal	0.6	0.18
	Cardiac, Apical	0.6	0.18
	Pulmonary, Midclavicular	1.0	0.20
	Pulmonary, Midaxillary	1.4	0.18
	Pulmonary, Posterior	1.0	0.14

Doppler Mode

	Anatomic Position	Mean Rating	SE
70 dB	Cardiac, Parasternal	2.6	0.23
	Cardiac, Apical	3.4	0.27
	Pulmonary, Midclavicular	3.4	0.18
	Pulmonary, Midaxillary	3.6	0.11
	Pulmonary, Posterior	3.0	0.24
90 dB	Cardiac, Parasternal	2.6	0.18
	Cardiac, Apical	3.4	0.27
	Pulmonary, Midclavicular	2.8	0.17
	Pulmonary, Midaxillary	3.4	0.18
	Pulmonary, Posterior	3.4	0.11
110 dB	Cardiac, Parasternal	2.2	0.26
	Cardiac, Apical	2.6	0.33
	Pulmonary, Midclavicular	2.2	0.30
	Pulmonary, Midaxillary	2.8	0.33
	Pulmonary, Posterior	2.2	0.30

Discussion

Digital recordings

Digital recordings for the NIS acoustic mode at 70 dB visually demonstrate discernable peaks of desired signal plus noise among a background of ambient noise for both heart and breath sounds. These discernable peaks are lost among ambient noise at the 110 dB extreme. The Doppler mode preserves these visual peaks, even at the 110 dB extreme for both heart and breath sounds (figures 9 and 11). The NIS is designed to be used without such a visual output, however. What remains of paramount importance to the end-user clinician is whether these signal peaks represent clinically useful information.

Signal-to-noise ratios

For heart sounds, the signal-to-noise ratio of the acoustic mode trended in a downward fashion with increasing ambient noise crossing zero at approximately 95 dB. Heartbeat signals were not audibly discernable by the investigator at or above 100 dB in the acoustic mode. The Doppler mode preserved signal-to-noise ratios of approximately 20 dB among the range of ambient noise from 70 to 110 dB.

For breath sounds, the signal-to-noise ratio of the acoustic mode did not trend in a downward fashion as expected. However, breath sound signals were not audibly discernable by the investigator at or above 105 dB in the acoustic mode. Again, the Doppler mode preserved signal-to-noise ratios of approximately 20 dB among the range of ambient noise from 70 to 110 dB.

It should be noted that the signal (both acoustic and visual) for breath sounds was observed to be highly dependent on inspiratory/expiratory effort on behalf of the subject (physiologic signal source). Deeper breaths with rapid flow rates generated louder signals (though this is no different than auscultation with a traditional stethoscope). Although the subject was instructed to maintain consistency as much as possible throughout the testing, the lack of a downward trend observed in signal-to-noise ratio for the acoustic mode likely represents an unconscious increase in subject effort (e.g., chest wall excursion, tidal volume of breath, and flow rate) with increased ambient noise. Without precise spirometry accompanying this data, however, this remains uncertain.

Qualitative assessment

Even with only five evaluators, the analysis suggests relatively good consistency among raters. The discord between Rater 1 and the remaining four should be noted. We have no reason to explain such difference. Increasing sample size would increase statistical power and perhaps improve consistency.

Evaluators supplied subjective data regarding quality and clinical usefulness of the audible signal in the specified noise environment with an overall impression of excellent (4), good (3), fair (2), poor (1), or simply noise (0). In the acoustic mode, mean ratings at all anatomic positions were of at least “fair” quality and clinical usefulness at 70 dB and 90 dB for both heart and breath sounds. In the Doppler mode, mean ratings of all anatomic positions were of at least “fair” quality and clinical usefulness at 70 dB, 90 dB, and 110 dB for both heart and breath sounds. Mean ratings in Doppler mode were highest for the apical position for heart sounds and the midaxillary position for breath sounds. This corresponds with the primary author’s experience as well, and can be explained anatomically whereby intercostal spaces are larger and the ultrasonic carrier wave is less likely to be reflected back off of the ribs.

Evaluator comments regarding experience with the device were solicited (appendix B). These comments acknowledge the distinct difference in audible returns of the Doppler mode from that of a traditional stethoscope. This reinforces the requirement for education and operator training, yet comments generally support that clinicians can learn to recognize and interpret these

sounds with training and practice.

Conclusions

Noise can render traditional clinical auscultation devices useless, and a need exists for a capability to defeat such noise and preserve this vital clinical tool. The NIS has demonstrated the potential to serve this need.

The "noise-immune" dual-function stethoscope represents a viable answer to the need for clinical auscultation in high ambient noise environments. Preliminary testing has validated the preservation of adequate signal-to-noise ratios and of at least "fair" clinical quality to approximately 90 dB in the acoustic mode and 110 dB in the Doppler mode, whereas a conventional acoustic stethoscope is limited to 80-85 dB. Furthermore, the Doppler ultrasonic carrier wave may present unique diagnostic information in quiet conditions that is not readily available by means of a traditional stethoscope.

