



Human Factors Feedback: Brain Acoustic Monitor

**by Valerie J. Rice, Gaylord Lindsay, Cory Overby, Angela Jeter,
Gary L. Boykin, Petra E. Alfred, Carita DeVilbiss, and Raymond Bateman**

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February 2012

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14. ABSTRACT The purpose of this report is to identify human use issues associated with using the Brain Acoustic Monitor. This report is the second of three reports examining human factors issues associated with technologies investigated for their potential to assist with identifying individuals who may have incurred a traumatic brain injury. The Brain Acoustic Monitor passively senses acoustic signals generated from the blood flow through an individual's brain and a reference point, such as the radial artery. If physiological alterations in blood flow due to damage to the cerebrovascular system occur, the corresponding acoustic changes should differ from those heard at the reference point, such as the radial artery. This assessment focuses on the training, setup, and operation of the equipment, identifying potential areas to consider for both users and developers of the equipment.					
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1. Introduction

1.1 Background

Traumatic brain injury (TBI) is considered a signature wound of the conflicts in Iraq and Afghanistan due to the increased use of explosive weapons, such as improvised explosive devices. However, mild TBI (mTBI) is difficult to diagnose since it is typically a closed head wound. A service member may not recognize the symptoms as being indicative of a TBI, as similar symptoms occur with increased stress, loss of sleep, etc. (e.g., cognitive deficiency, chronic daily headaches, etc.). Service members may also mask symptoms by not seeking care. The motivation to remain with one's unit is strong, even when an individual has been injured, perhaps even more so when the injured service member is uncertain whether the injury is real or a set of symptoms related to stress. Undiagnosed mTBI can endanger not only the individual but also the unit. A Soldier's cognitive deficits may not be evident until a mistake is made that could put both the service member and his or her team in jeopardy. Accurate diagnostic technology for mTBI that can be fielded with the Troops would be of great value to the U.S. Military.

1.2 Objective

The technology that is the subject of this report, i.e., the Brain Acoustic Monitor (BAM), is one of four technologies evaluated under the protocol "The Investigation of Emerging Technologies for Use in Screening for Traumatic Brain Injury." This document contains after-action and lessons-learned reviews and proposes future design considerations for improving the device's functionality based on applied human factor domain principles assessed during subject testing. This report focuses on everyday fundamental operating procedures and usability processes, to include military clinical processes and potential field deployment operations. Research results using the BAM to potentially identify Soldiers with mTBI will be detailed in a subsequent report.

1.3 Overview

Initial testing using the BAM began on 27 January 2009 at Brooke Army Medical Center, Fort Sam Houston, TX, in the TBI clinic in accordance with Protocol HPRO Log Number A-15155, titled "The Investigation of Emerging Technologies for Use in Screening for Traumatic Brain Injury." BAM research commenced using a blinded design involving eight team members, with two researchers unblinded to volunteer's diagnosis. Ninety-six volunteers consented to the research study. Volunteers were screened for signs and symptoms of TBI and PTSD by interviews and questionnaires administered by TBI clinical staff and were placed in one of four categories based on the following diagnostic results: (1) TBI only, (2) PTSD only, (3) both TBI and PTSD, and (4) neither condition. Data collection continued through June 2010. Throughout the research project, during training on the use of the device and testing of volunteers,

researchers kept a log of issues related to human factor domain principles. This report includes the results of that log and is based on the researcher's experiences during the planning and execution of the study. No additional users were observed, as would be expected in a comprehensive human factors usability evaluation.

1.4 Terminology

The following terms will be used throughout this document. It is important that the reader understand the meaning of each term.

1.4.1 BAM System

The "BAM" acronym is used to refer to the Brain Acoustic Monitor system, i.e., software and hardware. This includes the standard computer system that hosts the independent software system.

1.4.2 Subject

The term "subject" is used to refer to the person who is being evaluated/monitored using the BAM. This convention is used because this human factors assessment was conducted in conjunction with the research protocol focused on the technology. In literature prepared by the vendor or others who may have used this system, this person is referred to as the "patient" since it is typically used in a clinical setting. The terms "participant" or "volunteer" may be utilized in this report as well.

1.4.3 Velcro

Velcro* is a brand name for a fabric hook and loop fastener. Although Velcro is a trademarked name, it has become synonymous with all hook and loop fasteners and therefore is a generalized trademark.

1.5 Brain Acoustic Monitor

Described in an original patent application as a "head-mounted brain sensor which passively senses acoustic signals generated from pulsing blood flow through a patient's brain" (Bridger et al., 2005), the BAM is state-of-the-art technology that is purported to detect changes in cerebral arterial blood flow when compared to another artery, such as the radial artery. A description on the Active Signal Technologies (2008) website is as follows:

The underlying theory for the BAM is that there is an acoustically detectable change where TBI occurs. That is, the accompanying physiological alterations in blood flow from damage to the cerebrovascular system result in corresponding acoustic changes that differ from those heard at a reference point, such as the radial artery. In a person without a TBI, the cerebrovascular acoustic wave forms are more similar to those at the reference point than in a person experiencing TBI. The BAM measures the time variant amplitude of pulse waveforms and the

*Velcro is a registered trademark of Velcro Industries B.V.

frequency response of those waveforms. Moreover, the system uses a signal processing algorithm that subtracts the frequency response from the brain after averaging, and sets allowable boundaries of divergence. If the patient is within those boundaries, the patient is considered ‘normal’ (BAM negative) and if outside, is considered suspicious for pathology (BAM positive).

