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TITLE: Enhancing Exposure Therapy for PTSD: Virtual Reality and Imaginal Exposure with a Cognitive Enhancer

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14. ABSTRACT During this research period, three enrollment sites, Weill Cornell Medical College, the Southern California Institute for Research and Education (SCIRE) at the VA Long Beach Healthcare System ("Long Beach VA"), and the National Intrepid Centers for Excellence (NICoE) in Bethesda, Maryland have continued enrolling, assessing, and treating participants in accordance with the protocol. Extensive recruitment efforts are being undertaken at all sites, and site specific and study- wide recruitment strategies have been developed. As of this writing, across the three enrolling sites, 600 individuals have completed the telephone screen, 219 have completed the baseline assessment, 107 have completed treatment, 95 have completed the 3-month follow-up assessment, 12 people are currently in treatment, and 42 have dropped out of the study.								
15. SUBJECT TERMS CRADA approval; Institutional Review Board and HRPO approval; online study database; recruiting participants; assessing and treating participants.								
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Annual Report

Enhancing Exposure Therapy for PTSD: Virtual Reality and Imaginal Exposure With a Cognitive Enhancer

1. INTRODUCTION: Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

We are conducting a multisite randomized clinical trial of an exposure therapy intervention for combat-related posttraumatic stress disorder (PTSD) delivered in two different formats virtual reality exposure therapy compared to prolonged imaginal exposure therapy – combined with D-Cycloserine (DCS), a cognitive enhancer that has been found to facilitate the extinction of fear in exposure therapy. We also aim to determine whether a common human genetic single nucleotide polymorphism (SNP) in a growth factor, brain derived neurotrophic factor, BDNF (Val66Met), predicts treatment response to PTSD. This 2 x 2 design will allow several important comparisons to be made: a direct comparison of the efficacy of virtual reality versus imaginal exposure therapy, which has never been conducted for the treatment of PTSD; a direct test of DCS as a facilitator of exposure therapy allowing a brief effective treatment to be delivered even more efficiently; and a direct test of whether the effects of DCS differ across the modes of exposure therapy. Additionally, findings may lead to the development of the first human genetic test that could guide treatment, ultimately allowing for more tailored treatment plans in the future. This study will include 300 subjects diagnosed with PTSD related to Operation Iraqi Freedom and/or Operation Enduring Freedom participating at Weill Cornell Medical College in New York City, the National Intrepid Center of Excellence (NICoE) in Bethesda, MD for Emory University, and the Southern California Institute for Research and Education (SCIRE) at the VA Long Beach Healthcare System ("Long Beach VA") for the University of Southern California.

2. BODY: This section of the report shall describe the research accomplishments associated with each task outlined in the approved Statement of Work. Data presentation shall be comprehensive in providing a complete record of the research findings for the period of the report. Provide data explaining the relationship of the most recent findings with that of previously reported findings. Appended publications and/or presentations may be substituted for detailed descriptions of methodology but must be referenced in the body of the report. If applicable, for each task outlined in the Statement of Work, reference appended publications and/or presentations for details of result findings and tables and/or figures. The report shall include negative as well as positive findings. Include problems in accomplishing any of the tasks. Statistical tests of significance shall be applied to all data whenever possible. Figures and graphs referenced in the text may be embedded in the text or appended. Figures and graphs can also be referenced in the text and appended to a publication. Recommended changes or future work to better address the research topic may also be included, although changes to the original Statement of Work must be approved by the Army Grants Officer's Representative. This approval must be obtained prior to initiating any change to the original Statement of Work.

Progress Toward Meeting the Goals Outlined in the Statement of Work

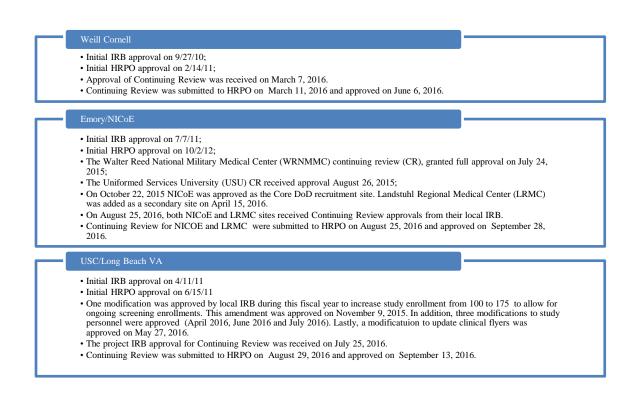
Study Set-up and Maintenance:

1) IRB Submissions and Approvals

Full IRB approval for Weill Cornell, Emory, and the Long Beach VA was attained in Year 1. USC agreed to be subsumed under the Long Beach VA's IRB. Additionally, the study was registered at the ClinicalTrials.gov website in Year 1. Emory's enrollment site, the National Intrepid Center of Excellence (NICoE), was granted initial site IRB approval in July 2011. However, full IRB approval at NICoE was pending the adoption of the Cooperative Research and Development Agreement (CRADA). The CRADA was approved on 7/26/12. NICoE's Continuing Review received approval on 8/23/12 through the Department of Research Programs (DRP) at Walter Reed National Military Medical Center (WRNMMC). Final IRB approval for the sub-contract to Emory/NICoE was then received. The CRADA was finalized by DRP on 9/12/12. In addition, the data sharing agreement between NICoE/WRNMMC, Cornell, Emory, and USC was approved by the Navy Bureau of Medicine and Surgery (BUMED) on 9/11/12. The DoD Human Research Protections Office (HRPO) approved NICoE's site IRB protocol on 10/2/12. The CRADA was updated to reflect the no cost extension year on 12/22/16.

Figure 1 provides an overview of annual IRB approvals for each site.

Figure 1. Summary of IRB approvals by site



We have submitted reports to Weill Cornell's Data and Safety Monitoring Board (DSMB) for periodic review on the following dates: 8/23/2011, 11/19/2011, 5/18/2012, 4/19/2013, 5/5/2014, 4/22/2015, and 5/20/2016.

The protocol was also submitted to each site's respective local IRBs for continuing reviews (Weill Cornell: submitted on 2/24/16 and approved 3/7/16; Emory/NICoE: submitted 6/16/16 and approved on 8/25/16 and LRMC submitted on 8/1/16 and approved on 8/25/16; USC/Long Beach VA submitted on 6/21/16 and approved on 7/25/16). IRB-approved documents were sent to HRPO on 3/11/16 (WCMC), 8/25/16 (NICoE/LRMC) and on 08/29/16 (LBVA) and approved on 6/6/16, 9/28/16 and 9/13/16.

2) DoD Human Research and Protections Office (HRPO):

After NICoE completed the process of obtaining Cooperative Research and Development Agreement (CRADA) approval from the Walter Reed National Military Center (WRNMMC), HRPO approved NICoE's site IRB protocol on 10/2/12. This allowed NICoE to begin enrolling participants at their site in year 3 of the study.

3) Contracting Issues – Second Request to Extend Period of Performance with Funds

The original period of performance for this project ended on September 26, 2014. WCMC previously requested an extension of time, with funds, for a fifth year of data collection, which was approved and awarded thereby extending the project through September 26, 2015. Two extensions of time without funds have been granted; the first extended the contract period through September 26, 2016; the second has extended the contract through September 26, 2017. Assessment and treatment will continue through the third quarter of 2017. All subcontracts have been renewed between the prime site, Weill Cornell and Emory, USC, and SCIRE. The contract between Emory and Henry Jackson has also been renewed; and Weill Cornell contracted with the Geneva Foundation to hire a research coordinator for LRMC.

4) Coordinating Between DoD, Weill Cornell, and All Study Sites

Weekly conference calls are in effect to facilitate coordination between sites and will continue for the duration of the study. The Principal Investigators at each site hold a weekly business call to discuss logistical issues, and other key personnel join the call as issues arise that are relevant to their study role. Separate supervision calls between the study therapists and between the study assessors are ongoing. Project coordinators at all sites hold a weekly conference call to discuss any site issues and recruitment efforts. Quarterly conference calls with all psychophysiological assessors began in October 2012 to ensure protocol adherence. A bi-weekly conference call occurs for all assessors with the goal of maintaining high diagnostic inter-rater reliability across sites. Meeting agendas, when applicable, are available upon request. All study personnel are encouraged to contact each other between meetings should any issue arise that needs to be addressed immediately.

On May 26th Drs. Difede and Rothbaum conducted a site visit with NICoE study personnel. On July 19th Dr. Difede initiated a site visit with all LBVA and USC study personnel. Both visits focused on recruitment strategies and goals for the coming year.

5) Hiring Study Personnel

Study personnel were assigned or hired at each site in Year 1, and new personnel are added as needed.

Nicolas Sirianni was hired in July as a Research Coordinator at LBVA. He assists in recruitment efforts and IRB-related activities. He replaced Stephanie Alley, who departed the study team in July.

Dr. Michael Valdovinos was hired on August 1st as study therapist at WCMC. Cheryl Napier was hired as the study coordinator for LRMC in late August.

6) Training Study Personnel in Study Methods

Paula Domenici, PhD, a new study therapist at NICoE site has been trained in the treatment (PE and VR) component of the research study methodology.

Michael Valdovinos, PsyD, ABPP, a new study therapist at WCMC has been trained the treatment (PE and VR) component of the research study methodology.

During Dr. JoAnn Difede's visits to NICoE (05/26/16) and LBVA (07/19/16) all team members received role-specific training. Conference calls for study coordinators, therapist, and assessors occur on an ongoing basis (weekly and bi-weekly, respectively) for training purposes.

Study personnel at LRMC were identified and trained in all study procedures following WRMC IRB and HRPO approval of the secondary site to NiCoE. Multiple training sessions were held with core team at Weill Cornell Medicine (WCM), via videoconferencing, to train personnel to the standard of all active enrollment sites according to study role (e.g., therapists trained and supervised by Drs. Difede and Rothbaum; assessor by Drs. Olden, Difede, and Rothbaum). The study coordinator, Cheryl Napier, was hired in late August, and subsequently trained by Dr. Difede and the core team at WCM.

7) Maintaining Study Equipment and Supplies at All Sites

The virtual reality equipment and equipment for the startle and fear conditioning paradigms are installed at each of the enrollment sites. Additional study medication and supplies are ordered as needed and shipped to the appropriate personnel. The virtual reality "Bravemind" system has been updated at all treatment sites as technical improvements become available.

The randomization table and procedures remain in place, and the randomization list has been provided to the necessary personnel at each site.

8) Preparing Study Assessment, Outcome Measures, and Participant Folders

All data are being collected in a secure HIPAA-compliant, internet-based data management program called REDCap (Research Electronic Data Capture). This database is available for use through the Weill Cornell Medical College Clinical and Translational Science Center (CTSC). The internet connections at each site have been configured to ensure that the data is transmitted in real time as it is entered by each clinician and study participant. All assessment and outcome measures are being submitted using the REDCap software.

REDCap is actively being used for data collection without significant incident. However, therapists and assessors have paper copies of self-report and clinical measures so that they are able to conduct their sessions should an error prevent the use of REDCap. When internet connectivity fails, the clinicians collect the data using paper copies, and the data is then entered into REDCap by hand. However, this has rarely occurred.

9) Setting up study database

The study database is linked to the REDCap data management system. The study coding system/ID scheme has been implemented at all enrollment sites. All study sites are completing tracking information (e.g., participant tracking spreadsheet, recruitment activity log, etc.) using a uniform spreadsheet in order to standardize data collection. These forms are uploaded into the REDCap database on a weekly basis for review.

10) Recruitment Efforts:

Extensive recruitment is underway at all sites (see Figure 2 for a summary). Key personnel have reached out to local and national contacts within civilian and military settings to maximize referrals from our professional networks. Mass mailings have been sent out to relevant community organizations (e.g., institutions of higher learning, public libraries, veterans groups). We have scheduled and offered seminars to relevant military-related organizations (e.g., West Point, Fort Hamilton, Bronx and Manhattan VAMCs and NYC Serves). Study investigators have been featured on major media outlets such as the New York Daily News, Lohud, RTÉ (Raidió Teilifís Élreann - Ireland's national public-service media), NPR's "Press Play", Engadget and Popular Science Magazine.

Information about the study is available on each site's website and on Weill Cornell's, SCIRE's, and Emory's Facebook pages. IRB-approved recruitment materials are in place at each site, including a "dear colleague" letter explaining the study, multiple flyers, and online advertisement text (i.e., for Craigslist ads). We have also incorporated new study giveaways at each site, including stress balls, coffee sleeves, pens, hand sanitizer, chapstick, stylus pens, all of which include study contact information, and PTSD screening cards. A template for tracking all recruitment activities is in use at each site, and recruitment efforts are monitored and discussed with the PI's and study coordinators weekly. Recruitment is expected to begin October 1, 2016 at LRMC so will be reported on in the next reporting period.

Type of Recruitment Effort	Examples
Major Public Promotions	Featured in the New York Daily News, Lohud, , NPR's "Press Play", Engadget and Popular Science Magazine, KCRW Radio show's "Press Play, Mental Health Channel TV episode on Virtual Reality Therapy, (CBC) radio show "The Current," Participant Media's kickoff for the documentary titled "That Which I Love Destroys Me,"
Intra-Institutional Outreach	For all sites, institution-wide broadcast e-mails with program information, meeting with Department Chairs and academic collaborators, institutional grand rounds, education and training new interns; WCMC opened a new enrollment site at their campus in Westchester County, NY, which is approximately 34 miles north of NYC and thus more accessible to potential participants who do not reside in NYC metro area

Figure 2. Examples of recruitment activity by type of outreach

Outreach to Military-related Organizations	West Point, Fort Hamilton, NYC Serves, VA Long Beach Caregiver Resource Fair, Serving Together, Montgomery County Health and Human Services, Wounded Heroes, Elizabeth Dole Foundation, Operation Homefront's Heart of Valor, National Alliance for Caregiving, US Vets Initiative
Attendance at Military-related Events	Veterans Day breakfast honoring veterans, sponsored by the New York City Mayor's Office, Team RWB (Red White and Blue) surfing events in collaboration with West Los Angeles VA
Outreach to Military Personnel	Contact with Director of Psychological Health at the Army's 99th Regional Support Command in Fort Dix, New Jersey and Fort Hamilton leadership; Warriors' Care Policy office at the Pentagon,
Online Recruitment Activities	Updating Facebook pages, Long Beach VA's Twitter feed, posting study materials on program websites, regular postings on Craigslist, becoming listed on military and mental health-related resource pages
Outreach to Veterans' Affairs	Met with the NYC Mayor's Office of Veterans Affairs Commissioner, presentation to VA peer support counselors, Women's Mental Health clinics, Long Beach VA Outpatient staff and Vet Centers, Long Beach VA Research week
Outreach to Community & Government Contacts	Includes Bravemind demonstrations at the USC Global Conversation event, NYC's Mayor's Office of Veteran Affairs, CUNY school system, NYC Metrovets, LA County Department of Mental Health's Veteran Services, veteran liaisons and student groups at undergraduate institutions, personnel at the Fire and Police Departments, Annual 3 rd Avenue Community Street Fair, NATW's National Night Out, attendance at VA Research Week events, Veterans in Film & Television, Contra Costa Veterans Voice, IAVA, Saddleback College; Santa Monica College; Los Angeles City College; Irvine Valley College; Long Beach City College; Santa Ana College; Cypress College; Otis College of Art and Design; Golden West College; Los Angeles Southwestern College; Art Institute of California; Antioch College; Coastline Community College, John Jay College, Westchester Community College, Pace University, Manhattanville College, CUNY, Los Angeles Police Department and Los Angeles Sheriff's Department, Annual Mental Health Community Providers Summit

Weill Cornell Medical College Enrollment Site

This year the Weill Cornell site has focused its effort on increasing our online presence through multiple social media platforms and disseminating information about our research study throughout the tri-state area (including New York, New Jersey, and Connecticut). On a weekly basis study personnel posts Craigslist ads in community boards throughout the tri-state area. This year we launched two Facebook Adverts campaign. Facebook Adverts advertise and demonstrate our study flyer through various mediums such as Facebook and Instagram. As part of our ongoing efforts to build and foster relationships with mental health providers and inform them about the research study, study personnel met Military and Veterans Service Coordinators at Pace University, Westchester Community College, John Jay College of Criminal Justice, Hostos Community College and St. Joseph's College. We have also expanded our network of contacts within local VA hospitals and vet centers. Study personnel have visited local veteran centers throughout the quarter to informally talk with the counseling staff, and have successfully scheduled several follow up visits at which study clinicians presented information about our services. These presentations have included the Bronx Vet Center, Manhattan Vet Center, White Plains Vet Center, and New Jersey Vet Center. Throughout the year, study personnel have also visited the Bronx, Brooklyn, and Manhattan VAs and have received many calls from patients at these locations who saw our study fliers.

Additional outreach has been conducted throughout the NYC Veterans community, including attendance at NYC Veterans Resource Expo at Brooklyn Borough Hall (10/20/15), Spring 2016 Veterans Information seminar at Hostos Community College (03/16/16), Telemedicine panel in VA New York Harbor for the Veterans Mental Health Coalition (06/15/16), and New York Presbyterian- Weill Cornell Third Avenue Fair (9/11/16).

Long Beach VA Enrollment Site and USC/ICT

Ongoing relationship building efforts continue between our team and LA Department of Mental Health, California Department of Veteran Affairs, as well as with local universities (UCLA, Cal State Long Beach, UC Irvine) and community colleges and their student veteran groups. Study staff remains actively in contact with the Region 8 Veterans Program Directors Consortium and includes occasional attendance at consortium events (monthly, by various team members). Ongoing individual community college visits to hand out fliers and speak with clinical staff and Veterans at the following locations: Saddleback College; Santa Monica College; Los Angeles City College; Irvine Valley College; Long Beach City College; Santa Ana College; Cypress College; Otis College of Art and Design; Golden West College; Los Angeles Southwestern College; Art Institute of California; Antioch College; Coastline Community College.