Recommendations

Testing and evaluation of the NIS prototype devices to date have verified the ability to function (preserve signal-to-noise ratio) in high ambient noise conditions in controlled environments. Future testing should include applications in real-world noise environments including fixed-wing and rotary-wing aircraft, ground evacuation vehicles, crowd conditions, emergency departments and intensive care units, space vehicles, submarines, and others.

Furthermore, NIS testing has only included small numbers of research clinicians and small numbers of 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) under conditions of *human pathophysiology* (e.g., pneumo- and hemothorax, thoracic trauma, pneumonia, arrhythmias, valvulopathy, heart failure, endotracheal tube misplacement).

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Appendix A.

Qualitative Assessment Questionnaire.

CLINICAL EVALUATION OF THE NOISE-IMMUNE STETHOSCOPE (NIS)

HGU-56/P Flight Helmet w/CEPs Acoustic Testing

This evaluation is to be completed following your orientation with the NIS device provided by the AST engineer, and you have had some time to practice in "quiet" conditions. Mark your overall impression (Excellent, Good, Fair, Poor, or simply Noise) of your ability to perceive distinct heart or breath sounds. Record any comments on the quality of the signal at the various ambient noise levels and anatomic locations (comments NOT required). Conduct your auscultation as you would with a traditional stethoscope in a clinical scenario. Spend no more than approximately 20 seconds listening at each location (you will NOT be timed).

70 dB – ACOUSTIC MODE

CARDIAC, LEFT/RIGHT PARASTERNAL
Excellent_____; Good_____; Fair_____; Poor_____; Noise_____
Comments:_____

CARDIAC, APICAL
Excellent_____; Good_____; Fair_____; Poor_____; Noise_____
Comments:_____

PULMONARY, LEFT/RIGHT MID-CLAVICULAR
Excellent_____; Good_____; Fair_____; Poor_____; Noise_____
Comments:_____

PULMONARY, LEFT/RIGHT MID-AXILLARY
Excellent_____; Good_____; Fair_____; Poor_____; Noise_____
Comments:_____

PULMONARY, LEFT/RIGHT POSTERIOR MID-LUNGFIELD
Excellent_____; Good_____; Fair_____; Poor_____; Noise_____
Comments:_____

90 dB – ACOUSTIC MODE

CARDIAC, LEFT/RIGHT PARASTERNAL
Excellent_____; Good_____; Fair_____; Poor_____; Noise_____
Comments:_____

CARDIAC, APICAL
Excellent_____; Good_____; Fair_____; Poor_____; Noise_____
Comments:_____

PULMONARY, LEFT/RIGHT MID-CLAVICULAR
Excellent_____; Good_____; Fair_____; Poor_____; Noise_____
Comments:_____

PULMONARY, LEFT/RIGHT MID-AXILLARY
Excellent_____; Good_____; Fair_____; Poor_____; Noise_____
Comments:_____

PULMONARY, LEFT/RIGHT POSTERIOR MID-LUNGFIELD
Excellent_____; Good_____; Fair_____; Poor_____; Noise_____
Comments:_____

110 dB – ACOUSTIC MODE

CARDIAC, LEFT/RIGHT PARASTERNAL
Excellent_____; Good_____; Fair_____; Poor_____; Noise_____
Comments:_____

CARDIAC, APICAL
Excellent_____; Good_____; Fair_____; Poor_____; Noise_____
Comments:_____

PULMONARY, LEFT/RIGHT MID-CLAVICULAR
Excellent_____; Good_____; Fair_____; Poor_____; Noise_____
Comments:_____

PULMONARY, LEFT/RIGHT MID-AXILLARY
Excellent_____; Good_____; Fair_____; Poor_____; Noise_____
Comments:_____

PULMONARY, LEFT/RIGHT POSTERIOR MID-LUNGFIELD
Excellent_____; Good_____; Fair_____; Poor_____; Noise_____
Comments:_____

70 dB – DOPPLER MODE

CARDIAC, LEFT/RIGHT PARASTERNAL
Excellent_____; Good_____; Fair_____; Poor_____; Noise_____
Comments:_____

CARDIAC, APICAL
Excellent_____; Good_____; Fair_____; Poor_____; Noise_____
Comments:_____

PULMONARY, LEFT/RIGHT MID-CLAVICULAR
Excellent_____; Good_____; Fair_____; Poor_____; Noise_____
Comments:_____

PULMONARY, LEFT/RIGHT MID-AXILLARY
Excellent_____; Good_____; Fair_____; Poor_____; Noise_____
Comments:_____

PULMONARY, LEFT/RIGHT POSTERIOR MID-LUNGFIELD
Excellent_____; Good_____; Fair_____; Poor_____; Noise_____
Comments:_____

90 dB – DOPPLER MODE

CARDIAC, LEFT/RIGHT PARASTERNAL
Excellent_____; Good_____; Fair_____; Poor_____; Noise_____
Comments:_____