1.6 Test Configuration

For this study, the BAM system was interfaced with a Panasonic Toughbook^{*†} and used LabView 6.1 to create a graphic user interface (GUI) to run within the Windows XP[‡] service pack 2 operating system (OS). The BAM resides inside an aluminum case and was connected to the Panasonic Toughbook laptop via the PCMCIA card port. The laptop is secured to the BAM with hook-and-loop fasteners. The BAM system is shown in figure 1.

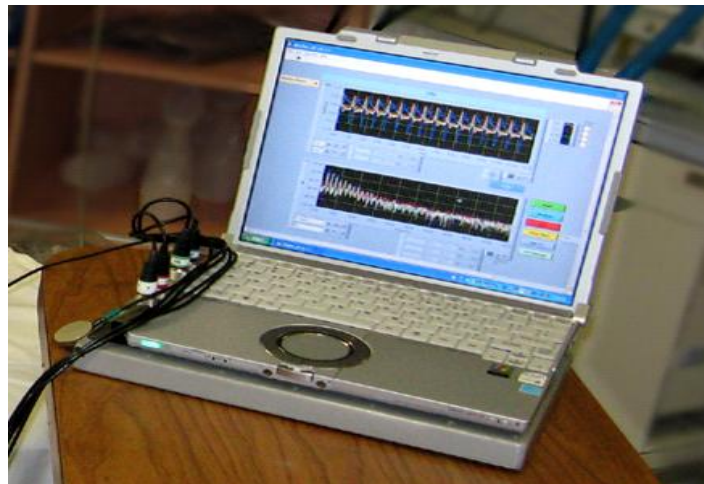


Figure 1. BAM system.

2. Technology Assessment

Lessons learned were recorded during training in the use of the BAM, during preparation for the research, and throughout testing. The results are presented in this section. The BAM system was assessed for portability, ease-of-use, intuitiveness of operation, hardware component performance, and software performance. Comments are also included for the potential future use of this technology in a military field setting. It shall be noted that usability testing with other users who might be expected to employ the technology, such as nurses or technologists, was not conducted.

^{*} See appendix A for technical specifications of the BAM/Panasonic Toughbook system.

[†] Toughbook is registered trademark of Panasonic Corporation.

[‡] Windows is a registered trademark of Microsoft Corporation.

2.1 Setup and Testing

Collecting data with the BAM system requires a relatively quiet, low-light environment in which the subject is able to relax and remain still. A subject's eye blink, speaking, or flinching in reaction to environmental sounds can result in inaccurate readings. Such occurrences required a repeat of the evaluative process, with commensurate changes in the results attained. That is, if a person reacted to a sound by flinching and a less than optimal reading was attained (red or amber), repeating the evaluation a few minutes later when it was quiet typically resulted in a normal reading (green).

The subject should be seated or lying down comfortably with enough room for the data collector to maneuver around the subject to attach the elastic headband, sensors, and finger reference sensor. The BAM system must be in close proximity to the subject so the three lead wires (6-ft length and 3.5-mm width) attached to the sensors can easily reach between the subject and the BAM system. These testing requirements could be challenging in a deployed military setting.

2.2 Portability

The BAM circuit board is adhered to the bottom of the laptop by placement of adhesive Velcro fasteners. A more durable and permanent connection or mounting mechanism, or even an "all-in-one" design where the circuit board is permanently integrated into the laptop, would be highly preferable to improve portability and ruggedness. Such a design would decrease modularity and lessen the risk of component separation, which could damage areas where the hardware interfaces (sensor wire connections and PC card slot). The system design, as configured, worked moderately well for the research setting. Some sliding occurred between the laptop and the circuit board when moving the system, and since the computer could be used separately for other purposes, there was an inclination to do so. There was a demand for a laptop computer. It is expected that the current configuration would also work well in a clinical environment; however, it is not suggested for a field setting that requires frequent moves in adverse working conditions or in conditions where the laptop could be procured for other purposes and not be available for use with the BAM.

2.3 Power Requirement

The power requirements are those of the laptop itself. The Toughbook utilizes a lithium ion battery pack (10.65 V), with an approximate operation time of 6.5 h. The Panasonic A/C adaptor plugs into a standard 120-V wall outlet for recharging of the battery and operation of the laptop itself (Panasonic, 2007).

2.4 Computer Operating System

The Panasonic Toughbook laptop was preloaded with Microsoft Windows XP service pack 2 OS. This OS is widely used on IBM-style personal computers, and the BAM system did not require any special configuration.