Other referring groups include the Los Angeles Police Department and Los Angeles Sheriff's Department. Information has been disseminated by maintaining an online presence via its website, Facebook and Twitter accounts. Staff also attended the Annual Mental Health Community Providers Summit hosted by the Orange County Global Medical Center, the VA Long Beach's Research Week which led to a public demonstration of the technology at the Summer Summit of Service. Study staff participated in the Hospital's PTSD Awareness Event with a tent and interactive Virtual Reality demonstration for event visitors and attended the US Vets Initiative Open House. Staff continues to participate in events for local groups such as Team RWB (Red White and Blue) and its surfing education and outreach for Veterans in collaboration with West Los Angeles VA.

NICoE Enrollment Site

Ongoing efforts to build relationships within WRNMMC for referrals continue. The team has been staffing recruitment tables at WRNMMC each week and FBCH biweekly. The tables include study flyers and clinician referral sheets. In addition, study promotional materials such as hand sanitizer, chapstick and stylus pens are available to clinicians and potential participants. We are hoping to spread study awareness within the WRNMMC, FBCH, and USU provider

community. Additional virtual and electronic recruitment is ongoing within local non-profit organizations, veterans groups, local military treatment facilities (MTFs), and social media. We have received one referral from a WRNMMC provider. We have a newly approved study specific website. Participants can obtain study information and contact study team directly.

We have a referral partnership with the Center for Neuroscience and Regenerative Medicine (CNRM). Dr. Roy is the Director of the Recruitment Core and Patricia Taylor is a Project Manager of the Recruitment Core.

11) Participant Enrollment and Treatment:

The tables below summarize participant enrollment and treatment. Specifically, Table 1 lists the statistics for enrollment and treatment in Year 6 alone, and Table 2 lists the cumulative statistics for enrollment and treatment.

Table 1. Study enrollment figures by site for Year 6 only

	Weill Cornell	Long Beach VA	NICoE	Total Across Sites
Completed the Telephone Screen	38	85	26	149
Number of Patients Assessed	10	24	10	44
Number of Patients Eligible and Enrolled in Treatment	2	21	8	31
Number of Treatment Sessions Held	38	184	122	344

	Assessed and Enrolled				Current	Completed Treatment			
	Completed Baseline Assessment	Assessed and Not Eligible for the study	Enrolled in the Study	Enrolled in study but did not enter Treatment	Currently In Treatment	Completed Post- treatment Assessment and 3- month Follow-Up	Completed Post- treatment Assessment and Awaiting 3- month Follow-Up	Awaiting Post- treatment Assessment and 3- month Follow-Up	Dropped Out During Treatment
Overall	219	54	165	12	16	95	11	1	30
Site:									
WCMC	69	28	41	3	2	27	3	1	5
LBVA	105	17	88	6	10	46	3	0	23
NICoE	45	9	36	3	4	22	5	0	2

Table 2. Study enrollment figures by site (Cumulative to date 10/07/16)

Sample description:

Across the three sites currently enrolling participants, 600 individuals have completed the telephone screen, 219 have completed the baseline assessment, 106 have completed treatment and 95 have completed the 3-month follow-up assessment, 16 people are currently in treatment, and 30 have dropped out of the study during treatment.

Of the 22 women (17%) and 197 men (83%) assessed, the majority were Caucasian (51%), followed by Hispanic/Latinos (25%), African/Americans (15%), Asians (5%) and Other (4%). The mean age was 34 (SD=7.8, range 21-58) and 39% were married or living with a significant other, 36% were single and 16% were separated/divorced. The education level was as follows: High School or GED -18%, Some College or Training -53%, College Graduate -16% and More Than College -13%.

Participants represented three branches of the Armed Forces: Army -57%, Marines -27%, Navy -10%, with the following history of deployments: one deployment -39%, two deployments -33%, three deployments -16%, and four or more deployments -12%. Twenty four percent were Active Duty at the time of their baseline assessment and 62% reported prior PTSD treatment.

Treatment Adherence and Inter-rater Reliability:

As part of treatment adherence monitoring in Year 5, the study independent monitors reviewed and provided feedback for 28 therapy sessions across sites during this grant year. We are on target to rate 10% of all treatment sessions conducted during the life of the study. This feedback is routinely discussed during weekly therapist supervision calls. Likewise, the interrater reliability ratings of study assessments are used to provide training and feedback to study assessors. In Year 5, 37 assessment videos have been reviewed and rated across sites.

12) Collection and processing of biological samples:

Saliva samples collected both as part of the psychophysiological assessments as well as for genetic testing are shipped in batches to Weill Cornell for storage and processing. In Year 5, 510 salivate tubes have been delivered for processing to the Weill Cornell Clinical & Translational Science Center (CTSC). In addition, Dr. Glatt's lab has received 29 new genetic samples during this grant year.

13) Software Development:

The following contains a list of the deliverables proposed for this work and the status of achievement on the software development components of this project. A technical user manual for Bravemind 1.0.3 was developed and distributed to study personnel at all sites (see Appendix).

3. KEY RESEARCH ACCOMPLISHMENTS: Bulleted list of key research accomplishments emanating from this research.

Software Development Year 5 Status

The following contains a list of the deliverables proposed for this work and the status of achievement on the software development components of this project.

- 1) Technical Support of Enrollment Sites
- 2) Continued provision of QA services
 - i) Provided step-by-step assistance over the phone for onsite staff setting up the new VR system;
 - ii) Completed successful setup of new VR system with onsite staff;
 - iii) Troubleshot over the phone new VR system monitor issue, resolving with onsite staff;
 - iv) Provided setup and troubleshooting for Bravemind VRET laptop for outreach purposes;
 - v) Supported and demonstrated latest Bravemind VRET software in outreach events to veterans and hospital staff at VALB.
- 3) Documentation
 - a) Updated manuals for new features and content additions;
 - b) Provided revised VRET components list for ordering equipment based on part optimizations and vendor supply, and assisted with ordering of new equipment.
- 4) Hardware development and evaluation
 - a) Audio
 - i) Added sound effects to universal library such as 'Male Breathing' and new ambient sounds such as, 'Rain' and 'Female Breathing.'
 - b) Devices
 - i) Continuing investigation of replacement options for the discontinued line of Sony HMZ HMDs in use by the current VRET systems.
 - c) Technology
 - i) New Functionality
 - (1) Eliminated apparent sliding of avatar in certain interior locations;
 - (2) Import of Navy and U.S. Air Force outfits for either NPC or avatar use;
 - (3) Fixed instabilities with encounters or vehicle functions such as toggling headlights that occurred from switch of the default avatar Humvee or MRAP convoys;
 - (4) Continuing improvements to avatar vehicle convoy system to allow for additional vehicle types and crew positions.
- 5) Enrollment-site system upgrades
 - a) Optimized Weill Cornell VRET system launch interface and peripheral setup;

- b) Performed checks on Weill Cornell VRET system and reviewed usage with clinician;
- c) Answered VRET software/hardware questions from study team members;
- d) Provided replacement head-strap for worn HMD unit at VALB site;
- e) Released new version of Bravemind software which combines optimized Iraq/Afghanistan base-scenarios. This version integrates the following improvements: robust vehicle physics; Village scenario NPC visibility toggling; new RPG and Mortar sounds; completed logic to conditionally load characters, vehicles, and props; expanded vehicle convoy system to allow for additional vehicle types, crew positions, and crew animations.
- 4. REPORTABLE OUTCOMES: Provide a list of reportable outcomes that have resulted from this research to include: (manuscripts, abstracts, presentations; patents and licenses applied for and/or issued; degrees obtained that are supported by this award; development of cell lines, tissue or serum repositories; infomatics such as databases and animal models, etc.; funding applied for based on work supported by this award; employment or research opportunities applied for and/or received based on experience/training supported by this award)
- 5. CONCLUSION: Summarize the results to include the importance and/or implications of the completed research and when necessary, recommend changes on future work to better address the problem. A "so what section" which evaluates the knowledge as a scientific or medical product shall also be included in the conclusion of the report.

The 2008 and 2012 Institute of Medicine (IOM) Reports on the treatment of posttraumatic stress disorder noted a paucity of effective, empirically validated treatments for combat-related PTSD. This study is using the one treatment noted by the IOM reports to have substantial evidence in other trauma populations, exposure therapy, and enhancing it with virtual reality and a novel pharmacologic agent, D-Cycloserine. Thus, this study is poised to provide several valuable contributions to the understanding of combat-related posttraumatic stress disorder. Improving the effectiveness of therapy through the use of virtual reality would have far-reaching, positive consequences for our wounded warriors. Results of this clinical trial will directly influence the future delivery of services, and may help disseminate a standardized treatment protocol as is being done for other psychiatric disorders. If D-Cycloserine, a benign pill, proves to be an effective way to enhance the effects of psychotherapy, the result would have a tremendous impact at very little cost. Additionally, there are currently no genetic or non-genetic biomarkers for assessing treatment response to any psychiatric disorder. Findings from this study may lead to the development of a human genetic test that could guide treatment of patients with PTSD with the BDNF SNP to therapeutic strategies, such as imaginal exposure therapy with DCS, prior to a trial of an SSRI. The BDNF SNP would be the first biomarker that would inform treatment strategy decisions for clinicians in the treatment of PTSD. The capability of predicting the best treatment for the individual would make treatment efforts more effective and efficient, and would decrease suffering and the costs associated with a PTSD diagnosis and treatment.

6. REFERENCES: List all references pertinent to the report using a standard journal format (i.e. format used in Science, Military Medicine, etc.).

W81XWH-10-1-1045

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- 7. APPENDICES: Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

The Appendix is attached.

Pages shall be consecutively numbered throughout the report. DO NOT RENUMBER PAGES IN THE APPENDICES.

Mark all pages of the report which contain proprietary or unpublished data that should be protected by the U.S. Government. REPORTS NOT PROPERLY MARKED FOR LIMITATION WILL BE DISTRIBUTED AS APPROVED FOR PUBLIC RELEASE. It is the responsibility of the Principal Investigator to advise the U.S. Army Medical Research and Materiel Command when restricted limitation assigned to a document can be downgraded to Approved for Public Release.

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"Enhancing Exposure Therapy for PTSD: Virtual Reality and Imaginal Exposure with a Cognitive Enhancer"

Policies and Procedures Manual

June 2011 (Updated December 5, 2011)

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<u>A. Recruitment</u>

Recruitment efforts will take place collaboratively between sites and individually at each site. Methods of recruitment should be varied and can include broadcast emails to military contacts, letters to colleagues, flyers posted in medical centers, information on medical center websites, and the use of online advertising including Facebook and other sites that will attract prospective patients.

Each site should determine their IRB rules regarding recruitment and approval of recruitment materials.

All IRB-approved recruitment materials from each site will be available online for all sites to access. To access these materials, log on to the DOD WIKI site using your Cornell ID at <u>https://nexus.med.cornell.edu/display/DoDStudy/ Home</u>

Program Coordinators should keep track of all recruitment efforts and contacts in the recruitment section of the **DOD STUDY RECRUITMENT & RESPONSE LOG**. This log should be password protected.

B. First Contact/Phone Screen

The first contact with the patient will likely be via phone when they call to inquire about the treatment study. Each site should have a central number for all inquiries. Inquiries should be entered in the response section of the **DOD STUDY RECRUITMENT AND RESPONSE LOG**.

When the prospective patient first contacts the site, he/she should be assigned a **SCREEN ID**. The screen ID consists of letters for the site + consecutive number 0001, 0002, etc., as determined by the next number on the **DOD STUDY RECRUITMENT AND RESPONSE LOG**, e.g., WC0001 for the Weill Cornell site, VA0001 for the LBVA site, NC0001 for the NICoE site. The **PHONE SCRIPT** should be followed for the call. It is important that the same general information is captured for each person who calls to inquire about the study, as this information will be used to describe the sample. It will also help to rule out people who are obviously ineligible for the study, while capturing those with potential for the initial assessment. Information generated from the phone script should be kept in a computer datasheet with fields for each piece of information and then transferred to the **Program Coordinator**.

After the phone script is completed, if the patient is potentially eligible as per the questions asked, an initial assessment should be scheduled with the assessor and a **SCREEN ID** number should be entered into the **TRACKING FORM**. Initial assessments will take a number of hours, the length of which will vary by site, and the patient should be informed of the approximate length of time, so the assessor should have their calendar clear.

The assessor, physician, and startle paradigm task facilitator will all be needed for the initial assessment. Additionally, because of cortisol collection, subjects should all be scheduled for the evaluations at approximately the same time of day. Each site should devise a system whereby the person administering the phone screen can schedule the caller for the in-person assessment with all three of these assessors consecutively *before* ending the call, unless there is a need to check eligibility with staff. It is important to remember that the more phone calls to the patient necessary for the scheduling, the greater the likelihood for the subject to fall through the cracks, or for the scheduling to take a long period of time, so this should be minimized.

If the patient is ineligible, other potential resources should be offered to him/her (it is advisable to have a list of resources at the ready for this purpose).

C. Tracking all Contacts and Assessment Points

As per **CONSORT** guidelines, all potential participants must be tracked in order to report attrition over the course of the study. This means that a thorough record must be kept at each site with the name and status of every potential, assessed, and enrolled patient. The record must also reflect number of sessions completed, so therapists and patients can be reminded to complete mid-treatment assessments at the proper time (after session 4 and 6). This <u>**TRACKING FORM**</u> will be managed by the **Program Coordinator**, who will also be responsible formaking sure that it is up to date.

The **Program Coordinator** should update the list weekly in time for the PI's weekly conference call, which takes place on Wednesdays at 4PM EST, during which this information will be reviewed. In addition, the **Program Coordinator** should remind the therapist when assessments should be taking place. Although the therapist should be tracking assessment timing as well, this additional duty of the **Program Coordinator** provides a safeguard so no data is lost from a missed assessment.

The **Program Coordinator** will upload the <u>**TRACKING FORM**</u> to REDCap weekly. **See <u>QUICK REDCAP REFERENCE SHEET for STUDY COORDINATORS</u> for detailed instructions on REDCap. The following information should be reported to Weill Cornell (using REDCap) on a <u>weekly</u> basis:**

- Number of screens by phone & reasons for ineligibility for the study
- Number of baseline assessments scheduled for the week
- Number of people actually assessed for eligibility (i.e., assessed in person by study assessor and/or physician) & reasons for ineligibility for the study
- Number of subjects/patients enrolled in the study (i.e., randomized)
- Number of weekly intervention sessions (participant ID, clinician name & session date and number)
- Number of assessment sessions (participant ID, clinician name & session date and number)
- Number of dropouts/terminated & reasons for dropout/termination (participant ID, clinician name & last session date and number)

D. Initial Assessment

The initial assessment for study eligibility entails four (4) steps. All four steps should be scheduled for the same day. Steps 1 and 2 (psychological assessment and genetic sampling, respectively) should be completed for all

potential subjects. If the patient is obviously ineligible as per information gathered on the psychological assessment, Step 3 (the medical assessment) does NOT need to be completed. If the patient is ineligible as per information gathered on the psychological or medical assessments, then Step 4 (the psychophysiological assessment) does NOT need to be completed.

1. Psychological Assessment

The first step to assessment is the psychological assessment, which is completed by the designated assessor at each site. The paragraph below describes the following steps for the assessor:

- a) Consent forms (study consent form, media recording consent form)
- b) HIPAA form
- c) Intake Interview Form
- d) CAPS (past month and past week)
- e) MINI
- f) DVBIC-3
- g) Review of traumatic event form
- h) Trauma History Questionnaire
- i) Patient preference and strength of preference questions
- j) Case Report Form
- k) Saliva sample for genetic testing (Oragene-DNA)

First the **Assessor** describes the study and gives the patient the **consent** forms and the HIPAA form to sign. The assessor then completes the INTAKE INTERVIEW FORM. Next. the assessor conducts the clinician-administered measures, beginning with the CAPS. For instructions on administering and scoring the CAPS, please refer to **DOD CAPS RULES.** If the patient does not meet criteria for PTSD as per the CAPS, there is no need to proceed with the assessment. In the case of ineligibility, the assessor should present the patient with their impressions regarding symptomatology and treatment, and provide resources for treatment. If they do meet criteria, the *MINI* is administered next, and scored according to the **DOD MINI RULES**. Next, the *DVBIC-3*, a screen for traumatic brain injury, is administered. The assessor then inquires briefly and helps patient identify the index trauma, completing the REVIEW OF TRAUMATIC EVENT FORM. It is unnecessary for the assessor to get a very detailed narrative, but he/she should ask enough to know whether or not the trauma can be loosely matched to the virtual environments. Next the assessor administers the TRAUMA HISTORY QUESTIONNAIRE, and the PATIENT PREFERENCE and STRENGTH OF PREFERENCE questions. All of these measures and forms are available on REDCap and assessors should have a backup file in their offices. **See OUICK REDCAP REFERENCE SHEET** for ASSESSORS for detailed instructions on REDCAP. Finally, the assessor completes pages 1-3 of the **CASE REPORT FORM (CRF)**.

The consent form and HIPAA form must be signed in order to continue with the assessment. The consent form and HIPAA form should then be placed in a file folder and given to the **Program Coordinator**, who files it appropriately together with the CRF. The patient is given a copy of the consent form and HIPAA.

If the patient is potentially eligible based on the clinician-administered measures, the patient is then given the computer/tablet and instructions for completing the self-report forms on REDCap. The following self-report measures will be completed for the initial assessment: PCL-M, BDI, PSS, Intent to Attend, CTQ, DRRI, QOLI, Client Expectancy Questionnaire, Impulsivity Questionnaire, and Immersive Tendencies Questionnaire.

A paper copy of all measures should be kept in the assessor's office as a backup in case there is trouble with the REDCap setup. If the paper and pencil backup system is used, please report this to your program coordinator immediately so that the data management site (Cornell) is aware of the problem and can work with you in "real time" to fix it. We do not want a backlog of paper measures, as this will undermine the efficiency of the data management team and waste valuable resources (i.e., time for data entry and money).