CARDIAC, APICAL
Excellent_____; Good_____; Fair_____; Poor_____; Noise_____
Comments:_____

PULMONARY, LEFT/RIGHT MID-CLAVICULAR
Excellent_____; Good_____; Fair_____; Poor_____; Noise_____
Comments:_____

PULMONARY, LEFT/RIGHT MID-AXILLARY
Excellent_____; Good_____; Fair_____; Poor_____; Noise_____
Comments:_____

PULMONARY, LEFT/RIGHT POSTERIOR MID-LUNGFIELD
Excellent_____; Good_____; Fair_____; Poor_____; Noise_____
Comments:_____

110 dB – DOPPLER MODE

CARDIAC, LEFT/RIGHT PARASTERNAL
Excellent_____; Good_____; Fair_____; Poor_____; Noise_____
Comments:_____

CARDIAC, APICAL
Excellent_____; Good_____; Fair_____; Poor_____; Noise_____
Comments:_____

PULMONARY, LEFT/RIGHT MID-CLAVICULAR
Excellent_____; Good_____; Fair_____; Poor_____; Noise_____
Comments:_____

PULMONARY, LEFT/RIGHT MID-AXILLARY
Excellent_____; Good_____; Fair_____; Poor_____; Noise_____
Comments:_____

PULMONARY, LEFT/RIGHT POSTERIOR MID-LUNGFIELD
Excellent_____; Good_____; Fair_____; Poor_____; Noise_____
Comments:_____

Please provide any other comments or suggests on the design of the device (e.g., were the buttons easy to use? Was the requirement for use of US gel acceptable? Do you feel confident in your ability to use the device to auscultate normal physiologic heart/lung sounds? At what sound levels?)

_____
_____
_____
_____

Appendix B.

Qualitative Assessment User Comments.

Ease of use of the device:

- Easy to use.
- Easy to use, not much to it.
- Buttons poorly positioned, not comfortable grip. Small and don't make intuitive sense.
- Requires lot of US gel—likely need to carry several tubes.
- Dark in back of aircraft makes direction finding difficult.
- Acoustic use @ 90 dB or higher is very difficult if at all possible. Doppler mode is great—some sites harder to get than others. Device was very easy to use once sites were established.
- Buttons were easy to use except for the fact that to keep the US transducer in the correct alignment, the buttons are not under my thumb.
- US gel is acceptable—it would be best if you could listen for carotid sounds since during enroute care flights, the neck would be exposed & you would decrease the risk of hypothermia by keep the torso wrapped. For lung sounds, you would of course need to unwrap the patient.
- Ergonomically challenging—need better "feel."
- The acoustic mode was pretty much unusable above 90 dB except for breath sounds.
- US was excellent except for L parasternal sounds, possibly because of techniquie.
- 110 good only for heart sounds.

Recommendations for training:

- Need CD with pathology and hands on training.
- Users would need a lot of training, esp with changing between modes and in high noise environments.
- Hands-on training is important. A DUD will not help until the user is able to use with a subject.
- I felt there was a fairly easy learning curve.
- 1 hour fairly adequate.

Which anatomical sites were best?

- Heart—apical for best sound.
- Cardiac—apical & pulmonary—mid-axillary.
- Breath sounds more difficult to hear in upper lobes.
- Doppler mode best at apical location.
- Mid-axillary and posterior lung fields, esp in high noise environment.

Correlation of Doppler returns with physiologic sounds:

- I feel I would need more experience with the device for that.
- Once I was used to what normal sounds like there was no issue.
- Doppler corresponds best with lung movement and cardiac sounds (in lower dB).
- Heart sounds are not physiologic (3-4 part beat instead of 2).
- Breath sounds mirror bronchial breathing which is pathological.

Potential applications:

- Would like to see if carotid sounds worked and if it could diagnose an avascular limb.
- Emergency Department; in flight (fixed and RW); other high noise (industrial medical) applications & even non medical apps, i.e. industrial/automotive where small U/S device would help with assessment of equipment.

Recommendations and improvements:

- Needs a lanyard and a holster for combat use.
- Software apps that isolate & enhance cardiac & pulmonary sounds, esp. in Doppler mode.
- Bell is large, pediatric size may be better to allow auscultation of carotid and lung apex.
- Small screen may help to give visual of heart beat.
- Would like visual U/S.

Acronyms

ABS	Acrylonitrile Butadiene Styrene
APA	Aeromedical Physician Assistant
AST	Active Signals Technologies, Inc., Linthicum Heights, MD
BMI	Body Mass Index (kg/m^2)
CEP	Communications Ear Plug
dB	Decibel
CI	Confidence Interval
GIPOS	Graphical Interactive Processing of Speech (software package)
Hz	Hertz (frequency per second)
NIS	Noise Immune Stethoscope
SBIR	Small Business Innovative Research
SPL	Sound Pressure Level
US	Ultrasound
USAARL	US Army Aeromedical Research Laboratory, Ft. Rucker, AL
USASAM	US Army School of Aviation Medicine, Ft. Rucker, AL
V	Volts

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