2.5 Training Requirements

Training and practice is required for operators to develop a technique that produces consistent readings in the current configuration. In order to correctly utilize the BAM, a user must be trained on the use of the software (e.g., trial session entry and navigation of recorded data), hardware, and interaction of the hardware with the subject (such as sensor placement). Training time for this team consisted of ~4 h of lecture and 16 h of hands-on training and practice. Training was provided over 2 days by experts who had assisted in the development of the BAM and/or the use of the BAM in emergency settings (in an ambulance and an emergency room).

The BAM program utilizes a color-coded, pop-up window that shows “green” when the results indicate no injury, “amber” indicating an uncertain reading (further assessment recommended), and “red” indicating a “probable pathology.” The current training guide can be seen in appendix B. The benchmark for “passing” the training was set by the trainers. Research staff trainees were to obtain three “green” readings in succession on an asymptomatic (no injury) test subject during a single training session. Training “sessions” were generally provided in 2-h blocks.

Training handouts consisted of PowerPoint* slides. During the two days of training, research staff trainees were able to use the BAM and attain proficiency; however, the research team found it necessary to create a guide sheet, which served as an initial aid during practice and early testing (appendix C). Training is best accomplished in the environment in which testing will be done and with the subjects or patients with whom the data collectors will work. That is, after practicing on each other, it was found that additional learning continued and improvements were made after beginning data collection with subjects, thus adding time to the original 24 h mentioned previously for training.

Future use of the system in a deployed capacity should allow for adequate training time and practice in order to utilize the system properly. The training and practice for a typical user would involve familiarization with the software and hardware, procedural practice, and post-session result interpretation. Practice both on other trainees and with patients is suggested. It is recommended that manufacturers develop requisite outcome criteria for demonstrating competence, rather than continuing to use the less well-defined “obtaining three ‘green’ readings in succession during a session of training.” For example, it is unclear whether obtaining three “green” ratings on a single, non-injured person during one session is sufficient or whether a trainee should be able to obtain three “green” readings with more than one subject over several sessions or even with the same subject during subsequent sessions. In addition, it was unclear whether a “session” referred to the 2-day training period or the shorter “sessions” between breaks (~1 h). Using the system for research purposes may require additional training and practice with review and recall of data (opening saved data for value entry into the database), dual data

*PowerPoint is a registered trademark of Microsoft Corporation.

checking, and exporting raw data to other applications such as Microsoft Excel* or SPSS for data analysis.

2.6 Input device

In its current configuration, cursor movement is performed using the laptop's standard touchpad. This could be problematic to some users who are less experienced using a touchpad or prefer not to use a touchpad. To some users, the touchpad "click/double click" sensitivity may be difficult to use. For example, they may start the recording process inadvertently. Wearing protective gloves (nitrile rubber or latex) or working in extreme heat or cold could also impact the ease-of-use of the touchpad. To remedy this problem, a standard mouse should be available as an alternative means of control.

2.7 Sensor Connector

The BAM makes use of passive sensors which connect to the BAM circuit board via a three-pin snap-lock connector (figure 2). The connections for the sensors are color coded, clearly labeled, and snap into place for a secure connection.



Figure 2. Sensor connector for the BAM system.

2.8 Sensor Placement

Sensor placement is critical to obtain a useable reading. Applying the sensors to an individual's forehead can be difficult as hairlines, hair styles, and foreheads vary (figure 3). Unintentionally having hairs caught below the sensors or sweat can also impact the readings. The instructions state that sensors should be placed on the forehead midway between the eyebrows and hairline and aligned with the center of the eye. This requires judgment by the data collector. It is recommended that an adjustable placement device be developed to assist with accurate alignment, especially for new users.

*Excel is a registered trademark of Microsoft Corporation.



Figure 3. Sensor placement on the forehead during use of the BAM.

Placement of the elastic band is critical to hold the sensors in place. The band consists of a single elastic strip with Velcro at each end. The Velcro is attached to form a “headband.” Care must be taken to avoid catching or pulling the hair of participants at the Velcro junction. While a covered single “headband” without a junction (closure) could eliminate this issue, several sizes would be necessary to accommodate various head dimensions. Having such a junction is helpful for use with subjects of various head sizes, as a single band can be used with many subjects. To ensure cleanliness, the bands were washed after use with a single subject. This could create a difficulty in a field setting if storage and washing facilities are not readily available. The elastic band can easily move if the participant moves during the session, requiring realignment of the sensors and adjustment of the band.

Readings appeared to be influenced when the wires were allowed to “hang,” perhaps due to the weight of the wires pulling on the elastic band or the subjects inadvertently touching/moving the wires. This was alleviated by hand the sensor wires from an IV pole in back of the chair, so the wires did not hang freely.

Time is also an important factor with the sensors. An approximately 3-min (manufacturer states 2-min) sensor sitting time (contact with forehead) consistently yielded the best results. Shorter times sometimes produced unacceptable readings. If a “red” reading is obtained with artifacts, the manufacturer recommends adjusting sensor placement; however, if proper placement is made initially, additional “sitting” time may simply be needed to obtain an accurate reading.