While filling out the self-report measures, the patient should know how he might access the assessor if he has a question and the assessor should remain available. The patient will check a box to answer each question on the computer. The page will not advance until all questions have been marked. The REDCap program saves the inputted data automatically. The assessor should assure the patient that though the measures are lengthy, they will not be repeated on a regular basis and their completion is appreciated and helpful in understanding how best to help the patient.

For any questions regarding REDCap, call Katarzyna (Kasia) Wyka at 212-821-0869 or email her at kew2008@med.cornell.edu. If she is not reachable during business hours, you may call Brittany Mello at 212-821-0783 and she will pageher.

2. Genetic Sampling

For all subjects, a saliva sample is collected to capture genetic data. Since multiple spits are necessary to fill the cup, it may be best to have the patient sit with the spit cup as they complete the self-report measures, and spit into it occasionally as they complete the measures. The patient is given the container and asked to spit into it until it is filled to the line. Note that foam/bubbles do not count and it should be solid saliva until the line. It is best to get a clean sample by not having had the patient eat in the last 30 minutes, but if the patient has eaten they should rinse their mouths so no food particles will be in the sample. It will take a number of spits to fill the container and the patient should not feel pressured for time. If they are having trouble, they can suck on a candy or have a drink of water to help salivation.

When the saliva has reached the line, the assessor should take the sample and close the top tightly. When the top is closed tightly, a seal will be broken that will release a fluid to be mixed with the sample. The assessor should shake the container vigorously to allow the saliva and fluid to mix, thereby allowing the sample to be stored at room temperature for an extended period of time. Each container has a unique ID number. The **Assessor** should record the container ID and the participant SCREEN ID on a separate page, and this information should be transferred immediately after the assessment to the **Program Coordinator** to be recorded in the **DOD ID FORM** (there are separate forms for each site). The genetic sample should be stored in a designated, locked cabinet in accordance with site regulations. The sample and identifying information should NEVER be stored in the same place, so that the genetic data cannot be linked to the individual subject. For shipping instructions, see section Q below.

After the psychological and genetic assessments are complete, the assessor should refer to the eligibility criteria to know whether the patient is absolutely NOT eligible for the study. Note: for the initial few patients, the assessor should try to consult with the site and/or head PIs on eligibility. The assessor should check the inclusion criteria on the **CRF** and indicate whether or not there is a diagnosis of current Major Depressive Disorder. If it is clear that they are not eligible, the assessor should present the patient with their impressions regarding symptomatology and treatment, and provide resources for treatment. If the patient is not obviously excluded, they should continue to the medical assessment.

The following constitute the inclusion/exclusion criteria for the study:

Inclusion Criteria:

- 1) Diagnosis of OEF-OIF (Operations Enduring Freedom or Iraqi Freedom) Combat Related PTSD
- 2) Ability to provide informed consent and function at an intellectual level sufficient to allow accurate completion of all assessment instruments
- 3) Participants must be literate in English
- 4) Patients must be medically healthy and willing to take the study drug
- 5) VRE stimuli available must be consistent with subject's trauma
- 6) Female participants of childbearing potential must agree to use an effective method of birth control (i.e., oral contraceptive, Norplant, diaphragm, condom, or spermicide) during the course of the study, or to remain abstinent from sex, to ensure they do not become pregnant during the course of the study

Exclusion Criteria:

- 1) Lifetime or current diagnosis of schizophrenia or other psychotic disorder, bipolar disorder
- 2) Participation in a clinical trial during the previous 3 months
- 3) Current evidence or history of significant unstable medical illness or organic brain impairment, including stroke, CNS tumor, demyelinating disease, cardiac, pulmonary, gastrointestinal, renal or hepatic impairment
- 4) Patients who, in the investigator's judgment, pose a current suicidal or homicidal risk
- 5) Alcohol, medication, or illegal substance dependence within the past 90 days
- 6) Treatment with any other concomitant medication with primarily CNS activity, or treatment with any medication that the PI judges not acceptable for this study;
- 7) History of seizures
- 8) Pregnancy or lactation.

Note: Patients are asked not to participate in any other exposure therapy or therapy specifically for PTSD while enrolled in this treatment. They are eligible for this study even if they have been treated with exposure therapy in the past, provided they are not enrolled at the same time as the study.

3. Medical Assessment

After having completed the psychological and genetic assessments, the patient should be seen by the site physician. The physician screens the patient for potential medical confounds to the DCS or VR. The physician then completes the **MEDICAL SCREENING FORM** and indicates whether the patient is medically cleared or not. The form is given immediately after the assessment to the **Program Coordinator** to be placed in a file with the consent form, HIPAA form, and the CRF. The date of the medical assessment should be recorded on the CRF page 3.

The physician also writes a prescription for the patient for "50 mg DCS or placebo 7 pills," which he/she gives to the **Program Coordinator**.

If there is a medical contraindication for the patient and it is therefore clear that they are not eligible, the assessor should present the patient with their impressions regarding symptomatology and course of treatment, and provide resources for treatment. If the patient is not obviously excluded, they should continue to the psychophysiological monitoring/behavioral task.

4. Psychophysiological Monitoring/Behavioral Task

Finally, when the other assessments are complete, the psychophysiological monitoring task is conducted. Because of the length of time necessary to complete all components (approximately 2 $\frac{1}{2}$ - 3 hours), it is likely that the patient will need a break for lunch and/or snack at this point. Assessors should discuss with the PIs the availability of funds for snacks and/or lunch.

Steps of the task include electrode setup, preliminary tests/checks, startle booth setup, "AXBX" test, Extinction task and VR task. Follow the instructions as detailed in the **DOD STARTLE MANUAL**. For the VR task, the lights should be turned off in the room.

Cortisol is also collected from subjects at 4 time points:

- Prior to prepping participant and putting on electrodes
- After finishing the participant prep, immediately before beginning the AXBX task
- After finishing the AXBX session and the exit report form (during 10 minute break)
- After finishing the VR session

Be sure to complete the **<u>CORTISOL FORM</u>** with the specific times of collection.

Salivette tubes used for saliva collection for cortisol should be clearly marked with the SCREEN ID and with the time point of collection. The cortisol samples need to be stored in a -80 degree freezer and so arrangements should be made for the use of a freezer for the duration of the protocol. If need be, the samples can be placed in a regular refrigerator for up to 24 hours before moving them to the -80 degree freezer.

Since cortisol is collected, it is best to run all subjects through this assessment at approximately the same time of day. The psychophysiological task should be completed in the afternoon, after 1pm is best.

This behavioral task will also be done at post-treatment assessment and 3month follow-up assessments. There will be compensation for all 3 assessments, which include the physiological monitoring piece (pre-treatment, post-treatment and 3-month follow-up).

At all time points for the assessment, if a patient is ineligible for the study after being assessed the <u>CASE REPORT FORM (CRF)</u> (p.4) should be completed, but the **TRACKING FORM** should ALSO be updated to reflect the correct status of the patient.

E. Randomization

After the initial assessment is complete, the **Program Coordinator** receives the CRF form from the assessor, indicating a) eligibility for the study and b) presence or absence of Major Depressive Disorder. The **Program Coordinator** also receives the consent and HIPAA forms, the medical clearance form and a prescription from the physician for "50 mg DCS or placebo 7 pills".

Once these elements have been received, the **Program Coordinator** checks the MDD+ or MDD- randomization list depending on presence or absence of MDD, which will include <u>only</u> psychotherapy treatment group. The **Coordinator** will assign the patient the next available STUDY ID number from the randomization list, noting psychotherapy type assignment (VR vs. IE).

The **Coordinator** will add the STUDY ID number to the **CRF** (page 1).

The **Coordinator** will notify the **therapist** of the eligible patient and the psychotherapy condition. The **therapist** will notify the patient of treatment condition at the first session.

Using the **PRESCRIPTION REQUEST FORM**, the **Coordinator** will then send via fax (or in person, depending on site) the following information to the **pharmacy** dispensing the medication in accordance with the site's IRB and pharmacy policies:

- 1) STUDY ID number
- 2) Presence/absence MDD
- 3) Prescription with patient's name, DOB, and address (and anything else required by the specific pharmacies)
- 4) Consent form (usually first and last pages)

The Prescription Request Form should be stored in the file with the other participant documents (consent form, HIPAA form, CRF, and medical clearance form).

<u>F. Pharmacy</u>

The **Pharmacist** will receive the already assigned ID number and patient information. The **Pharmacist** will check the ID number against their MDD+ or MDD- full randomization list, which will indicate whether the patient should receive DCS or placebo. (Note: ID numbers will not overlap so if MDD information is missing, the pharmacist will be able to check both lists and find the appropriate ID number).

The **Pharmacist** will fill the prescription with 7 pills in a bottle labeled with the patient's name and/or ID number. The **therapist** or other **staff member** will pick up this bottle <u>BEFORE</u> the third session, during which the first pill will be taken.

<u>G. Double-blinding Considerations</u>

The importance of maintaining a double-blind warrants its own section in this manual. The double-blinded nature of this study means that:

1) No one is aware of the DCS vs. placebo assignment of the patient except the pharmacist.

To maintain this blinding, only the pharmacist will have ready access to the randomization list with the medication condition. In addition, medication condition will not be written on the pill bottle. The only exception is in the case of an adverse reaction, which is described below.

2) The assessor is not aware of treatment assignment.

Though the therapist and patient (obviously) as well as the program coordinator will know the treatment condition, the assessor should stay blinded to whether the patient is receiving the VR or PE. The patient should be instructed to make every effort not to reveal this information to the assessor during the assessment appointments. Furthermore, every effort should be made so the assessor won't see the patient going into a room solely for VR treatment. This may be done by having the VR and PE treatments done in the same treatment room, or by having the assessor in a different location in the medical center. The assessor will also not be present on calls discussing patient progress or treatment. (Note: this is applicable only to the psychological symptom assessor, and not to the psychophysiological monitoring assessor).

H. Treatment

When the therapist receives the patient information and treatment assignment from the program coordinator, they will contact the patient and schedule the first appointment. Prior to treatment, the therapist should scan the assessment materials, especially the review of traumatic events form and the CAPS. A copy of the questionnaires (pdf) should be requested from the site program coordinator or from Kasia Wyka (kew2008@med.cornell.edu). The treatment consists of nine (9) weekly sessions, lasting 90 minutes apiece. Exposure therapy is introduced in session 3 and concludes in the final session of treatment in session 9. For each patient, the DCS/placebo pill containers will be stored in an approved location by the therapist. Beginning at session 3, the patient should be instructed to arrive for their session a minimum of 30 minutes prior to the treatment sessions. For sessions 3-9, at 30 minutes prior to the session, the therapist will give the pill container to the patient and instruct him/her to take one pill. Water bottles should be kept in the office for the patient's use in taking the pills. They will then give them the computer with the weekly self-report forms to complete. The session should begin precisely 30 minutes after the pill is taken, so if a patient takes longer to fill out the forms, the timing should be altered accordingly.

There is no exposure homework assigned as part of this study. The entire treatment protocol is detailed in the **TREATMENT MANUAL**. Because of the nature of a clinical research study, it is important that all therapists follow the guidelines and language of the protocol as closely as possible, without veering from it. Every session should be videotaped for supervision and treatment fidelity rating.

Sessions should be scheduled weekly, and as consistently as possible. A clinical <u>SESSION PROGRESS NOTE</u> should be completed weekly and kept

in a clinical file by the therapist in accordance with your site's regulations. Templates are available for each session and have been distributed to the therapists. For a copy, please contact Judith Cukor atjuc2010@med.cornell.edu.

Importantly, if for some reason the first treatment session does not occur within **30 days** of the initial assessment, the CAPS should be administered to the patient again by the **Assessor** prior to the first treatment session.

I. Weekly Self-report Measures

Prior to each treatment session, the patient will complete a small battery of self-report forms on the computer via REDCap, including: PCL-M, BDI, PSS and Intent-to-Attend. Some additional measures will be administered at sessions as follows: Session 1 – Index Trauma Interview (administered by therapist and kept as a hard copy with progress notes), Sessions 3,6,9 – Presence and Immersion Questionnaires following the exposure (post-session self-reports via REDCap), Session 9- Blinded Medication check (administered by therapist). Each therapist will use a different link to the REDCap weekly session self report (e.g., DOD WEEKLY <u>SESSION - Self-Report CUKOR</u>) and will be able to view patients' responses prior to each session. Each therapist has received the **QUICK REDCAP REFERENCE SHEET** for THERAPISTS with detailed instructions about REDCap.

A paper copy of all measures should be kept in the therapist's office as a backup in case there is trouble with the REDCap setup.

The patient should arrive a minimum of 30 minutes prior to the treatment sessions, take their pill at 30 minutes prior to the session, and then complete the weekly self-report forms. The session should begin precisely 30 minutes after the pill is taken, so if a patient takes longer to fill out the forms, the timing should be altered accordingly. The therapist should assess potential side effects since the time

the pill was taken that day, using the **SIDE EFFECT SCREENING CHECKLIST** at the beginning of sessions 3-9. It is important for the therapist to identify symptoms if they are likely related to the treatment, and to indicate what action was taken after the symptom was reported. The checklist is available via REDCap. For each exposure session (3-9) the therapist will also fill out SUDS form (including a description of exposure, and pre-exposure, post-exposure and peak exposure SUDS scores) available via REDCap.

J. Mid-treatment Assessments

Assessments with the assessor will take place after sessions 4 and 6. These appointments should be scheduled in between the weekly sessions without delaying them (i.e., ideally a week's session should not be skipped to do the assessment), but the next session cannot take place if the assessment has not been completed.

The mid-treatment assessments are comprised of self-report and clinicianadministered measures PCL, BDI, PSS, Intent to Attend, Client Satisfaction Questionnaire and CAPS (**past week only**).

A paper copy of all measures should be kept in the assessor's office as a backup in case there is trouble with the REDCap setup.

The assessor remains blind to treatment condition and the subject should be instructed not to reveal treatment condition to the assessor. Data from the assessment cannot be shared with the treating therapist.

K. Post-treatment Assessment

The post-treatment assessment should occur within one week of the completion of treatment and contains the following self-report and clinicianadministered measures: PCL, BDI, PSS, QOLI, Client Expectancy Questionnaire, Client Satisfaction Questionnaire, CAPS **(past week only)** MINI, Trauma History Questionnaire (for traumas since the initial assessment) and blinded medication/treatment check.

The psychophysiological monitoring/startle paradigm task is also administered.

A paper copy of all measures should be kept in the assessor's office as a backup in case there is trouble with the REDCap setup.

The assessor should remain blinded at the conclusion of this assessment, as they will still assess the subject at a later date.

The subject receives \$50 compensation for completing this assessment. The project coordinator or assessor should make sure to arrange to have the money available to give at the time of the assessment.

The **Project Coordinator** should record the study completion date on the <u>CRF (page 4)</u> and on the <u>TRACKING FORM</u>.

L. 3-month Assessment

The **Assessor** should schedule the 3-month assessment at the post-treatment assessment. One month and again one week prior to the date, a reminder phone call should be placed to the patient.

The following self-report and clinician measures are administered: PCL, BDI, PSS, QOLI, Client Expectancy Questionnaire, Client Satisfaction Questionnaire, CAPS **(past month and week)**, MINI and Trauma History Questionnaire.

The psychophysiological monitoring/startle paradigm task is also administered.

A paper copy of all measures should be kept in the assessor's office as a backup in case there is trouble with the REDCap setup.

The subject receives \$75 compensation for completing this assessment. The project coordinator or assessor should make sure to arrange to have the money available to give at the time of the assessment.

The **Project Coordinator** should record the 3-month follow-up date on the <u>CRF</u> (page 4) and on the <u>TRACKING FORM</u>.

<u>M. Data Management</u>

The REDCap system will be used to collect data for the study. WCMC is the data management site. Please contact Katarzyna Wyka (<u>kew2008@med.cornell.edu</u>, 212-821-0869) with any REDCap related questions.

There are three types of REDCap data collection tools used in the study:

- REDCap for self-reports (to be completed by study participants)
- REDCap for clinical interviews (to be completed by study assessors and therapists)
- REDCap for recruitment/retention data (to be completed by study coordinators)

Each data collection tool can be accessed by using a permanent link provided by WCMC. Separate **QUICK REDCAP REFERENCE SHEETS** has been created for study assessors, therapists and coordinators:

- QUICK REDCAP REFERENCE SHEET for ASSESSORS
- **<u>QUICK REDCAP REFERENCE SHEET for THERAPISTS</u> (each therapist has a unique sheet)**
- **QUICK REDCAP REFERENCE SHEET for STUDY COORDINATORS.**

Refer to these sheets for easy access to REDCAP links and REDCAP instruction. To receive a copy of these sheets, contact Kasia Wyka atkew2008@med.cornell.edu.

Each link has a title that clearly describes the intended user (study participant or assessor/therapist or study coordinator) and type of assessment/session (e.g., baseline assessment, treatment session, mid-treatment assessment, etc.)

It is important to note:

- The data can be submitted all at once or the SAVE & RETURN LATER option can be used (to be used only in unusual circumstances). If the SAVE & RETURN LATER option is used, <u>a validation code must be recorded</u> in order to continue where stopped. If the code is lost, please contact Kasia Wyka (kew2008@med.cornell.edu).
- The font can be magnified by using "Ctrl" and "+" keys together (for PC users) and "Alt" and "Apple" and "+" (for Mac users). REDCap links display this information but study participants should also be alerted verbally to make sure that they can take advantage of this option.

If the paper and pencil back-up system is used, please report this to your program coordinator immediately. The **Project Coordinator** should notify Kasia Wyka as soon as possible and coordinate data entry into REDCap.

<u>N. Adverse Events</u>

The Weill Cornell Data Safety and Monitoring Board (DSMB) will be used to monitor all possible adverse events including, but not limited to, the potential side effects of DCS. A DSMB is not required for this study; however' it was recommended because the study medication is an off-label use. As per the DSMB's guidelines, we will send the DSMB administrator quarterly reports that will include the adverse event and recruitment data from all three sites as well as a summary of timeliness of data entry and any missing data.