2.9 Reference Sensor

When using the finger reference sensor (figure 4) practitioners should evaluate the subject’s fingers for warmth and assess capillary refill. A finger press with capillary refill of <2–3 s indicates good blood flow. Lack of warmth and slower capillary refill are indicators of poor circulation, which may give a weak and unusable reference reading. In the event that a subject entered with cold hands, it was sometimes necessary to “warm them up” by rubbing them and/or

stretching or having subjects clench and release their fingers in a fist. If these techniques did not result in warm or sufficient capillary refill (and an unusable reference reading resulted), then the sensor was placed over the radial artery sensor (placement is described in the next paragraph). Data collectors found the middle finger was best suited for the placement of reference sensor. It is also important to place the finger sensor on a finger that is free from scars or calluses. Placement of the cushioned rectangular sensors should be on the finger pad. We recommend an audible or visual “check sensor” alert to warn the operator of possible irregular sensor placement, loose wiring, or poor skin-to-sensor conductivity.

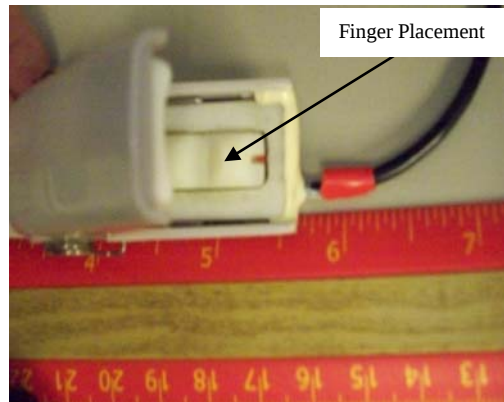


Figure 4. BAM finger reference sensor.

If an acceptable signal is not found using the finger reference sensor, the radial artery can be used. In this case, the sensor is placed above the radial artery, and a small elastic band with Velcro closures is placed around the sensor to hold it in place (figure 5). The subject must hold the wrist still after placement, as movement will introduce artifacts into the reading. In some instances, a weak radial artery signal required the subject to extend his or her wrist to achieve a better connection and reading. Adequate support of the lower arm, wrist, and hand is necessary for the subject to keep the wrist still. This requires a broad, stable arm rest.



Figure 5. Correct placement of the radial artery reference sensor.

2.10 User Interface

The BAM system makes use of a GUI called LabView (version 6.1), developed by National Instruments. The BAM GUI is made to look like any other Windows-based application to facilitate ease-of-use, minimize errors, and reduce training requirements. However, the software is unique and has some features that are not clearly intuitive, such as data retrieval. Even for those data collectors familiar with Microsoft Windows and other operating systems, familiarization with the functionality of the GUI required additional time. Familiarity was established within ~2 h of training time. For obtaining and interpreting the data, the GUI was easy to interpret. Each trial showed the scores except when a “red” or “amber” was obtained.

The differences between the OS and the GUI are notable when attempting to review previously recorded data. For example, the data (amplitude, divergence, and ratio) are not displayed when the result is an “amber” or “red” reading. The only data displayed for an “amber” or “red” reading will be those that fall into the pre-established parameters for acceptable by the manufacturer. Other values must be retrieved manually. However, evidence-based clinical practice may necessitate an easier mechanism for viewing such information. The process of retrieving and viewing data does not use Windows-based conventions, such as opening files by double clicking on a filename. Instead, the user must go to the desktop and open the GUI by clicking the software icon labeled as “V1. Of 15” and utilizing its “Browse” function. The user then must select which data files to review by selecting the subject. The system displays only the last seven trials. From these seven trails, the user may select and view one at a time, as there is no multiple “Windows-style” view option. Creating a more usable, “invisible” interface would be beneficial.

During the course of research, each session was stored separately in its own file. This required the creation of a new file for each visit the subject made during the study (three in all). In the current GUI configuration, to create a new patient file, the data collector must select the “new patient” command from a dropdown menu, enter the information, and close the file. The user must then re-enter the dropdown menu to find the newly created file. This process could be easier if the new patient information for an existing patient could be entered by an automatic selection and loading process.

3. Limitations and Considerations

Additional factors may affect BAM readings. This section addresses factors encountered during this study, as well as some that may occur in a non-research, forward facility.

3.1 Ruggedness

Some extraneous factors may cause inaccurate readings aside from pathology, which may lead to a false reading. Although not documented in a user manual and not officially measured by any objective means (e.g., survey instrument), there were inconsistent readings during the five trials from volunteers who reported experiencing a considerable amount of personal stress or anxiety at the time of the BAM administration. Examples are provided as follows:

- One subject required a “restroom break” during the session. Prior to this break, readings were either red or amber. Following the break, a green was obtained on the first and subsequent readings.
- A subject reported being “stressed” during one of the three sessions (visits). It was difficult to obtain a “green” reading during the session of the self-reported stress; however, in subsequent visits, a “green” reading was easily acquired on this subject.

On several occasions, a subject fell asleep. There were difficulties in obtaining accurate readings when the sleeping participant either made body movements (e.g., twitches) or vocalizations (e.g., sleep talking). In such cases, it was necessary for the operator to wake the person, ask them to refrain from talking or moving, remind them to remain relaxed but awake, and then retake the reading.