Additionally, each site must act in accordance with local IRB, as well the DoD regulations. Be sure that you have reviewed local requirements with your site PI before assessing or treating your first patient.

This manual outlines our DSMB and DoD reporting requirements only.

Serious Adverse Events Requiring Immediate Action (within 24 hours):

- Suicide
- Death (if unexpected and at least probably related to the research procedures)
- Breach of Confidentiality
- Any protocol deviation that was made in order to eliminate an apparent immediate hazard to the participant
 - Protocol deviations that harmed participants or others or that indicated participants or others might have been at increased risk of harm
 - Failure to follow the protocol due to the action or inaction of the investigator or research staff

All serious adverse events should be reported to the lead PI, JoAnn Difede, and the Cornell IRB coordinator, Kasia Wyka, as well as the site PI and independent medical monitor for the study, as soon as possible but no later than 24 hours after the event, and to the site IRB in accordance with their regulations. Cornell will report these events to the DoD.

In addition, the following events should be reported as soon as possible but no later than 24 hours to the above-mentioned people, although they are not mentioned in the DSMB:

- Mental Status Change (i.e., not oriented x 3)
- Active suicidal ideation, intent, and/or plan
- Active homicidal ideation, intent, or plan

The medical monitor is required to review all unanticipated problems involving risk to volunteers or others, serious adverse events and all volunteer deaths associated with the protocol and provide an unbiased written report of the event to the USAMRMC Office of Research Protections (ORP) Human Research Protection Office (HRPO). At a minimum, the medical monitor should comment on the outcomes of the event or problem and, in the case of a serious adverse event or death, comment on the relationship to participation in the study. The medical monitor should also indicate whether he/she concurs with the details of the report provided by the study investigator. Reports for events (1) determined by either the investigator or medical monitor to be possibly or definitely related to participation and (2) reports of events resulting in death should be promptly forwarded to the HRPO.

Adverse events that require reporting within 7 days to the Cornell DSMB (unexpected and study-related Adverse Events):

- Any information that indicates change to the risk or potential benefits of the human research (e.g.
 - An interim analysis, safety monitoring report, publication in the literature, or revised brochure that indicates an increase in the frequency or magnitude of a given harm, uncovers a new risk, or provides more information about the benefits of the human research
 - Change in FDA labeling or withdrawal from marketing of a drug
 - Protocol deviation that harmed participants or others or that indicates that the participants or others may be at increased risk of harm
 - Complaint from a participant that indicates that participants or others might be at increased risk of harm or at risk of a new harm
- Any harm that is unexpected and related or possibly related to the research procedure or intervention experienced by a participant or another individual

- A harm is "unexpected" when its specificity and severity are not accurately reflected in the consent document or Investigator's Brochure
- The harm is "related or possibly related", where there is a reasonable possibility that the harm may have been caused by the research procedure(s), intervention(s) or device(s)
- The harm suggests the research places subjects at greater risk of harm (including physical, psychological, economic or social harm) than previously known or recognized

All unexpected and study-related adverse events should be reported to the lead PI, JoAnn Difede, and the Cornell IRB coordinator, Kasia Wyka, as well as the site PI and independent medical monitor for the study, as soon as possible but no later than 7 days after the event, and to the site IRB in accordance with their regulations. Cornell will report these events to the DoD.

Other (expected) Adverse Events that require quarterly reporting to Cornell DSMB and yearly reporting to the local IRB are related to:

1) The Study Drug

Though we are using DCS "off-label", the FDA has granted us an IND waiver. For its FDA indicated uses (e.g., TB) DCS is used at much higher doses and frequencies, so the side effects listed in the consent form are those associated with the drug at much higher doses (e.g. 500 mg/daily) and with long-term administration. We do not expect any serious side effects, at the dosage and frequency used in this study (based in part on the experience of the Weill-Cornell and Emory sites in other studies, in which medication was administered at low doses)

The **Side Effect Screening Checklist** will be used to record data on known possible side effects at each session in which the patient is given the study medication. After the patient completes the self-report forms, and immediately before beginning the treatment from sessions 3-9, the therapist should administer a side-effect checklist to the patient. The therapist should ask about changes in the symptoms in the past half-hour of that day, since the patient took the pill, get enough information to evaluate whether this is a change from usual status, and indicate the answer (i.e., if the patient usually has moderate irritability and it has not changed, it should be marked 'none').

If the patient indicates there has been an adverse effect that he/she thinks is due to the pill, the prescribing physician should be contacted in session and should speak by phone to the patient. They can determine what, if any, course of action should be taken. The call to the physician and the course of action should be recorded on the side effect sheet in REDCap, as well as in the progress note for that session. Reported side effects included: drowsiness, dizziness, headache, confusion, tremor, twitching, increased nervousness, irritability, psychosis and suicidal ideation.

Much less common side effects at that dose include seizure, visual disturbance, rash, arthritis, anemia, and liver damage (symptoms of liver damage are nausea, itching, light colored stools, and yellowish skin and eye color).

Some symptoms may necessitate the consideration of subject termination from the study:

- Subjects who develop confusion involving a change in mental status, seizure, rash, visual changes, or any other medically significant side effects should be assessed by the site PI and physician for determination of whether termination of the subject's participation is indicated, and to make a referral for treatment if indicated.
- 2) Subjects who develop psychosis, or who become actively suicidal or violent should be provided with appropriate emergency care and treatment referrals and terminated from the study.
- 3) Female subjects of reproductive age who cease using birth control through the study, refuse to have a urine pregnancy test in each follicular phase visit after starting DCS until the end of the study, or who become pregnant during the study will be terminated from the study.

In the case when the medication blind must be broken during business hours, the PI can contact the site pharmacy to obtain information regarding whether the patient is taking the DCS or placebo. To break the blind after hours, Kathy Rosenberg will keep a sealed, master list of group assignment. The study PIs can reach Kathy on her cell phone in the case of an emergency.

The Project Coordinator should record information about adverse events on participant's **CRF** (p. 4).

Other potential risks of the study include:

- Distress associated with exposure. Clinicians should use their clinical judgment to know what levels of distress are appropriate and how to decrease levels of distress. If the patient cannot tolerate their distress, the exposure session should be discontinued and the incident reported.
- 2) Distress associated with clinical interviews. Assessors and clinicians should use their clinical judgment to know what levels of distress are appropriate and when to discontinue the interview and report the incident.
- 3) Adverse events associated with psychophysiological assessments

The Program Coordinator is required to keep an **Adverse Events Cumulative Table & Protocol Deviation Log** that contains detailed records of all aforementioned adverse events/protocol deviations that occur during the course of their research. Such logs must be kept and submitted to the DSMB for each STUDY ARM SEPARATELY. In addition, the DSMB requires narratives of adverse events that have resulted in any of the following outcomes:

- Death
- A life-threatening adverse experience
- Inpatient hospitalization
- Prolongation of existing hospitalization
- A persistent or significant disability/incapacity
- Congenital anomaly/birth defect
- Any adverse events that are important medical events that may not result in death, be life-threatening or require hospitalization, but based on appropriate medical judgment require medical or surgical intervention to prevent one of the outcomes listed above, such as:
 - 1. Allergic bronchospasm requiring intensive treatment in an emergency room or at home
 - 2. Blood dyscrasias or convulsions that do not result in inpatient hospitalization
 - 3. Development of drug dependency or drug abuse
 - 4. Exacerbation of psychiatric disease

O. Dropouts/Termination

For the sake of the patient as well as the study, dropout should be minimized to the extent possible. If a patient does not attend a session, the therapist should contact him/her to follow-up and reschedule the appointment. The therapist should also discuss with their supervisor at the next weekly conference call and also alert their site PI as soon as possible (i.e., next weekly meeting). If a patient reports considering dropping out, this should be addressed openly and directly and barriers to participation should be minimized. The tendency for avoidance symptoms to lead to dropout should be raised in the early sessions (as per the treatment manual) and desire to avoid should be predicted. Supervisors should be consulted regarding patients who seem to be at increased risk for dropout.

If a patient drops out or is terminated from the study, the therapist will indicate this in clinical notes and will report probable reasons for dropout or reasons for termination to the Project Coordinator. The Project Coordinator should record probable reasons for dropout or reasons for termination on the **CRF** (p. 4) and the status of the patient on the **TRACKING FORM**.

P. Supervision

Separate weekly group supervision/consultation calls will take place for all therapists and assessors. Current times for supervision calls are:

- Assessors call Thursdays 12:00 PM EST
- Therapists call Tuesdays 12:00 PM EST

These calls currently take place on the Weill Cornell bridge line at 212-746-7295. Assessors cannot join the therapist call and vice versa, so assessors remain blind to treatment condition, and so therapists do not get information from mid-treatment assessments. Therapist calls will be devoted to discussion of clinical issues, protocol questions, and VR issues as needed.

Q. Inter-site Communication & Shipping Procedures

The multi-site nature of the study necessitates excellent communication between all sites by all parties. Information that will need to be communicated includes:

- 1) Data
- 2) Updates necessary for quarterly reports
- 3) Information for IRBs
- 4) When DCS/placebo supply is running low
- 5) Budgetary issues

Lines of communication should always remain open, and effective systems to transmit necessary information should be created as needs arise.

A weekly call for administrators and program coordinators currently takes place:

• Administrators' call – Mondays at 12:00 PM EST.

The shipment of genetic and cortisol samples between sites must also be coordinated.

Genetic Data:

Genetic samples* should be sent directly to Weill Cornell using FedEx.

1) Storage at room temperature

2) Samples should be shipped when you have 24 samples, or when 6 months have passed - whichever comes FIRST

3) No special handling requirements, though we recommend using a sturdy box and bubble wrap, if available.

4) Ship via FedEx to:

Dr. Charles Glatt Weill Cornell Medical College 1300 York Ave., Room LC-925 New York, NY 10065 212-746-6723

When sending the samples, please include a cover sheet that includes the following information: (1) the number of samples being shipped; (2) the genetic IDs of the samples in the shipment; (3) the protocol title and lead PI; (4) and Katarzyna Wyka's contact information.

Template:

Enclosed please find genetic samples for the study "Enhancing Exposure Therapy for PTSD: Virtual Reality and Imaginal Exposure with a Cognitive Enhancer" (PI: JoAnn Difede, Ph.D.).

Number of samples included in this shipment: _____

Genetic IDs: _____

If you have any questions, please contact Katarzyna Wyka at 212-821-0869.

Please alert Katarzyna Wyka (<u>kew2008@med.cornell.edu</u>) when preparing a batch of genetic samples for shipment to verify that this information is up to date.

*<u>Note:</u> If a participant has been excluded after collection of the genetic sample (and signing the consent form), the sample should still be stored and shipped along with the samples of eligible participants.

<u>Cortisol:</u>

All cortisol samples should be sent directly to Weill Cornell's CTSC lab using FedEx or UPS.

1) Needs to be stored frozen at -80 degrees. According to our cortisol expert at Cornell, usually freezers just come in -4 (household) -20 and -80. She has found that cortisol values dropped when the samples were kept at -20 for a year, and she doesn't know how long that takes to happen, so she thinks storage at -80/-70 is better.

2) The samples MAY be in the fridge or regular freezer for a few days if necessary before they are put into the -80. So it is not an emergency if you collect the samples on a Friday, to wait until Monday to get them into the freezer.

3) Samples are stable for at least a year when frozen at -80, so samples should be shipped when you have 40 samples or at 1 year, whichever comes FIRST.

4) Samples should be shipped in a styrofoam box filled with dry ice. The styrofoam box should be an inch thick and have a few inches of ice surrounding the sample boxes.

5) Samples should be shipped via FedEx or UPS, for Monday to Friday delivery (last shipments accepted at 5 PM) to:

Please send cortisol samples to: Mr. Drury Philip CTSC Core Laboratory @ Weill Cornell Medical College 525 East 68th Street Room F-265 New York, NY 10065 212-746-3469 All shipments should include the <u>Clinical & Translational Science Center</u> <u>(CTSC) Core Laboratory Assay Request Form</u>. The lab is closed on Saturdays and Sundays. If given the option from your carrier, please ensure the samples arrive early in the day (no earlier than 7am). Samples will not be accepted after 5pm.

Please alert Kathy Rosenberg (212-821-0669; <u>kar2015@med.cornell.edu</u>) when preparing a batch of cortisol samples for shipment to verify that this information is up to date.

R. Treatment Fidelity Monitoring

All treatment sessions should be recorded. A percentage of tapes (approximately 10%) will be randomly selected for review by outside evaluators for treatment fidelity to the protocol. The **Program Coordinator** will be provided with a list of the sessions that will be given to the independent assessors and they will provide them to the assessor as they occur. More information regarding this process is forthcoming.

S. Interrater Reliability Monitoring

All assessments should be recorded. A percentage of tapes will be randomly selected for review to determine inter-rater reliability. More information regarding this process is forthcoming.

<u>T.</u> Appendix

- 1. Phone Script
- 2. Tracking Form
- 3. Case Report Form (CRF)
- 4. Medical Screening Form
- 5. Prescription Request Form
- 6. DOD Study Recruitment & Response Log
- 7. Genetic Sampling Instructions
- 8. DOD MINI Rules
- 9. DOD CAPS Rules
- 10. Cortisol Form
- 11. Clinical & Translational Science Center (CTSC) Core Laboratory Assay

Request Form (for shipping)

DOD PHONE SCREEN

Enhancing Exposure Therapy for PTSD: Virtual Reality and Imaginal Exposure with a Cognitive Enhancer

Today's Date: _____

IDENTIFICATION: Identify yourself by name and affiliation,

If returning a call, indicate that you are doing that. If you leave a message, leave only your name, phone number, for whom the message is, and that you are returning a call.

STUDY DESCRIPTION: "We are currently offering 9 sessions of individual treatment to eligible individuals through a study being conducted by _________(site PI). All participants receive exposure therapy, which is the gold standard of treatment for PTSD. Some individuals are randomly assigned to receive traditional exposure therapy, and some are assigned to do the exposure with virtual reality enhancement. In addition, we are assessing the use of d-Cycloserine or DCS –an antibiotic in very low doses because it has been shown to make exposure therapy work faster. The pills are only taken on the days of the exposure therapy sessions, so some individuals will take the DCS 7 times, and others will take a placebo pill 7 times. Are you interested in this study?"

"Eligibility is determined through a detailed, free assessment. Is it okay if I ask some basic questions now so we can see if looks like this study is right for you and see if we should schedule the in-person assessment? First let me get your demographic information."

DEMOGRAPHICS AND GENERAL INFORMATION:

Nam	e:		
Addr	ess:		
Day	Phone#:	н	lome Phone#:
Cell	Phone#:		O.K. to leave messages?
Age:		Date of Birth:	Marital Status:
Sex:	Male:	Female:	
Perm	nission to re	e-contact at a later date (if	not currently eligible for study)? YesNo
How	did you lea	arn about the study?	

IF OBVIOUSLY INELIGIBLE: If answer to any questions below indicate that the caller is obviously ineligible, then thank them for their time and inform them that they won't be able to participate in the study. Provide them with information on other treatments that may be available to them: *"Thank you for taking the time to speak with me. Unfortunately, it looks like this study is not the best option for you. Would you like to hear about other treatment options?"*

If the person asks why only certain Veteran or Service Member groups are being included, explain that the protocols we use in the study will only be meaningful to those who served in Iraq or Afghanistan.

<u>EXPOSURE</u>: "Have you been deployed by the military to Iraq or Afghanistan during Operation Iraqi Freedom or Operation Enduring Freedom?"

"If not, were you a contractor, journalist or have another role in Iraq or Afghanistan during OIF/OEF?"

(Answer to one of the above must be affirmative to continue)

LANGUAGE: Note to screener – if you notice the caller is speaking English with some difficulty, you should inquire as to whether the patient would be comfortable filling out a number of self-report forms and engaging in weekly 90 minute psychotherapy in English. Screener should indicate below if caller is fluent in English.

Y____ N____

Y____

Y

N____

Ν

PREGNANCY:

If female, are you currently pregnant? Y___N___ (Exclusion criteria if affirmative)

Just be aware that pregnancy would preclude participation in the study it were to occur because we don't want to introduce unnecessary medication when the individual is pregnant.

PTSD ASSESSMENT:

Could you very briefly telling me about your experience, or what occurred?

<u>Note to screener</u>: there is no need for the caller to give a detailed account over the phone that might be upsetting. It is just helpful here to get enough information to determine if the major event or events would be a good match for the virtual environments.

When did the trauma occur?		
Have you been diagnosed with Posttraumatic Stress Disorder?	Y	N
Are you aware of any other diagnoses? If so, what?	Y	N

What is your primary complaint? (Note to screener: if the caller has already indicated his reason for seeking treatment, do not ask again and there is not need to get details)

Are you currently receiving treatment for PTSD? YN	

If so, please be aware that you cannot be in an active CBT treatment during the course of this study, or just beginning medication management. You must be stable on psychiatric medication for 8 weeks.

CONTRAINDICATIONS:

This study involves taking medication (one pill prior to 7 separate treatment sessions), which we'll discuss more at the assessment. Are you willing to take medication? Y____N____

I also want to let you know that the following conditions are excluded because the study may not effectively treat individuals with: current substance dependence, glaucoma and seizure disorder. Do any of those apply to you?

Y N____

CONCLUSION: If no obvious ineligibility, tell the patient there is a thorough initial assessment with a clinician to determine eligibility and a physician to make sure there are no medical contraindications. "It sounds like it would be a good idea to have you come in for the assessment. The assessment will start with having our clinician ask you a number of questions to get more detailed information. If from that interview it sounds like the treatment might be a good match for you, we'll ask you to fill out some self-report questionnaires and then meet with a physician to get medical clearance. Then, if it we find the treatment will be a good match, we'll ask you complete a psychophysiological assessment which entails looking at some stimuli on a computer screen while we measure some markers like your heart rate and cortisol. The entire process may take a while, like anywhere from 2 to 5 hours so you should clear some time on your calendar, but we'll provide you with some snacks or lunch and try to make it as easy as possible. After that, you'd be ready to schedule the treatment. Does all that sound all right? Let's schedule that now, then."