These sensitivities may have implications for the BAM as a deployable technology for frontline assessment. Having an individual remain motionless and quiet for several minutes (which the BAM requires for an accurate reading) may not be easily accomplished, and environmental factors (loud noises, bright light, heat/cold) of the battlefield might impact the ability of the system to obtain an accurate reading (Bond, 2010). Thus, “ruggedizing” the BAM appears important for use in moving air and ground vehicles, as well as for locations in which environmental constraints cannot be implemented (quiet and still).

3.2 Obtaining a Final Reading

For each trial, the BAM reading will provide one of the following three color-coded results: a red reading indicates a probable pathology, an amber reading indicates an “undetermined” status, and a green designates a lack of pathology. However, false positives (red or amber) may be obtained when the reading is not the result of pathology but some other variable, such as a problem with the equipment or the subject moving, coughing, or talking. To ensure true pathology readings were obtained, it was necessary to rule out equipment or sensor placement concerns during testing. To circumvent this concern, we created a systems performance checklist. The checklist prompted administrators to stop testing procedures if an initial red reading was obtained, recheck all sensor placements for direct skin contact, and check wiring harness cables for connectivity. If a defect was identified, the administrator would take the necessary corrective action before conducting subsequent testing.

Also, it is unclear how many readings should be taken and which reading should be used for the “final reading.” During training, the guideline used was to stop taking readings when one attained a green signal. For this study, the convention of taking up to three readings to try to obtain a green signal was adopted (i.e., if the first and second reading were yellow or red, then a third attempt should be made). However, a maximum of five readings could be taken, and an algorithm was developed to select the most accurate reading for data analysis. Figure 6 shows a flow chart depicting the procedures for determining the final reading. This process was developed in conjunction with representatives from Active Signal Technologies, in accordance with their guidance. It is suggested that guidelines be similarly developed for use of this device with patients.

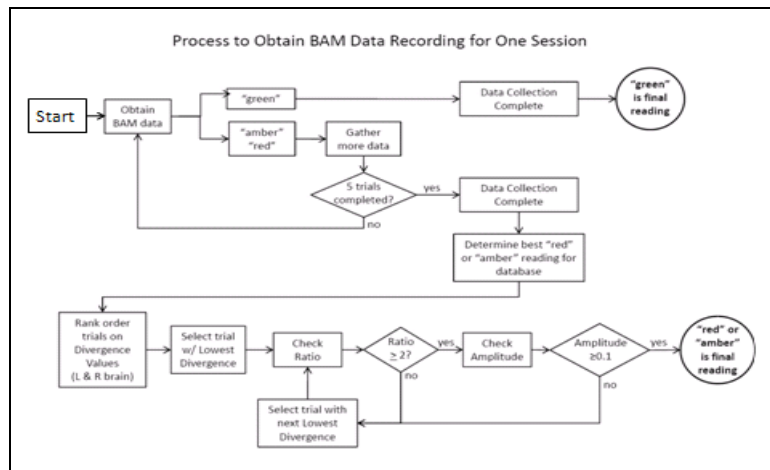


Figure 6. Flow chart depicting algorithm for obtaining final readings for BAM use during research on traumatic brain injury.

3.3 Software Considerations, Data Loss, and Data Corruption

Due to the nature of change in the software industry, the GUI for the BAM will need to be updated regularly to ensure compatibility with changes in operating systems (e.g., drivers). The current system utilizes LabView* 6.1, introduced by National Instruments in 2002 and designed to be compatible with Windows XP (among other systems such as Apple’s OSX†) and National Instruments lists, for use with Windows Vista x32 and x64, LabView 8.2.1 (National Instruments, 2009). These issues will need to be addressed for deployable systems to remain in accord with current military information technology.

The BAM automatically saves the data from each reading to a predetermined area of the hard drive. However, as a precautionary measure to prevent data loss, a daily backup procedure to an external source (external hard drive) was employed and is highly recommended for future applications. Should this device be used in patient care, an alternate method of saving data to a

* LabView is a registered trademark of National Instruments Corporation.

† OSX is a registered trademark of Apple.

patient's medical record might be devised, or a simple recording of the results in a patient's written or electronic medical record might suffice as backup.

A problem with data was found during this study—some of the recorded data changed slightly between the initial reading (during which we hand recorded the information) and subsequent review of the data file. The change was encountered while conducting a double check of the data, prior to final entry into a dataset for statistical analysis. It was noticed that many of the readings had changed from what was recorded in the thousandths and ten-thousandths places. To investigate, scores obtained by the data collector were independently verified by another member of the research team. The reviewing member also saved a screenshot of the data results for further verification. After a period of ~2 weeks, data were re-inspected, and some of the values in the ten-thousandths place had changed from what was recorded in the volunteer record and what was captured on the screenshot (figure 7). Although these small changes may not be significant in determining TBI status, it may confuse data collectors and trainers and should be mentioned in a training guide or manual. Even a small error can erode the confidence of the data collector in the instrument, instrumentation, and findings.

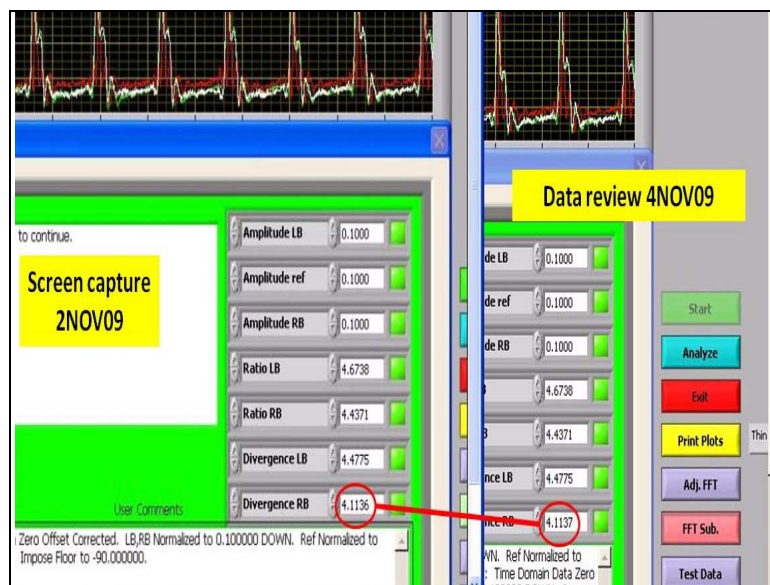


Figure 7. Data change between initial reading and subsequent data review.

3.4 Exporting Data Into Microsoft Office Excel

The data were exported from the BAM system into Microsoft Excel for further analysis. This may not be necessary for a typical user involved in patient care but is detailed here for others who may use this technology during research, clinical investigation, or organizational effectiveness testing. Exporting data is confusing, as there is no means for direct export through LabView. In order to export the BAM data into an Excel spreadsheet, several steps must be

followed.* First, the user must open Excel and within Excel select “open.” The selection of the file (the BAM filename.stp file) must be made after adjusting the browser to search “all files” by file type. Once the filename.stp file is selected, the import wizard will ask if the document will be delimited or fixed width. The user selects delimited for import into the spreadsheet. The user should select both tab and space delimiters to provide the best division for the data in Excel. There is no need to adjust the columns, and the default of “general” is adequate.

If imported into Excel in this manner, the relevant BAM data should appear in rows 24–31, including the overall result as well as the amplitude, ratio, and divergence scores. Imported below these results are the exact wave measurements over time from 0 to 10 s; these are easily plotted into a graph within Excel and could be utilized for a more in-depth analysis. This process was slow, as it had to be done for each individual and each session. Any additional data, such as subject number of demographics, were combined with the BAM data for later analysis. It is recommended that an automatic extraction system be developed to move stored data into a database more amenable to research, data analysis, and for potential inclusion into a patient’s file (such as graphics).

4. Conclusions

The BAM system is described by the manufacturer as a noninvasive instrument for detecting and monitoring vertebral blood flow disruptions. It should therefore be useful as a tool to assist in identifying an individual who may have brain trauma in closed head injuries (such as concussion/mTBI) sustained “from blast, vehicular impact, etc.” (Active Signal Technologies, 2008). The BAM was included as one of four technologies that were investigated for their effectiveness in identifying whether research volunteers had a previously identified head injury (HPRO Log Number A-15155, “The Investigation of Emerging Technologies for Use in Screening for Traumatic Brain Injury”). The focus of this technical note is to provide human factors information on the BAM generated during the research effort. This report includes descriptive information on the observed human factors issues noted during training, data collection, data entry, and data manipulation. Other results from the research study will be contained in later reports.

Being noninvasive and purporting ease of use, as well as the claimed ability to discern mild traumatic brain injury (mTBI), makes the BAM a possible instrument for deployment in theater (Kennedy, 2008) should research results support the claim. While the current system may be usable in a clinical setting, its effectiveness, suitability and survivability in an operational

* Microsoft Excel is used in this example. Other users may not be utilizing this software, and therefore their procedure may differ.

environment remain unknown until an operational version and subsequent operational test and evaluation are performed. The system, as currently configured, may benefit from some changes to include updating of software (an ongoing process), an assessment of the GUI functionality, refinement of the system to work with alert and fatigued Soldiers under elevated stress (which would be encountered in theater), and making the system more rugged (to endure environmental exposure to extreme heat, sand, use in multiple first-line situations, and rough use). The fact that subjects have to remain very still may make it difficult to use in a busy operational environment (especially if gunfire or other loud sounds might startle the patient).

Additional research should include the investigation of the impact of high personal stress on accuracy of readings, as stress appeared to impact readings during this study. Forward-deployed military members are under considerable stress (Hoge et al., 2006).

Future research should also focus on both new injuries and older injuries and comparing BAM results with other, known indicators of mTBI. Additional recommendations include standardizing training and certification of user competency.