Schedule assessment or tell caller the assessor will call them within the next 24 hours to schedule. Thank the caller for being patient with all questions.

If caller wants to know more about the study, you can provide more information.

Phone screen completed by:

DOD WEEKLY TRACKING FORM

Date Last Updated:

	r				r		r				
Participant STUDY ID	Status	First Contact Date	Initial Assessment Date	therapy sessions 1 date	therapy sessions 2 date	therapy sessions 3 date FIRST TIME PILL TAKEN	therapy sessions 4 date	Assessmen t 4A date	therapy sessions 5 date	therapy sessions 6 date	Assessmen t 6A date
	Participant STUDY ID	Participant STUDY ID Status		Participant First Contact Assessment	Participant First Contact Assessment	Participant First Contact Assessment sessions 2	Participant First Contact Assessment sessions 2 PILL	Participant First Contact Assessment sessions 3 date First Contact Assessment sessions 2 PILL sessions	Participant First Contact Assessment sessions 3 date First Contact Assessment sessions 2 PILL sessions	Participant First Contact Assessment sessions 3 date sessions 4 sessions Participant First Contact Assessment sessions 2 PILL sessions Assessment	Participant First Contact Assessment Initial therapy FILL sessions Assessmen sessions

Status:

0- screened by phone, ineligible/not interested

1- screened by phone, scheduled for in person

assessment

2 - assessed in person-ineligible

2a- assessed in person- not interested

3 - assessed in person- eligible- scheduled to start tx

4- in treatment

5 - completed treatment

6 - completed 3-month follow-up

7 - dropout/terminated

10- no show Add status categories as needed

CONTINUED NEXT PAGE

therapy sessions	therapy sessions	therapy sessions	Post-tx Assessment	Date of Eligibility for 3-month	3-Month Follow-up	therapist	assessor	Natas
7 date	8 date	9 date	Date	follow-up	date	name	name	Notes

CASE REPORT FORM

Enhancing Exposure Therapy for PTSD: Virtual Reality and Imaginal Exposure with Cognitive Enhancer

SITE:	WCMC	NICoE	VALBHS
Date:		Screening ID Study ID	
Name of Clinic	zian:		
Volunteer Nam	ne:		
Address:			
Preferred Phon	e number:		
Sh	ould the message be Yes	No	
Gender: M] F [] Year of	of Birth	
Ethnicity/Race	 African American/Black Asian Caucasian Native American/Pacific Is Other: 		ispanic/Latino lot Hispanic/Latino

Clinical Impressions: (only include relevant information regarding diagnosis, substance abuse, psychiatric history, suicidal ideation)

Medication Review Record (past 3 months)

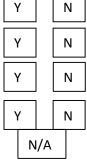
1. Drug	Name:	Dosage:	_Frequency
Starting	Date: / /	Stopping date	/
2. Drug	Name:	_Dosage:	_Frequency
Starting	Date: / /	Stopping date	/
3. Drug	Name:	_Dosage:	_Frequency
Starting	Date: / / /	Stopping date	
4. Drug	Name:	_Dosage:	_Frequency
Starting	Date: / /	Stopping date	
5. Drug	Name:	_Dosage:	_Frequency
Starting	Date: / / /	Stopping date	
6. Drug	Name:	Dosage:	_Frequency
Starting	Date: / /	Stopping date	
7. Drug	Name:	Dosage:	_Frequency
Starting	Date: / /	Stopping date	
8. Drug	Name:	Dosage:	_Frequency
Starting	Date: / /	Stopping date	
9. Drug	Name:	Dosage:	_Frequency
Starting	Date: / /	Stopping date	
10. Drug	Name:	Dosage:	Frequency
Starting	Date: / /	Stopping date	
11. Drug	Name:	Dosage:	Frequency
Starting	Date: / /	Stopping date	
12. Drug	Name:	Dosage:	Frequency
Starting	Date: / /	Stopping date	
Have you	ever taken psychiatric medications?	<i>Yes No</i> If yes, please	list

Inclusion Criteria:

Υ	N
Y	N

Diagnosis of OEF-OIF (Operations Enduring Freedom or Iraqi Freedom) Combat Related PTSD Able to provide informed consent and functions at an intellectual level sufficient to allow accurate completion of all assessment instruments

Literate in English



VRE stimuli consistent with subject's trauma

Medically healthy and willing to take the study drug

If female of child childbearing potential: agreed to use an effective method of birth control (i.e., oral contraceptive, Norplant, diaphragm, condom, or spermicide) during the course of the study, or to remain abstinent from sex, to ensure they do not become pregnant during the course of the study.

			Exclusion Criteria:
Y		N	Lifetime or current diagnosis of schizophrenia or other psychotic disorder, bipolar disorder
Y		N	Participation in a clinical trial during the previous 3 months
Y		Ν	Current evidence or history of significant unstable medical illness or organic brain impairment, including
			stroke, CNS tumor, demyelinating disease, cardiac, pulmonary, gastrointestinal, renal or hepatic impairment
Y		Ν	Current suicidal or homicidal risk
Y		Ν	Alcohol, medication, or illegal substance dependence within the past 90 days
Y		N	Treatment with any other concomitant medication with primarily CNS activity, or treatment with any
			medication that the PI judges not acceptable for this study
Y		Ν	History of seizures
Y]	Ν	Pregnancy or lactation
		PAI	RTICIPANT IS ELIGIBLE FOR THE STUDY IF <u>ALL INCLUSION CRITERIA ARE YES (N/A)</u> AND <u>ALL EXCLUSION CRITERIA ARE NO</u>

No

No

Is participant eligible for the study? Yes Is Major Depressive Disorder present? Yes Medical clearance date: _____

If eligible but did not enter the study, state reason_

Study Completion Timeline:

1. Did participant complete the study: Yes No
If yes, date completed:
In no, date withdrawn:
Reason (detailed)::
2. Did any Serious or Unexpected Adverse Incident or Reaction Occur?: Yes No
If YES, explain:
3. Did participant complete 3-month follow-up: Yes No
If yes, date of 3-month follow-up: / / /

MEDICAL EXAMINATION FORM

Enhancing Exposure Therapy for PTSD: Virtual Reality and Imaginal Exposure with Cognitive Enhancer

Participant Information:

Medical Examination date:

1. History (includes medication, allergies, head injuries, seizures, prior treatment)

2. Current Medical Problems:

3. Drug and alcohol use: please quantify:

4. Potential Side effects reviewed? Yes No

As you go through the side effects list, please quantify baseline level of these symptoms

Study INCLUSION CRITERIA:

- 1. Diagnosis of OEF-OIF (Operations Enduring Freedom or Iraqi Freedom) Combat Related PTSD
- 2. Able to provide informed consent and functions at an intellectual level sufficient to allow accurate completion of all assessment instruments
- 3. Literate in English
- 4. Medically healthy and willing to take the study drug
- 5. VRE stimuli consistent with subject's trauma
- 6. If female of childbearing potential: agreed to use an effective method of birth control (i.e., oral contraceptive, Norplant, diaphragm, condom, or spermicide) during the course of the study, or to remain abstinent from sex, to ensure they do not become pregnant during the course of the study

Study EXCLUSION CRITERIA:

- 1. Lifetime or current diagnosis of schizophrenia or other psychotic disorder, bipolar disorder
- 2. Participation in a clinical trial during the previous 3 months
- Current evidence or history of significant unstable medical illness or organic brain impairment, including stroke, CNS tumor, demyelinating disease, cardiac, pulmonary, gastrointestinal, renal or hepatic impairment
- 4. Current suicidal or homicidal risk
- 5. Alcohol, medication, or illegal substance dependence within the past 90 days
- 6. Treatment with any other concomitant medication with primarily CNS activity, or treatment with any medication that the PI judges not acceptable for this study
- 7. History of seizures
- 8. Pregnancy or lactation

Clearance for current study: Yes No

Potential medical concerns to monitor:

Prescription Request Form

Fax Cover Page

STUDY NAME: Enhancing Exposure The	erapy for PTSD: Virtual Reality and Imaginal
Exposure with Cognitive Ex	nhancer (IRB#)
DATE	
DATE:	# of pages:4
To: Research Pharmacy	
From:	_
Tel:	-
Participant STUDY ID	
Major Depressive Disorder present?	Yes No
Participant Name	
Participant Address	
Participant's DOB	

In attachment please find:

- 1) Prescription for the above referenced study participant.
- 2) The first and the last page of the research study consent form signed by the above referenced study participant.

We will need to pick up the prescription no later than______.

Please contact me should you need additional information.

Thank you.

Log of All Recruitment Efforts

List of IRB approved recruitment materials: *Study letter, dear colleague letter, online posting text*

Date	Type of Advertising	Recruitment Material Used	Name of Recipient	Recipient's Organization	Contact Info (phone, e- mail or mailing address)	Notes
7/26/2011	Site visit to Bronx VA to discuss study	Study flyer and Dear Colleague Letter	Joe Smith, Ph.D.	VA	joesmith@va.gov	Recommended contacting Jane Roberts @ the Veterans Institute
				1	1	

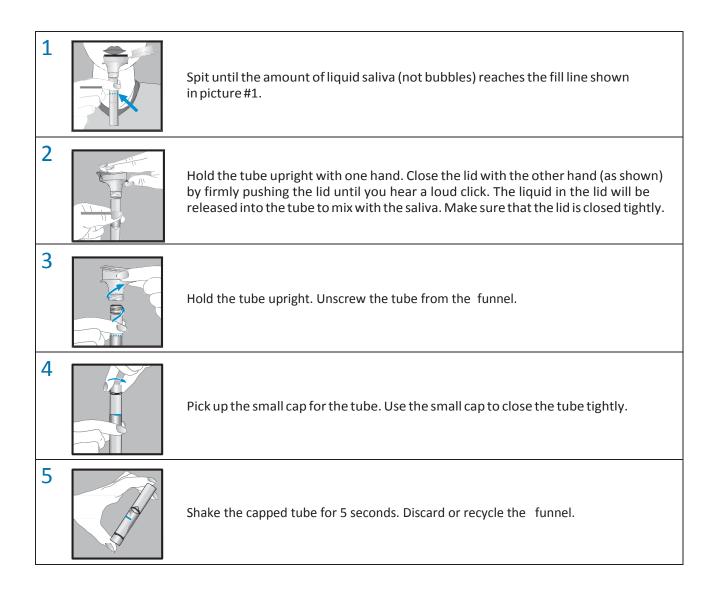


Oragene®•DNA Self-Collection Kit User Instructions

Instructions: Do not eat, drink, smoke or chew gum for 30 minutes before giving your saliva sample.

Do NOT remove the plastic film from the funnel lid.

Preparation: Most people take between 2 and 5 minutes to deliver a saliva sample following steps 1 to 5. Before spitting, relax and rub your cheeks gently for 30 seconds to create saliva. If you find it hard to create saliva, place ¼ tsp of white table sugar on your tongue.

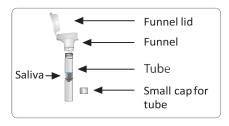


Intended Use: This product is designed for the safe collection of human saliva samples. Warnings: Wash with water if the liquid comes in contact with eyes or skin. Do not ingest. Storage: Store at room temperature 15-30°C

Storage. Store at room temperature 15-30

 ${\ensuremath{\bigtriangleup}}$ Caution: Small cap, choking hazard

PD-PR-118 Issue 1.0





Manufactured by DNA Genotek Inc. Ottawa, ON, Canada K2K 1L1 www.dnagenotek.com

Enhancing Exposure Therapy for PTSD: Virtual Reality and Imaginal Exposure with a Cognitive Enhancer

MINI Rules

Re: Inter-Rater Reliability Rules for Mini International Neuropsychiatric Interview (M.I.N.I.)

General: If criteria is met for a specific disorder but clinical judgment rules this as more accurately accounted for by a primary PTSD diagnosis "NO" will be circled in the diagnostic box; assessor will document any contrary diagnosis made (with the exception of MDE).

If the answer to a question had already been previously elicited on the CAPS, say, "You've already said you have trouble...." and mark "yes" as response.

Module A. Major Depressive Episode

Rule:

- While there is overlap in PTSD symptoms and MDE symptoms (loss of interest, insomnia, poor concentration) those symptoms previously rated (CAPS) for PTSD should be rated independently in MINI Module A.
- If 5 of 9 criteria (DSM-IV) are met for MDE regardless of overlap, a diagnosis of MDE, Current is warranted.
- Question c of A3 (fidgety, restless), should be scored not only based on patient's answer, but also based on behavior in session.
- If "yes" to A3, assessor must determine start/length of episode to accurately answer A4
- If "no" to A3, assessor moves to Supplemental A Module to determine MDE, Lifetime. To accurately determine Supplemental A Module assessor must determine if patient has ever previously met full criteria for MDE (single episode or recurrent).
- If answer to initial question for MDE, lifetime is "yes," section A3 should be asked again with the past period of time as the referrent.

Module A Continued: MDE with Melancholic Features (only for current MDD, not lifetime)

Module B: Dysthymia (Note: this is skipped if there is current MDD).

Module C: Suicidality

Rule:

- C3 (Think about suicide?): May include patient's thoughts about ending their life, potential methods, and/or thoughts about a suicide note.
- C4 (Have a suicide plan?): Method only does not qualify for rating. Must include logistical information such as day, time, place, etc.

Module D: (Hypo) Manic Episode

Rule:

• D2 (irritability): Do not double code if this is related to PTSD. Flesh out if this is independent of the PTSD.

Module E: Panic Disorder Module F: Agoraphobia Module G: Social Phobia

Rule:

- In regards to Panic/Agoraphobia/Social Phobia; assess patient's experience of panic and utilize clinical guidelines to determine if panic attacks are a separate, co-morbid issue or if they are more accurately explained via the patient's primary PTSD.
- Do not continue to assess E4 Questions if Panic Attacks are more accurately explained by primary PTSD.
- Asking about when symptoms began may help discern between an independent diagnosis outside of PTSD, and symptoms better explained by PTSD.
- Rate "Yes" in symptom boxes if symptoms are present even if explained by PTSD
- Rate "No" in diagnostic boxes (Panic Disorder/Agoraphobia/Social Phobia) if symptoms are clinically explained by primary PTSD. Note this accordingly.
- Data will reflect diagnostic categories only

Module H: Obsessive-Compulsive Disorder

Rule:

- Don't double-code if symptoms of OCD better explained by PTSD
- BUT OCD may develop as a result of PTSD and this should be diagnosed.

Module I: PTSD (Skip due to CAPS)

Module J: Alcohol Abuse and Dependence

Rule:

• Due to the nature of this target population clinical judgment will ultimately determine enrollment as it pertains to alcohol dependence. On a case by case basis participants may be enrolled with appropriate documentation.

• Questions elicit information for the past 12 months, so if the answer is "yes" further questioning must elicit information for the past 90 days in order to address inclusion criteria for the study

Module K: Non-Alcohol Psychoactive Substance Use Disorders

Module L: Psychotic Disorders

Rule:

- Paranoia related to PTSD may be elicited, but is not diagnostic.
- Paranoia may also be normative from a cultural perspective. Evaluate these possibilities before determining that a person is psychotic.

Module M: Anorexia Nervosa

Module N: Bulimia Nervosa

Module O: Generalized Anxiety Disorder

Rule:

- Common worries (not necessarily valid for diagnosis) will include finances, employment, and family concerns.
- Anxiety must include a wide variety of areas, be excessive (i.e. financial or medical concerns may be warranted depending on the situation) and cause significant distress/dysfunction.

Module P: Antisocial Personality Disorder

Enhancing Exposure Therapy for PTSD: Virtual Reality and Imaginal Exposure with a Cognitive Enhancer

CAPS Rules

Inter-Rater Reliability Rules for Clinician-Administered PTSD Scale (CAPS)

A. General:

- 1. Rate symptoms regardless of patient attribution
- 2. Time frame is one month; i.e. "from March 26th through today"
- 3. If score falls between two ratings first clarify, if still unsure then rate up
- 4. 0 Never = at no time during the week
 - 1 Once or twice = 1-2 times during the month
 - 2 Once or twice a week
 - 3 Several times a week = 3-4 times per week
 - 4 Daily or almost every day = 5-7 times per week

B. Individual Items

Question 1: Intrusive recollections

Frequency Rule:

• Internal or somatic symptoms (i.e. pain from a combat injury, persistent headaches, aches/pains) are not considered triggers for CAPS purposes. If a patient is having intrusive thoughts as a result of pain/somatic symptoms those will contribute to Question #1 Frequency.

Intensity Rule:

• For intrusive recollections it is possible to have a frequency level indicated with an intensity of zero; patients thoughts may be characterized as unwanted (frequency prompt) but not distressing (intensity prompt).

Question 2: Psychological distress upon exposure to triggers

Common Triggers/Avoided Situations Include: Driving near the edge of pavement, running over trash, trash on the side of the road or blowing, driving home the same route twice, using bottled water, hot spaces/heat, driving on the highway, entering crowds, the VA, combat films, news stories related to Iraq, Veteran gatherings, malls/stores, individuals who remind them of the enemy and smells such as amo, urine, sweat, sewage, bodies burning, spices.

Question 3: Acting/feeling as though the event were recurring (flashback)

Question 4: Recurrent distressing dreams/nightmares

Rate for worst intensity (i.e. less frequent nightmares at intensity of 4 is scored over more frequent nightmares at intensity of 2).

Intensity Rule:

• "4" = At their worst, any inability to return to sleep

Question 5: Efforts to Avoid Thoughts/Feelings

Intensity Rule:

- "3" = If patient avoids thoughts/feelings every time they arise OR if the patient uses distraction (i.e. phone calls, projects, music, "keeping busy")
- "4" = If patient reports any alcohol/drug use as a means to avoid; asked "how often do you use drugs/alcohol to avoid thinking about the event?"

Question 6: Efforts to Avoid Activities/Situations

Common Triggers/Avoided Situations Include: Driving near the edge of pavement, running over trash, trash on the side of the road or blowing, driving home the same route twice, using bottled water, hot spaces/heat, driving on the highway, entering crowds, the VA, combat films, news stories related to Iraq, Veteran gatherings, malls/stores, individuals who remind them of the enemy and smells such as amo, urine, sweat, sewage, bodies burning, spices.

Avoidance can also be exhibited by not doing things as you normally would, such as speeding under a bridge, bringing a friend with you in a crowd, or only going shopping late at night.

Intensity Rule:

- "1" = Patient reports avoidance but is unable to provide a solid example
- "2" = Patient reports avoidance; provides at least one solid example
- "3" = Patient reports avoidance; provides more than one solid example
- "4" = Avoidance is reported as taking up much of the patient's time AND causing impairment in functioning.

Question 7: Inability to Recall Important Aspects of the Trauma

Question 8: Markedly Diminished Interest in Significant Activities

Note: don't confuse lack of interest with avoided activities

Intensity Rule:

- "2" = Definite loss of interest but still has some interest in previous activities OR has developed some interest in new activities
- "3" = A marked loss of interest in most activities (rates accordingly in frequency) OR if they express significant loss of interest in an activity that used to identify them with no replacement activities
- "4" = If the patient reports he/she has zero interest in engaging in any of the activities that previously (before the traumatic event) gave pleasure AND have no interest in new activities

Question 9: Feeling of Detachment/Estrangement

Question 10: Restricted Range of Affect

Note: if patient reports anger, there is not completely restricted range of affect

Frequency Rule:

• Questions refers to patient's ability to experience their full range of emotions – good and bad

Question 11: Sense of Foreshortened Future

Intensity Note:

- Foreshortened future may include patient's feelings of extreme vulnerability (regarding self or family) or personal competence. Includes premature death that is not within the patient's control.
- Foreshortened future will not include patient's suicidal ideation.

Clarifications may include:

Can you picture bouncing your grandchildren on yourknee? Are you constantly waiting for the other shoe to drop? Do you expect danger from around every corner? Do you picture yourself growing old? Lack of achievement in one's life is scored under Intensity by the amount of achievement the patient reports he/she will notattain

Intensity Rule:

- "2" = Patient reports feelings of increased vulnerability; i.e. danger around every corner, waiting for the other shoe to drop
- "3" = Patient reports specific thoughts related to not growing old, aging, dying prematurely or at a younger age than previously imagined. This can include less specific predictions regarding their own death
- "4" = Patient offers a specific prediction regarding his death; i.e. will die by age XX. Patient is convinced, regardless of odds/facts, that he/she or family members will exprience harm or die at a younger age than previously thought

Question 12: Difficulty Falling/Staying Asleep

Frequency/Intensity Rule:

• Calculate total hours per night AND total hours desired according to extreme range (i.e. patient states they are getting 4-5 hours of sleep, count 4 hours. Patient reports a desire for 7-8 hours, count 8 hours).

Question 13: Irritability or Outbursts of Anger

Intensity Rule:

- Intensity is rated "in general" as opposed to "at its worst"
- "3" = Patient reports hitting a wall/car seat, throwing objects, slamming a door or anger sticks around for a considerable amount of time
- "4" = Any interpersonal aggression/physical violence

Question 14: Difficulty Concentrating

Intensity Rule:

- Rated "in general" as opposed to "at its worst"
- "3" = Patient reports having a difficult time concentrating but can finish a task after taking a break and returning
- "4" = Consider patient's ability to follow the interview as difficulty with this may warrant a rating of "4"

Question 15: Hypervigilance

Intensity Rule:

- "2" = Patient reports being watchful in public/unfamiliar places (chooses a particular place to sit in a restaurant)
- "3" = Patient reports feeling alert in public places as well as at home or persistent worries regarding family's safety
- "4" = Guarded behavior during interview or excessive safety checking behavior (considerable amount of time/causes impairment in functioning)

Question 16: Exaggerated Startle Response

Intensity Rule:

- "3" = Patient reports feeling a more intense reaction than just "jumpy" with some sustained arousal
- "4" = Patient reports self-defense postures, jumping, ducking, crouching, reaching for a weapon, "hitting the dirt", along with sustained arousal. Also counted towards a "4" are offensive reactions such as grabbing someone or reacting aggressively.

Question 17: Physiologic Reactivity upon Exposure to Triggers

Common Triggers/Avoided Situations Include: Driving near the edge of pavement, running over trash, trash on the side of the road or blowing, driving home the same route twice, using bottled water, hot spaces/heat, driving on the highway, entering crowds, the VA, combat films, news stories related to Iraq, Veteran gatherings, malls/stores, individuals who remind them of the enemy and smells such as amo, urine, sweat, sewage, bodies burning, spices.

Frequency Rule:

- Interviewer may reiterate patient examples from previous questions OR suggest symptoms if none offered spontaneously (i.e. nausea/vomiting, increased heart rate, sweating, lump in throat, tingling, dizziness, difficulty breathing, muscle tension)
- Physical reactions are NOT in response to nightmares but may be reported at night or upon wakening from sleep (i.e. wakes due to noise).

Intensity Rule:

- May suggest a scale of "mild, moderate, severe, extreme" to the patient
- Consider number of symptoms and degree of sustained arousal when rating

 Date:
 Psychophys. Assessor:

 Participant Screening ID:
 Assessment Type:

Cortisol Form

Saliva Cortisol Sampling

There will be 4 saliva samples collected for cortisol at the following timepoints:

Have participant rinse mouth out with water.

- 1. Prior to prepping participant and putting on electrodes (Sample 1, baseline—record the time)
- 2. After finishing the participant prep (Sample 2—record the time)
- 3. After finishing the AXBX session and the exit report (Sample 3—record the time)
- 4. After finishing the VR session (Sample 4—record the time)

Event	Time
Water	
Sample 1	
Sample 2	
Sample 3	
Sample 4	

Notes:

Tube labels:

Screen ID: WCMC_SubID

Tube #:1, 2, 3, 4

Other: Date, Assessment Type (baseline, posttreatment, 3-month follow-up)

(212)746-8348
6-3480
6-7698

Clinical & Translational Science Center (CTSC) Core Laboratory Assay Request Form (A separate copy of this submittal form is required to accompany each sample or time series. For batches of identical assays, fill in one form and attach a list of samples)				
Requestor: Dr. JoAnn Difede	Phone number: _212-746-3079			
	E-mail address: jdifede@med.cornell.edu			
Department/Institution:Psychiatry/WCMC				
Principal Investigator: JoAnn Difede IRB#:1005011047 (required) Project Title: Enhancing Exposure Therapy for PTSD: Virtual Reality and Imaginal Exposure with Cognitive enhancer.				
Sample:	Submission date: / /			
Sample ID #: (Requestor's reference number)*	[] Male [] Female			
	Investigation date: / /			

If time series, list all time points: _____

Assays Requested:

Tube Type (e.g. red-top, blue-top, etc)	# of Tubes	Volume/ tube (ml)	Sample Type (e.g. blood, urine, etc)	Assays Requested (e.g. total testosterone, TNFα, etc)	Special Procedures, if any (sample preparation, extra aliquots, etc)
Cotton for Saliva collection		0.2 ml	Saliva	Cortisol	Squeeze cotton to release saliva into a vial, freeze @ -20*C.

Identify unusual biological hazards:

Received by _____ Date __/ /

* Note: Privacy regulations require that the samples be identified by reference numbers (and investigator's name) only. The Core Lab *cannot accept* samples for assays labeled with the *subjects' names*.

"Enhancing Exposure Therapy for PTSD: Virtual Reality and Imaginal Exposure with a Cognitive Enhancer"

Clinician's Treatment Manual

October 2011

Session 1

Overview:

- Present session agenda (5 min) page 2
 Provide overview of treatment (30 min) page 2
- 3) Gather information from patient (35 min) page 4
- 4) Breathing retraining (15 min) page 5
- 5) Assign homework (5 min) page 6

Forms Needed:

- 1) Index Trauma Interview
- 2) Breathing Instructions
- 3) Rationale for Treatment by Prolonged Exposure

1) Present session agenda

"Thank you for filling out the self-report forms. As you know you'll be doing that each week and I'll be looking them over. Your answers should provide us with important information about any changes in your symptoms. Today's session will be an introduction to our treatment. I'll tell you a bit about what to expect, some basic information about our treatment, and an overview of the interventions we will use and how they will target the symptoms and problems you are having. Then I'll ask you to tell me more about your symptoms, your experience, and yourself in general. Finally, we'll introduce and practice our first skill, a breathing technique that should be helpful for you. This entire treatment is collaborative. So throughout the entire session and treatment, feel free to ask questions and express any concerns you might have. It's best we talk about everything openly so we can get the most from our time together so please feel free at all times to honestly discuss any problems, concerns, etc. that may arise. Before I begin, do you have any questions?"

2) Provide overview of treatment

Introduction: "At the assessment visit, the clinician reviewed all of your symptoms and problems and found that you have posttraumatic stress disorder, which we call PTSD for short, as well as..." (*List other diagnoses/problems*). This treatment is designed to treat all of the symptoms of PTSD, but many of the interventions we will use are effective in reducing feelings of depression and generalized anxiety as well.

The good news is that PTSD is a disorder for which there are effective treatments, and our treatment program includes several interventions that have been shown to be very helpful in reducing symptoms and helping people recover from trauma. I will review the treatment plan and interventions now, and we will discuss them in detail when they are introduced in later sessions."

Treatment Duration: "This treatment involves our meeting weekly for 8 more sessions after today, 9 total. Each session will be 90 minutes long with an additional 30 minutes prior to the session for taking the pill and filling out paperwork. In addition to the treatment sessions, as was discussed with you at the assessment, the treatment program includes assessment visits after Sessions 4 and 6 so we can track your progress, as well as an assessment at the conclusion of treatment, and one again 3 months later. I will remind you about those visits after the sessions, and the clinician who will conduct those evaluations will contact you to schedule the appointment. You will receive a reimbursement for the two assessments following the end of treatment."

Goals of Treatment: "The goal of this treatment is to help you deal with what happened in Iraq [or Afghanistan] and to hopefully decrease the posttraumatic stress symptoms that you have been experiencing. The way we view PTSD is that someone is haunted by something that happened in their past. What we want to do in treatment is to help them process the traumatic experience and come to some peace with it. **To that end, several techniques will be utilized to address two of the primary factors that maintain post-trauma symptoms: avoidance and unhelpful thoughts and beliefs.** We know that avoiding thinking about the trauma can lead to symptoms of PTSD becoming chronic. When you allow yourself to think about the trauma in a safe environment, you are able to challenge some of the unhelpful thoughts and beliefs. The core of the treatment will be exposure therapy, not exposure as in wartime, but helping you confront the memory of what happened in a therapeutic manner, so it gets easier. In trauma research, exposure therapy has been found to be the most effective technique for helping PTSD."

Treatment Group Assignment/Exposure: "This study randomly assigns people to do either traditional imaginal exposure which has been shown to be the most effective treatment for PTSD, or to do exposure while immersed in a virtual environment. You have been assigned to the ______ condition (tell patient here what type of treatment they will be receiving)."

<u>If imaginal exposure</u>: "Imaginal exposure requires a person to retell his or her trauma experience repeatedly in the present tense as if it is happening now. Though we may tend to avoid the memories because they are painful, this only serves to perpetuate our symptoms. By approaching and facing the memories in a controlled manner through the exposure exercise, they can cease to have such control over your life. Therefore, during the exposure, the person is instructed to narrate the experience in the present tense, describing out loud everything that s/he sees, smells and hears. Though this may seem daunting and may indeed be a difficulttask, it is a very important part of treatment that works to help you process what happened. By going through it repeatedly, it does get easier."

<u>If virtual reality</u>: "Imaginal exposure requires a person to retell his or her trauma experience repeatedly in the present tense as if it is happening now. Therefore, the person is instructed to narrate the experience and in the present tense, describing out loud everything that s/he sees, smells and hears. In order to enhance the reliving component, we are building on the traditional exposure technique by using the virtual reality as a tool for the exposure. The virtual reality helps to engage your senses, thereby enabling you to reexperience the memory of the trauma more realistically. You will use the virtual reality to aid in the retelling of your experience repeatedly over the course of treatment. Though this may seem daunting and may indeed be a difficult task, it is a very important part of treatment that works to help you process what happened. By going through it repeatedly, it does get easier."

(Allow patient here to voice any concerns about treatment assignment)

DCS/Placebo: "As you already know, in this study we are also trying to test whether a drug, D-cycloserine (DCS), will enhance the exposure helping it to work faster. DCS is an antibiotic that has been used for decades in the treatment of tuberculosis. More recently, studies have shown that it may enhance learning, specifically extinction learning which is the kind of learning believed to occur during exposure. To test this, you will be randomly assigned to take the DCS or a placebo (sugar pill) only on the days we will be doing the exposure in session. The exposure will take place in sessions 3 through 9, so that means a total of 7 pills. This study is double-blinded, which means that neither you, nor I, nor the assessor will know which pill you are getting. You will take the pill 30 minutes before the

session begins, so I'll give you the bottle when you arrive, then you'll fill out the self-reports and we'll start at our designated time."

Other techniques: "A couple of other techniques will also be used throughout the course of treatment and I will briefly review them now, though we will discuss them in detail when they are introduced in later sessions.

Breathing: Following a trauma, people often find that their bodies are at a constant state of alertness. Symptoms such as irritability and difficulty sleeping and concentrating are common. Relaxation and breathing exercises are instrumental in addressing these symptoms. In this treatment we use a brief breathing relaxation method to help our bodies relax and decrease these symptoms at times when it's not the right time to do exposure, like going to sleep or at work or while driving.

Cognitive Distortions (unhelpful thoughts): A traumatic event can also change a person's view and perspective about him/herself, about other people and about the world in general. Sometimes, these thoughts are inaccurate. During treatment, we will discuss whether your views about yourself, and about the world in general, have changed and evaluate the accuracy and helpfulness of these beliefs and thoughts."

Treatment Adherence: "As you may have already guessed, **this treatment can be intense, and at times distressing**. The reason that we do it, however, is because it is the treatment that has the most success. You might find yourself thinking of cancelling sessions or not showing up, since you know the sessions might be tough. But this is a short-term treatment for only 9 sessions. Your symptoms have been distressing and causing problems in your life for [how long]. If you can bear with at the most, 8 more appointments, hopefully you can have some relief from the problems that have been bothering you.

If you experience urges to not come to your session, it is <u>very</u> important that we talk about it. I will <u>not</u> be offended. We know that it can be challenging for people to confront their worst fears, but we also know that the interventions included in this treatment, especially the exposure, are the most effective PTSD treatments out there, and our experience is that most people who stick with the treatment find it worthwhile.

These interventions really do work best if you come each week. This is really important once we start the exposure exercises. If for some reason your schedule changes or things happen in your life that make regular attendance difficult, it is very important for us to talk about it and I will be as flexible as possible in scheduling the sessions to be convenient for you."

Elicit any questions: "I know that was a lot of information I just provided. Do you have any questions about anything at this point?"

If they say they are nervous or not sure they want to do this, the therapist can respond, "that's exactly why you need to do this. If it were easy or didn't bother you, we wouldn't need to do this. It does take courage and we don't use that word lightly. We define courage as being scared and doing it anyway because it's the right thing to do."

3. Gather information from patient

"Now that I've told you about the treatment, I'm going to ask you a bit about yourself. I have the information from the assessment, but I want to give you the chance to tell me in person about why you're seeking treatment, what problems you find most distressing, and a bit about yourself in general." (Fill out trauma interview form during this period)

Information to elicit from patient:

- Why did he/she seek treatment?
- What symptoms are most distressing?
- Describe their deployment(s).
- Some information on the most distressing trauma identified in the pre-treatment assessment. If there is a close second, it can be noted and will be the focus of exposure if there's time for an adequate response.
- Other trauma history.
- Social situation and any current social stressors
- Occupational situation and any occupational or financial stressors
- Social support and resources they can rely on during this treatment
- Suicidal ideation and contracting for safety.

4. Breathing Retraining

Make sure that you are set up to record the breathing instructions for the patient to take home.

"There is a direct link between breathing and emotional state. Very often, when people become frightened or upset, they feel like they need more air and may therefore breathe fast or hyperventilate. Hyperventilation, however, does not have a calming effect. In fact it generates anxious feelings. Unless we are preparing for fighting or fleeing from real danger, we often don't need as much air as we are taking in. When we hyperventilate and take in more air, it signals our bodies to prepare for fighting or fleeing and to keep it fueled with oxygen. This is similar to a runner, taking deep breaths to fuel his body with oxygen before a race and continuing to breathe deeply and quickly throughout the race. Hyperventilating also produces bodily reactions that resemble fear. These bodily reactions, in turn, can make us more afraid. Usually, when we hyperventilate, though, we are tricking our bodies. And what we really need to do is to slow down our breathing and take in less air. So learning to breathe slowly and calmly provides a useful tool for reducing stress or tension.

Most of us realize that our breathing affects the way that we feel. For example, when we are upset, people may tell us to take a deep breath and calm down. Again, however, we think that it is not really **deep** breathing that helps, but **slow** breathing. In order to calm down or relax one should take normal breaths and exhale slowly. It is exhalation that is associated with relaxation, not inhalation. Also, it can be helpful to associate your exhalation with a word that has a calming or relaxing effect. So while you exhale, say the word **CALM** or **RELAX** silently to yourself very slowly. Like this, c-a-a-a-a-a-a-a-m."

When suggesting a cue word for relaxation, ask the patient if he has a preference for a specific word. Most people find the word **CALM** or **RELAX** helpful.

NOTE: Patient will be given a recording of the breathing exercise. This can be a previously recorded version in the therapist's voice on a CD, or it can be recorded now on a recording device of the patient's choice.