5. References

- Active Signal Technologies. Brain Acoustic Monitor (BAM). <http://www.activesignaltech.com/BAM1.html> (accessed 2008).
- Bond, C. *68W Advanced Field Craft: Combat Medic Skills*; Jones and Bartlett: Sudbury, MA, 2010.
- Bridger, K.; Cooke, A.; Kuhn, P.; Lutian, J.; Passaro, E.; Sewell, J.; et al. Brain Assessment Monitor. U.S. Patent No. 6,887,199, 2005.
- Hoge, C.; Auchterlonie, J.; Milliken, C. Mental Health Problems, Use of Mental Health Services, and Attrition From Military Service After Returning From Deployment to Iraq or Afghanistan. *J. of the American Medical Association* **2006**, 295 (9), 1023–1032.
- Kennedy, K. Testing Breakthrough for Mild TBI. http://www.armytimes.com/news/2008/02/military_220208_braintrauma_w/ (accessed 2008).
- National Instruments. National Instruments Product Compatibility for Microsoft Windows Vista. <http://zone.ni.com/devzone/cda/tut/p/id/6893> (accessed 2009).
- Panasonic. Toughbook W5. ftp://ftp.panasonic.com/pub/Panasonic/toughbook/specsheets/TB-W5_ss.pdf (accessed 2007).

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Appendix A. Technical Specifications

This appendix appears in its original form, without editorial change.

Brain Acoustic Monitor/Panasonic Toughbook CF-W5 System

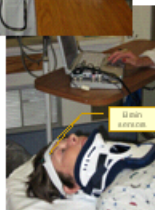
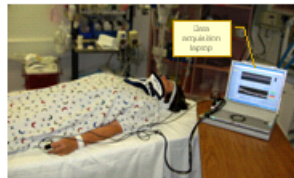
Name:	Brain Acoustic Monitor
Manufacturer:	Active Signal Technologies 611 N. Hammonds Ferry Rd #Q Linthicum Hts., MD 21090-9350
Website:	www.activesignaltech.com
Operating System:	Windows XP SP2
RAM:	512 MB
HDD:	60 GB Ultra ATA/100, 5400 rpm, NTFS magnetic hard disk
Monitor:	12.1-in LCD screen with 1024 × 768 max resolution
Interface:	LabView 6.1 GUI
Measurements:	Laptop: 10.5 × 8.75 × 9.5 (open) or 1.75 (closed); System: 12 × 8 × 10.5 in (open laptop)
Weight:	2.9 lb
Laptop Power Supply:	Panasonic A/C Adaptor (Matushita Electric Industrial Co Ltd.) 100–240 V
LabView 6.1:	Application size: 3,169 KB on HDD; 13,605 KB for GUI interface; Entire application suite: 6.84 MB on HDD

Appendix B. Brain Acoustic Monitor Training Guide

This appendix appears in its original form, without editorial change.

Brain Acoustic Monitoring
Active Signal Technologies
San Antonio Military Medical Center

PASSIVE BRAIN ACOUSTICS—LISTENING TO THE BRAIN



Very sensitive sensors mounted on forehead 'listen' to brain signals

Other sensor listens at a reference point, e.g. radial artery

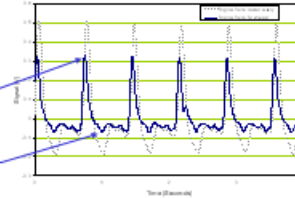
Normal response will show the reference and brain signals overlaying

Damaged or diseased brain will be indicated by a 'noisier' response and the two signals differing

WHAT THE SIGNAL LOOKS LIKE: NORMAL

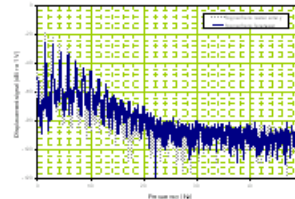
- The time scale signals of both brain and reference appear as a pulse waveform (blue = brain, gray = reference) with:

1. Amplitude of $\sim 0.1V$
2. With 'ratio' of lower to higher peak referenced to '0' of > 2



- The frequency scale plot appears as a descending series of 'lines' to ~ 20 Hz with:

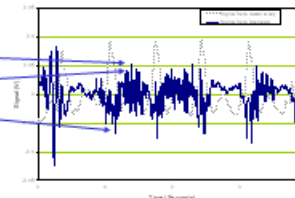
1. Monotonically descending harmonics
2. Overlapping traces



WHAT TBI PATIENT'S SIGNALS LOOKS LIKE:

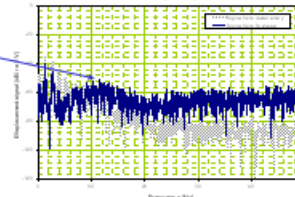
- Time Scale Signal resembles less a normal pulse waveform

1. Amplitude $< 0.1V$
2. Ratio of lower to higher peak referenced to '0' < 2



- Frequency Scale Plot appears erratic

1. Brain response rises above reference, i.e. is noisier
2. Plots do not overlap



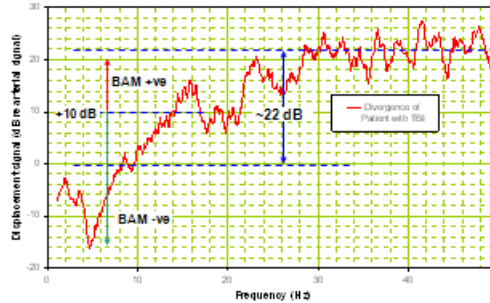
EASIER VIEW-- DIVERGENCE

The program averages and subtracts the reference from the brain signal to give the "relative frequency response"