Model for the patient how to inhale and exhale slowly through the nose, and then ask the patient to perform the exercise according to the following instructions: "In addition to concentrating on slow exhalation while saying **CALM** to yourself, I want you to do one other thing to slow down your breathing. After you finish exhaling, and your lungs are empty of air, I'd like you to pause for a count of 4 before inhaling again. So it will go like this: "Inhale (a normal breath).....exhale (very slowly)

....Caaaaaaaaaalllllmmmmm"...pause....2...3...4...Inhale (normal breath)......exhale...,etc.".

Repeat the entire breathing sequence for 15 breaths:

"Normal breath......Caaaaaallllmmm"...pause....2...3...4...normal breath..... Caaaaaalllmmm", etc. Thus while he is exhaling slowly, you will say the word "calm" aloud, dragging it out very slowly. Fade away the instructions while allowing the patient to continue.

Give patient breathing retraining handout

5. Assign Homework and End Session

Homework:

- Practice breathing retraining three times per day
 - Read "Rationale for Treatment by Prolonged Exposure" handout

Remind patient that the more they practice the breathing, the better trained their body will be to relax and to use it when they really need it.

End session:

Elicit any questions, doubts or concerns

Instill hope and excitement for starting this work together

Make sure next session time is scheduled – it is okay also to schedule all 8 sessions and write them down for patient

Give therapist's card with contact information

Give patient rationale for treatment by prolonged exposure

Session 2

Overview:

1)	Review homework (5 min)	page 7
2)	Present session agenda (5 min)	page 7
3)	Discuss common reactions to trauma and normaliz	e patient's reactions (45 min).
		page 7
4)	Present detailed rationale for exposure (20 min)	page 9
5)	Introduce SUDS Scale (10 min)	page 11
6)	Assign homework (5 min)	page 11

Forms Needed:

1) Common reactions to trauma

1) Review homework

- Check-in on week in general
- Check-in on breathing practice
- Check-in on reading rationale for treatment by prolonged exposure
- Check-in on perceptions regarding treatment

2) Present session agenda

"This session we will focus in detail on common reactions to traumatic events, and see how your symptoms may or may not be similar to what we discuss. Then I will present a more detailed rationale for the exposure therapy we will begin next week."

3) Discussion common reactions to trauma and normalize patient's reactions

<u>Note</u>: make this a conversation rather than a lecture. This can best be done by asking the patient for their experience after each symptom or two, saying "Is that something you've been experiencing?" after each cluster of symptoms.

"Now I'd like to give a detailed description of what PTSD is, and then find out from you which parts of the description most apply to you."

Normalizing symptoms/Overview of PTSD: "It is normal for people who are exposed to a traumatic event to feel anxious for a short while, especially when they are initially confronted with things that remind them of the trauma. These feelings usually resolve over time, but some people go on to develop PTSD, which consists of 3 groups of symptoms that persists in trauma survivors for one or more months. The primary emotions inherent in PTSD are **fear** and **anxiety**. Sometimes the feelings of anxiety may be a result of being reminded of the event; at other times, it may seem as though these feelings come out of the blue. The feelings of anxiety and fear that are experienced can be understood as a natural response to a dangerous and life-threatening situation that may last after the trauma has ended."

Reexperiencing: "We view PTSD as when someone is haunted by something that happened in the past. The haunting nature of PTSD comes out in the reexperiencing symptoms. Some

people have thoughts and images about the trauma that keep returning even though they try to push them away; some people have nightmares about the trauma, or have flashbacks in which it seems as though it is happening again. You might find that right now, certain triggers and cues remind you of what happened and activate your fears. These triggers may be certain times of the day, certain places, an argument with someone you care about, a certain smell, or a noise. Some people become very distressed when reminded of the trauma, and some experience physical reactions to reminders, like a pounding heart, sweating, nausea, or headaches. What re-experiencing symptoms have you noticed?"

Avoidance: "In general, people with PTSD are very avoidant. A common strategy to alleviate the anxiety and distress associated with a traumatic event is to try to avoid places, people, or other reminders of it, or try not to think about it or talk about it. This is a human reaction – if you know putting your finger in a socket will hurt, you avoid doing so. So too, if you know thinking or talking about it will hurt, you try to avoid it. The problem is that as logical as this sounds, we know from a lot of research that in the long run avoidance actually makes the fear and anxiety worse. We're going to discuss that at length soon. Another avoidance symptom is that some people find that they have memory gaps about the trauma; some find that they shut down emotionally after a traumatic event. They might become emotionally numb, have problems feeling happy or enjoying things. They may feel distant or cut off from loved ones, like they can't trust anyone or that no one understands or cares about them, leading them to withdraw from others and isolate themselves. Some people start thinking that bad things will happen to them, and they are always waiting for the other shoe to drop. What have you been avoiding? Has anyone close to you complained that you are emotionally numb or distant?" **NOTE:** When discussing avoidance, psychoeducation should include the negative aspects of avoiding situations, people or places. However, no in vivo exposure should be directly suggested or assigned. If over the course of treatment the patient reports he has begun approaching situations on his own, this should be congratulated and encouraged.

Hyperarousal: "The last group of symptoms is the hyperarousal symptoms. This is the body staying at a red alert level. It's as if the body is saying 'I was not prepared for that terrible thing, so now I'll be on alert so I'm not caught unaware again.' While this makes sense, our bodies aren't built to do this for such a long extended period of time. This leads to problems with sleeping and concentrating, or being especially irritable or easily angered. People may also feel jumpy and easily startled, and find that they are always watchful and "hypervigilant" to any possibility of danger. Have you noticed physical hyperarousal symptoms?"

Impairment/Co-morbid problems: "As you can see, these are logical consequences of a trauma. The problem is, that they are not adaptive for life, and interfere significantly with your ability to live life happily. It is common for people with PTSD to also have depressed mood, and a lack of desire to do things they used to enjoy including decreased interest in sex. Sometimes people try to self-medicate with alcohol or other substance use, which leads to a whole host of other problems. The symptoms of PTSD often affect relationships with friends and family as well as occupational functioning. What have you had problems with?"

Cognitions: "Trauma exposure can be associated with changes in how survivors think about themselves. So, in addition to thinking that the world is a dangerous place and that others can't be trusted, the self-image might also be changed. We often hear people who tell us that the incident has changed them. They say 'Before, I was not afraid of anything. I could cope with any kind of stress no matter how difficult the situation was, and get along with others. And now I am afraid of my own shadow and I cannot cope even with minor problems'. Some survivors have feelings of guilt, shame, or self-blame, which are typically associated with thinking that what happened was their fault. It is common for survivors to second guess their

reactions and blame themselves for what they did or did not do. People sometimes feel out of control of their own reactions. Our treatment will target these symptoms and hope to ultimately improve overall quality of life and help you feel more in control. Have you noticed you have unhelpful thoughts about what happened?"

Elicit information from the patient about his/her symptoms: "So does any of that sound familiar? What parts of that description are relevant to what you are going through?"

Revisit most distressing symptoms and suicidality as needed.

Give the patient the "common reactions" handout for review at home. Ask them to read it and come in next session with any questions or thoughts that arise. They should feel free to share the handout with family or friends.

4) Present detailed rationale for exposure

Rationale for exposure: "As we have mentioned previously, exposure is the first line of treatment for posttraumatic stress disorder because of its proven effectiveness. You may remember that during the exposure, you will relate your traumatic experience in as much detail as possible, repeatedly, in a structured way. I am going to take some time now to explain the mechanism by which exposure works."

Processing/File cabinet metaphor: "People take their experiences throughout life and file them away in their minds. When a trauma comes along, it is so immense and unfathomable we do not know how to file it. I like to give an example of a file cabinet. You take every file and file it in its proper place in the file cabinet. Then one file comes along which does not seem to have a place. It is large and complicated, so rather than sort it out, you just open the file drawer and throw the file on top and try to forget about it. The problem is that in the future whenever you open the drawer, the file is right there staring you in the face. The only way to have it stop being right there, is to take the time to really address that file, going through every single paper, so that you can file it away in its proper place.

"This comparison is quite apt to a trauma. We file away all of our experiences. Then a trauma occurs that simply does not fit into our cognitive sets – there is no place to file it. We think that by ignoring it, it will go away, but in fact whenever we "open the file drawer" or access our memory banks, there it is staring us in the face. The exposure exercise is designed to force us to truly sort through the experience. By repeating the experience over and over it allows our mind to make some sort of sense of it and file it away. Once it is filed, it is no longer as intrusive as when it was not dealt with.

"This technique may seem counterintuitive, as our natural reaction is not to dwell on disturbing memories; however, it has been shown to work. I have faith in this technique because I have seen it work with many patients, though I know you may doubt it because you have not seen it work as I have. But I am going to walk you through it and we'll work at a pace that you can manage. It is certainly not an easy task and takes courage to face these memories head on. However, avoiding the memories simply doesn't work. While avoidance may help reduce the anxiety for the moment (i.e., work in the short-run), in the long-run it maintains PTSD symptoms and prevents new learning. The only way to move forward, is through it. You can think of it like a broken nose. When you break your nose, the doctor often has to rebreak it in order to set it so it will heal properly. The rebreaking certainly hurts, but otherwise the nose won't heal, so the intervention is necessary. This may be difficult, but it is

the path to proper healing. It is also a short term treatment. You have been living with these symptoms for an extended period of time. This treatment is only 7 more sessions. Although it may be painful initially, it becomes less painful as exposure is repeated."

Distinguishing between exposure and intrusive thoughts: "Some people tell us that they think about it all the times anyway, so how is this different? The way most people with PTSD think about the traumatic event is not therapeutic. It's like if the event were a book, the book falls open and they read a line, and they hate it and slam the book shut. Then something opens up the book again, they read a line, and they hate it and slam the book shut again. In contrast, this treatment consists of therapeutic exposure. We will open the book and read it all the way through over and over again to try to make some sense of it and to help you feel in control if and when you want to read it.

"So the central idea behind this type of treatment is that the trauma needs to be emotionally processed, or digested and organized, so that it can become less painful. The process is similar to the grief process: when a loved one dies, it is extremely painful, but by expressing that pain like through crying, and by spending the time focused on it at the funeral, it gradually becomes less painful. Eventually, we can think about that person without crying, although the loss will always be sad."

Distinguishing between event and memory: "Your body is also reacting to reminders of the event as if the event was happening again. Exposure to the memories **helps the body to distinguish the memories from the event itself, recognize the memory is upsetting but not dangerous, and importantly, realize you can handle the memories. Then, as you do the exposure repeatedly, the overwhelming emotion that accompanies it will decrease.** So the memory will become something sad or upsetting, but not something overwhelming that controls your life.

So to summarize, by confronting the memories through the exposure, it helps to:

- 1) block avoidance
- 2) process and organize the trauma
- 3) discriminate the memories from the trauma itself
- 4) make you realize that memories are not dangerous and that you can handle them – giving you mastery over this experience
- 5) As you confront the memory repeatedly, anxiety and distress decreases through a process known as habituation
- 6) Gives you back a feeling of control and competence

Facing the exposure gives you control over the memories that feel like they are controlling you.

In this process, you'll need to try to confront the memories and any emotions they bring up. Any attempts to distance yourself from those emotions can negatively impact the treatment. This is true both during the session, and for the day or so afterwards when your brain is still processing the exposure. So for the duration of this treatment, feeling bad emotions isn't the enemy, but avoiding them is. For that reason, as much as possible you'll need to avoid taking medications or substances that you don't take on a regular basis that will interfere with this process. That includes benzodiazepenes like Xanax, Klonopin, Valium and Ativan and pain medication that you take prn. If you take any of these medications, they should be taken on a regular schedule, and not in response to anxiety or distress that might come up from the session. If you don't take them on a regular schedule, you should not take them on the day of the session before the start of the session, or for about 24 hours after the session. This also includes alcohol or illegal drugs, which you should not take for the day or so prior to the session, since we don't want you coming in hungover, and for at least 24 hours following the session, or in response to distress that comes up from these memories. Do you have any concerns about that?

5) Introduce SUDS Scale

"For your account of the trauma, we will be evaluating your discomfort at the time by using a SUDS scale. The acronym SUDS stands for subjective units of distress. It is a scale from 0 to 100. Distress may mean feelings of anxiety, anger, fear or whatever emotion it may evoke. A SUDS rating of 100 indicates that you are very distressed, the most you have ever been in your life and 0 indicates no distress at all. I will be asking you for your SUDS before you begin the exposure, and then after it's completed I'll ask for your SUDS at the end, and I'll ask you to report the highest SUDS you reached during the exposure. You'll just give a number indicating how you are feeling RIGHT NOW, SITTING IN THE ROOM WITH ME, not how you were feeling at that point in Iraq [or Afghanistan]."

Elicit anchors from the patient of a '0' rated time in his/her life and a '100' rated time in his/her life.

6) Assign Homework

Homework:

- Continue to practice breathing retraining
- Read "common reactions" handout several times

Session 3

Overview:

1)	Review homework (10 min)	page 12
2)	Present session agenda (5 min)	page 12
3)	Present brief review of rationale for exposure (5 min).	page 12
4)	Instructions for exposure (10 min)	page 13
5)	Conduct exposure (30-45 min)	page 14
6)	Process exposure (15-20 min)	page 14

Forms Needed:

- 1) SUDS data collection
- 2) Presence questionnaire

Prior to session, administer SYMPTOM CHECKLIST via REDCAP. Symptoms should be indicated as yes if they represent a change from normal, <u>and are possibly or likely due to the treatment.</u> For further information about symptom checklist and adverse events see the policy and procedure manual.

1) Review Homework

- Check-in on week in general
- Check-in on breathing practice
- Check-in on reading common reactions to traumatic events
- Check-in on perceptions regarding treatment

2) Present session agenda

"This session we will start by briefly reviewing the rationale for the exposure. Then I will give you the specific instructions on how to do the exposure, and then we'll finally conduct our first exposure session. After the exposure, we'll spend some time processing it before the end of the session. Do you have any questions about the agenda?"

3) Brief review of rationale for exposure

"Just to review from last time, in the long-run, avoidance maintains PTSD symptoms. The goal of the exposure is to revisit the memory in a controlled and structured environment, in order to help you to process and organize this trauma memory so that it will no longer feel overwhelming to think about, nor will it intrude upon your life. By repeatedly confronting your fear, and connecting the feelings about the event with the memory where it belongs, you will learn that the memory, and you will be more in control of it. The repetition of the memory will facilitate habituation and decrease anxiety and other symptoms of PTSD. The memory and experience will remain a part of you, but you will be able to choose to think about it if/when you desire to do so."

Elicit any questions or doubts about the rationale.

4) Instructions for exposure

Relating narrative details: "I'm going to ask you to start at a point just prior to the incident and recount, in full detail, a narrative of the trauma. It is key to the exposure to really immerse yourself in the memory so that it feels almost like you're back there, even while you know that you are really here in this room and safe and it is just a memory. We say it's like keeping one foot here (in the present) and one foot there (in the past). It is very important to try and experience all the feelings and emotions that are connected to this event, and that you not try to hold back the emotions though it might be your inclination to do so.

In order to increase your engagement in the memory, you should tell it in the present tense as though it were currently happening, for example, 'I get my orders and find I am suppose to go to... I am driving down... I see...".

As you relate the event, add every detail you can think of, using all of your senses to describe what you are seeing, hearing, smelling, thinking, and feeling throughout every aspect of the experience.

As you relate the details, focus on putting yourself there and letting yourself feel any emotions that arise. Remember that avoidance is the enemy, not emotions, so if you feel negative emotions we don't want to avoid them, and in fact that means we are doing what we need to do. We are going to shoot for a target time of 30-45 minutes for the exposure, since it has to be long enough for the habituation process to start occurring. That means that when you're done, I'll ask you to start again right back at the beginning without taking yourself out of the memory. I may also ask some questions or clarifications, but I'll try to minimize that since I don't want to disrupt your immersion in the memory.

If imaginal exposure: "Please keep your eyes closed for the entire exposure exercise and focus on putting yourself there and allowing yourself to feel whatever emotions arise. Do you have any questions before we start?"

If virtual reality: The patient will recount the most traumatic memories while immersed in the virtual world. The patient will recount his or her memories with eyes open and the therapist will match the virtual reality environment to the patient's recounting as much as possible. Though one of the clinician's goals is to re-create a virtual scenario with as much content as possible that matches the patient's reported traumatic memories, it is not likely, nor necessary, that the clinician match the scenario exactly to the trauma. In this first session, the therapist should minimize the amount of sensory elements that are added, and may utilize less intense elements; for example, a small explosion instead of full IED stimuli. Depending on the patient's engagement, they may just stay in the environment without many added elements.

"We will be using the virtual reality to aid in the exposure exercise. You will focus on your own experience and tell it while immersed in a virtual environment. Let me explain the function of each piece of equipment. You will be wearing headphones and a head mounted display that will allow you to view three-dimensional computerized images. The virtual world is programmed such that I control what you experience in VR by touching pre-programmed keys on the keyboard and you can control your movements by looking around and moving with a joystick. As you view the scenes through the head mounted display, I will be watching the same images simultaneously on the computer screen. I will speak into a microphone that will allow you to hear me through your headphones, and I can hear when you speak to me. In addition to the sights and sounds, you will be sitting on a platform that may vibrate in conjunction with certain sounds to add a tactile element. The sensory elements will be added gradually throughout the sessions, at a pace individualized for you. The elements and environment may not be a perfect match for what you experienced, but our experience has shown us that a match is not necessary, and an approximate environment, or cues that trigger your memory are sufficient. We are using the virtual reality to help you engage with the memory. If certain aspects aren't a great match, try not to let yourself get distracted by them. Do you have any questions before we begin?"

(The clinician should direct the patient to sit in appropriate chair and put on the headphones and head mounted display and introduce to the HMD and components).