When the two signals diverge significantly, as with the TBI patient, the relative frequency response reveals the divergence of the brain signal as a rise above the baseline (0 dB)

Divergence of >10 dB (~22 dB shown in plot) is indicative of TBI

Divergence of the brain signal from the artery signal is caused by the noise associated with flow disturbance



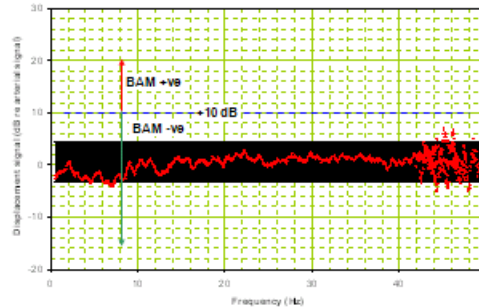
NORMAL DIVERGENCE

When there is no brain injury, or there is little noise, the relative frequency response (brain-artery) should be close to 0 dB

Typically, the divergence is below 10 dB as shown below

Average of 27 readings from normals

The black bar represents ± 2 SD from mean



INSTRUCTIONS: PATIENT PREPARATION AND SENSOR PLACEMENT

- The first step is to place Bands on head so that there is about a 3" stretch of the band from its relaxed position
- Then place sensors on the forehead early so that they can settle on the patient
 - Place sensors midway between eyebrows and hairline
 - Avoid placing a sensor in the centre of the forehead above the nose, since the sinus cavity will interfere with the signal
 - Avoid cocking the sensors -- e.g., by aligning the velcro section of the band above them
- **BE SURE THAT THE SENSOR WIRES ARE LOOSE SO AS NOT TO PULL THE SENSOR. WHEN POSSIBLE, EXTEND WIRES FROM THE TOP OF THE BAND AND OVER THE BACK OF THE HEAD**
- If using the finger sensor, place it over index finger.
- If using radial artery, palpate artery; place band on wrist before placing sensor
 - Place the sensor under the band and over the radial artery with flat side facing up
 - Be sure that the wrist does not turn after sensor placement
 - If signal is weak as determined from the instructions in the next slide, extend hand back so that wrist arches up.

MONITORING INSTRUCTIONS

- Turn on computer and select program icon
- From drop down menu, select "Add New Patient"
- Enter patient id number and monitoring code (Refer to label on top of machine)
- From the drop down menu, select the newly added patient id number
 - ***BE SURE THAT THE SENSOR WIRES ARE LOOSE SO AS NOT TO PULL THE SENSOR***
 - ASK THE PATIENT TO BE STILL AND SILENT WHILE THE BAM IS ACQUIRING DATA
- Start the "NEWBAM" program -- the program will automatically run for 10 seconds
- After 10 seconds a screen will appear giving you 2 options, either "Analyze data" or "Reject data" -- the patient may now speak
 - Choosing "Reject data" will not save the reading
 - Only choose this button if you are absolutely certain that the signal is not acceptable (i.e. patient coughed, moved, etc.)
 - Artefacts from patient motion will show up as "spikes" in the time-domain display

MONITORING INSTRUCTIONS CONTINUED

- . Choose "Analyze data" button
 - . This will automatically save the data and a new colored screen of green or yellow will appear
 - . The Comment box is located on this screen
- . If the screen is GREEN, then the reading is good -- click the "Cancel" button and Exit the program.
- . If the screen is RED (a problem with both sides) or YELLOW (a problem with one side) make adjustments to the sensors
 - . Then click "Repeat Test"
 - . Repeat this step a couple more times if needed
 - . Note -- "Repeat Test" will automatically start the reading over for another 10 seconds
 - . After 3 attempts discontinue the process if readings do not improve
- . Exit program

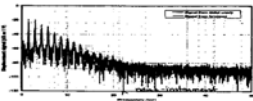
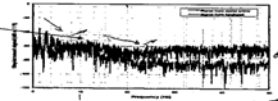
WRAP UP

- . Remove sensors
- . Remove and discard bands
- . Clean sensors before restoring to storage pouch
- . Take system to office and plug in
- . If any issues with equipment are noted, call Active Signal at 410 636 9350 and ask for Dennis. If issues with monitoring, etc. contact either Carmen or John.

Appendix C. Reference Sheet

This appendix appears in its original form, without editorial change.

Brain Acoustic Monitoring Reference Sheet

Characteristic	Normal Scan	TBI Scan
Amplitude	~0.1 (approximately)	<0.1 (less than)
Ratio of Lower to Higher Peak	>2 (greater than)	<2 (less than)
Divergence	<10dB (less than)	>10dB to 22dB (greater than)
Frequency Scale Plot	Monotonically descending from 0 to 10 Hz with overlapping traces 	Brain Response rises above reference and is noisier. Traces are not overlapping. 

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