For all: "Okay, so as we discussed, you'll begin describing the events leading up to the incident on that day, describing the sights, sounds, smells, your thoughts and feelings, and as many details of the experience as possible, speaking in the first person and the present tense. Before we start can you tell me your SUDS score right now sitting in the room?" Record response on SUDS rating form (see appendix). "Okay, let's get started. Its [date] and you are [location]. Tell me what's happening now."

5. Conduct exposure

During the exposure, **prompt for present tense if necessary** by repeating patient's last phrase back to them in the present tense, e.g., "I AM driving back to the FOB." **Offer periodic encouragement** such as:

"You're doing great" "Stay with it " "What happens next?" "This is exactly what you need to be doing; keep going" "You're safe here, go on" "I know this is very painful for you to talk about, but you're doing a good job"

At the end of the exposure ask for a final SUDS score and an estimate of peak SUDS that was reached during the exposure, and record the numbers into the SUDS form.

Target time for exposure exercise: 45 minutes.

6. Process exposure

Instructions for clinician: In addition to fear extinction which occurs during exposure therapy, you are attempting to help the participant to emotionally and cognitively process the event by placing it in a broader context, allowing it to be examined from different vantage points, to eventually gain a sense of peace with the experience. You are trying to make certain experiences explicit, for example, that by staying with the memory repeatedly, it becomes less distressing. You will try to identify unhelpful thoughts and help the patient challenge them and identify paths they need to take to think about them differently.

Following completion of the imaginal exposure, ask the participant for their reactions, using an open-ended query such as, "How was that experience for you?" Often they may express surprise at the intensity of the feelings experienced, or about some of the details which were recalled during the exposure. Allow them to sit with how they are feeling and validate these reactions. Always acknowledge the difficulty of the task and reinforce the effort to complete

the exposure exercise and tolerate the affect. Remind them again that this processing of emotions is what could not happen at the time of the trauma, but needs to happen now.

It is also helpful to then share some of your observations, such as noting increasing amount of detail present in the narration over consecutive recountings, noting how much was going on (thoughts and feelings) in a short amount of time, noting changes in levels of distress, or noting particular areas of difficulty. It also may be helpful to assist the individual in labeling some of their feelings.

Approach areas of difficulty with a Socratic questioning approach: For example, if the participant is questioning whether he/she might have done something to prevent a given outcome, ask specifically about what that might be, or how they might have anticipated the event, or what other factors might have been relevant to the outcome. Another important query might be regarding the participant's assessment of their own and others' performance in doing their jobs and making decisions under such stressful conditions, and perhaps leading to the acknowledgment of being in a position in which there was often no "good" choice to make. With this approach, your goal is to have the participant begin to entertain other interpretations of the way events transpired, and to begin to challenge some assumptions or judgments which may be inaccurate.

Sometimes an obvious topic will emerge, and you may judge that the patient is not yet ready to discuss it or hear alternative approaches, it which case you may choose not to raise it until a later session. You can acknowledge it and bookmark it, e.g., "It sounds like you are really struggling with I think that is going to be an important part for us to work on and we will come back to it."

Common themes to explore include feelings of guilt or blame, anger and grief related to the incident, as well as generalizations drawn from the incident to current behavior like hatred of an ethnic group or questions of own or command competency.

VR patients fill out immersion and presence questionnaire prior to end of session via REDCAP, PE patients fill out immersion questionnaire

Session 4

Overview:

- **5)** End session (5 min) pg 17

Prior to session, clinician should administer symptom checklist via REDCAP

1) Check-in

- Check-in on week in general
- Check-in on changes in symptoms in past week, including more frequent thoughts of trauma
- Normalize any changes, telling patient symptoms may increase logically since they are facing something they've tried to avoid, but that indicates that what we are doing is working
- Check-in on perceptions regarding treatment

2) Present session agenda

"This session we will get right into the exposure and focus on the exposure and processing pieces. You did a great job last time. This time we're going to dig even deeper and I want you to include everything in your memory and really let yourself feel it. Do you have any questions before we begin?"

3) Conduct exposure

Conduct exposure to entire trauma memory as last time. If VR, may add more sensory elements. For both groups, may ask more questions to flesh out details or evoke emotion.

At the end of the exposure ask for a final SUDS score and an estimate of peak SUDS that was reached during the exposure, and record the numbers into the SUDS form.

Target time: 45 minutes

<u>4)</u> Process exposure

- Ask patient "How was that for you? Did you notice anything in particular?
- You may check-in on discussion from previous week.
- You may raise themes that you have noticed.

5) End session

- Make sure patient is scheduled for post-session 4 assessment BEFORE next session Schedule next session •
- •

Session 5

Overview:

- 1) Check-in (10 min)pg 18
- 2) Present session agenda (5 min)pg 18
- **3)** Introduce and identify hot spots (10-15 min)pg 18
- 4) Conduct exposure (45 min)pg 19
- **5) Process exposure** (20 min)pg 19

1) Check-in

- Check-in on week in general
- Check-in on changes in symptoms in past week, including more frequent thoughts of trauma
- Normalize any changes, telling patient symptoms may increase logically since they are facing something they've tried to avoid, but that indicates that what we are doing is working
- Check-in on perceptions regarding treatment
- Identify potential hot spots "have you noticed any parts of the memory bothering you more than others?"

2) Present session agenda

Note: Only start with hot spots once patient is ready. Can discuss in supervision.

"This session we are going to move to the next step in the exposure where we focus on hot spots. We'll spend a bit of time discussing hot spots, and then we will do the exposure and processing."

3) Introduce and identify hot spots

Hot spots are the specific moments in the trauma memorythat cause more anxiety than the rest of the narrative. It is often the moment the explosion occurred, or gunfire started, or when the patient or a comrade was injured or thought they would die. There are usually several hot spots in any trauma narrative. The therapist should make notes during exposure about which moments seem to be the hardest for the patient, and talk to the patient about what bits of the memory trigger more anxiety during the exposure in session.

Explanation for patient: "We've spent a couple of sessions going over the entire memory from start to finish. Now we'll start focusing on smaller pieces of the experience which we call hot spots. I'm going to ask you to identify 2-3 parts of the trauma that were the most intense emotionally. This could be a 10 minute segment or a 10 second segment. Then we will choose one to begin with, and you will conduct the exposure on just that one segment of the experience. You'll try to uncover every detail of that hot spot, and retell it repeatedly, possibly retelling it 8 times in one session. By focusing on the most intense pieces of the trauma, you can really facilitate habituation to that part. It has been shown that as you habituate to the hot spots your arousal to the less intense parts of the memory decreases as well.

"We think about it a bit like getting a massage. If you're having back discomfort and go for a massage, the massage therapist may work on your whole back, but if she finds a knot, she will

focus on that knot and go over and over it in order to work it out. We're going to do the same thing – we'll focus on the area which is the most distressing and go over and over it to address it. Does that make sense to you?

"Can you tell me what those hot spots might be for you?"

Have the patient identify their hot spots and rate them from least to most intense. Start with the worst and repeatedly expose the patient to that in minute detail, as if in slow motion, over and over until it gets easier. At that point, move on to the next highest hot spot and repeat as above.

4)_Conduct exposure

Conduct exposure to the specified hot spot. Allow patient to tell it once through, and then help them to flesh it out in subsequent retellings, leaving no stone unturned, by asking questions like

- What thoughts are going through your head at that moment?
- What kinds of feelings are you having at that moment?
- What is your body feeling at that moment?
- What other sounds do you notice?
- Describe the details of ...(may be clothing, person's face, dead body, wreckage, etc)
- Focus discussion on hot spot

If VR, match sensory elements to the hot spot.

At the end of the exposure ask for a final SUDS score and an estimate of peak SUDS that was reached during the exposure, and record the numbers into the SUDS form.

Target time: 45 minutes

5) Process exposure

- Ask patient "How was that for you? Did you notice anything in particular?
- You may check-in on discussion from previous week.
- You may raise themes that you have noticed.

Sessions 6-8

Overview:

1)	Check-in (10-15 min)	pg 20
2)	Present session agenda (5 min)	pg 20
2)	Conduct ormaging to hat goat (15 min)	na 20

- 3) Conduct exposure to hot spot (45 min)..... pg 20
- **4) Process exposure** (30 min) pg 20
- **5) End session** (5 min) pg 20

1) Check-in

- Check-in on week in general
- Check-in on changes in symptoms in past week, including more frequent thoughts of trauma
- Normalize any changes
- Check-in on perceptions regarding treatment

2) Present session agenda

"This session we will continue with the hot spots and try to really engage in everything that is there. Do you have any questions before we begin?"

3) Conduct exposure to hot spots

Conduct exposure to hot spot. If patient has shown habituation to last hot spot, then continue with next one. If not, repeat the last hot spot, with goal of completing all hot spots by end of session 8. By end of session 8, aim for description of all details and habituation to all sensory elements. If habituation is not occurring, troubleshoot with consultants to facilitate habituation.

At the end of the exposure ask for a final SUDS score and an estimate of peak SUDS that was reached during the exposure, and record the numbers into the SUDS form.

Target time: 45 minutes

4) Process exposure

- Ask patient "How was that for you? Did you notice anything in particular?
- You may check-in on discussion from previous week.
- You may raise themes that you have noticed.
- Process all themes that have emerged

5) End session

- Make sure patient is scheduled for 6a assessment PRIOR TO session 7
- Have patient complete immersion/presence questionnaires via REDCAP after session 6
- Schedule next session

Session 9

Overview:

1)	Check-in (10 min)	page 21
2)	Present session agenda (5 min)	page 21
3)	Conduct exposure to entire trauma memory (25-30 min)	page 21
4)	Process exposure (15 min)	page 21
5)	Review treatment program and patient's progress (20-30 mi	in)page 21
6)	Termination (10 min)	page 22

1) Check-in

Check-in on week in general

2) Present session agenda

"This session is our final one. We will conduct our final exposure to wrap up the whole exposure exercise and note the differences between the first time you did the exposure and this time. Then we will review the skills we introduced in treatment, your progress over the course of therapy, and how to continue working for further improvement. Do you have any questions before we begin?"

3) Conduct exposure

Conduct exposure to entire trauma memory, from start to finish for the last time, as many times as time allows up to 30 minutes. (Note: this may be one time through, or may be more than once depending on the length of the trauma.)

Target time: 30 minutes

4) Process exposure

- Ask patient "How was that for you? Did you notice anything in particular?"
- Ask patient "How was that different than your first exposure? And how was it different after working on the hot spots"

5) Review treatment program and patient's progress

Review of skills: "We introduced a couple of skills in this protocol. We began with psychoeducation to describe what PTSD is and how it manifests itself. We spent a long time describing the rationale behind the exposure therapy. We utilized a breathing exercise to help induce a relaxation response when necessary. Then we focused on the exposure exercises, and implemented processing to evaluate themes, emotions and changes in cognitions that were due to the trauma. Were any of those in particular helpful or not helpful for you?"

Review of progress in treatment: "There were some major changes that occurred over the course of treatment." Review any changes here, including:

- PTSD symptom changes
- Comorbid disorder symptom changes
- Relationship/quality of life changes
- Habituation to exposure

I know there is more you would like to improve. There is evidence that in many cases, symptoms continue to improve after the end of treatment.

Symptom exacerbation: It is not uncommon for people to have periods of time when a flare up of symptoms occurs again. It may be due to a certain trigger like an anniversary or meeting someone connected to the event, or come out of the blue. It is important in those situations to remember you are able to handle the emotions related to the event. Make sure not to avoid or isolate, use breathing skills, and process your own reactions.

Positive feedback about work: This was a very difficult treatment and you should give yourself a lot of credit for facing this head on and giving it your all. I enjoyed working with you and wish you the best of luck.

Discuss future goals and referral to other programs if applicable.

Have patient complete immersion/presence questionnaires via REDCAP

Make sure to ask patient about guess about medication group and add to REDCAP

6. Termination

- Make sure patient is scheduled for outcome assessment BEFORE leaving
- Terminate with patient

Session #1 Index Trauma Interview

Participant#/initials_	/	Session Date	Therapist _		
Date and location of traumatic event					
Details					
		· · · · ·			

Participant wounded?	Y	N
Other soldier wounded/killed?	Y	N
Civilian wounded/killed?	Y	N
Enemy wounded/killed?	Y	N
Participant action resulted in death of fellow soldier/civilian/enemy?	Y	N
Attacked by civilians?	Y	Ν

Session #1 BreathingInstructions:

- 1. Take a normal breath in through your nose with your mouth closed.
- 2. Exhale slowly with your mouth closed.
- 3. On exhaling, silently say to yourself the word **CALM** or **RELAX** very slowly, for example: c-a-a-a-a-l-m or r-e-e-e-e-e-l-a-x
- 4. Pause, holding your breath, for a count of 4 and then take the next inhalation.
- 5. Practice this exercise several times a day, for 10 minutes each time.

Treatment Rationale for Prolonged Exposure

The treatment program you are participating in is called Prolonged Exposure. During the treatment sessions, we will engage in exposure to your trauma memory, in which you relive the trauma repeatedly in your mind. Many people who have experienced a trauma try to avoid thoughts and feelings associated with that event. However, while avoiding can make you feel more comfortable in the short run, it actually can make the problem worse in the long run, because it prevents you from overcoming your fears. Exposure addresses this problem.

How does exposure work? When you confront feared memories or situations in a systematic way under relatively safe circumstances, several things happen. One, reliving the memory helps to emotionally process the traumatic experience and make sense of it. Two, you learn that thinking about the traumatic experience is not dangerous, and that being upset or anxious is not dangerous. Three, you become less fearful of other situations that remind you of your trauma. Four, you learn that you can handle your fear and anxiety and you feel better about yourself. Finally, you learn that when you repeatedly confront memories or situations you have avoided, the fear and distress gradually decrease. In other words, you again become relatively comfortable in these situations. We call this habituation. Habituation is the process by which anxiety comes down on its own. When you stick it out and stay in a frightening but safe situation for a long enough time and you go back to that same situation often enough, you simply become less frightened of this situation. In a way, it's similar to "getting back on a bicycle" after falling off. If you refuse to try again, over time you become more and more frightened of riding bicycles. But, if you force yourself to ride them despite your fear, you become less afraid.

Habituation works with frightening memories too. Letting yourself engage in the traumatic memories rather than avoiding them will allow you to remember the trauma with less distress, and you'll learn that the memories are not dangerous. Exposure to the painful memories, i.e., reliving the trauma in the session, also allows you to gain control over them and they will be less likely to pop up at times you don't want them to. Thus, the painful memories and thoughts that many trauma survivors often experience are less likely to occur after you repeatedly relive the trauma, and when they do occur, they are less upsetting.

Following a trauma, a person's beliefs about him or herself and about the world may change in basic ways. You may view situations as dangerous when before the trauma they would not have bothered you at all. By facing your trauma now, we hope that you will feel relief in the long run, and not experience negative consequences from the trauma.

25

COMMON REACTIONS TO TRAUMATIC EVENTS

Hand-out

A traumatic event produces emotional shock and may cause emotional problems. This handout describes some common reactions to traumatic experiences, although each person responds in his or her own unique way. You may find that you have some of these reactions more intensely than others, and some you may not have at all.

Remember, many changes after a trauma are normal. In fact, most people who directly experience a major trauma have severe problems in the immediate aftermath. Many people then feel much better within three months after the event, but others recover more slowly, and some do not recover enough without help. Becoming more aware of the changes you've experienced since your trauma is the first step toward recovery.

Some of the most common problems after a trauma are described below.

1. The primary reactions people experience after a traumatic event are **fear** and **anxiety**. Sometimes your feelings of anxiety may be a result of being reminded of the event; at other times, it may seem as though these feelings come out of the blue. The feelings of anxiety and fear that you are experiencing can be understood as a natural response to a dangerous and life-threatening situation that may last after the trauma has ended. You may experience changes in your body, your feelings and your thoughts because your view of the world and your perceptions about your safety have changed as a result of the traumatic event.

Certain **triggers** and **cues** may remind you of the traumatic event and activate your fears. These triggers may be certain times of the day, certain places, an argument with someone you care about, a certain smell or noise. Typically, after a traumatic event, fear and anxiety are experienced in two primary ways:

- a) continuing to reexperience memories of the traumatic event
- b) feeling aroused and jumpy.

A common strategy people use to alleviate the anxiety and distress associated with a traumatic event is to try and avoid places, people or other reminders of the event or to try and distract themselves. It is helpful to pay attention to the changes that you are experiencing in your body, and your thoughts that have resulted from the traumatic event.

2. People who have experienced a traumatic event often **reexperience** the trauma. You may have **unwanted thoughts** of the trauma, and find yourself unable to get rid of them. You may find that you are having **flashbacks** when visual pictures of the place where you experienced the traumatic event or some other aspect of the event suddenly pops into your mind. Sometimes, the flashback may be so vivid that you might feel as if the event is actually occurring again. These experiences are intrusive and you probably feel that you don't have any control over what you are feeling, thinking, and experiencing during the day or at night.

You may also find that you are reexperiencing the traumatic event though **nightmares**. These symptoms occur because a traumatic experience is so shocking and so different from everyday experiences that you can't fit it into what you know about the world. So in order to understand what happened, your mind keeps bringing the memory back, as if to better digest it and fit it in.

3. You may also find that you are having **trouble concentrating**. This is another common experience that results from a traumatic event. It is frustrating and upsetting to be unable to concentrate, remember, and pay attention to what is going on around you. This experience also leads to a **feeling that you are not in control of your mind or a feeling that you are going crazy**. It is important to remember that these reactions are temporary. Difficulties concentrating are due to intrusive and distressing feelings and memories about the traumatic event. In an attempt to understand and digest what happened to you, your mind is constantly going over this material, bringing it back up, chewing on it, and trying to digest it.

4. Another common reaction to trauma is **arousal**, agitation, feeling jittery, feeling **overly alert**, trembling, being **easily startled**, and having **trouble sleeping**.

Feeling tense and jumpy all the time may also lead to feelings of **irritability**, especially if you are not getting enough sleep. These changes in your body are the result of fear. Animals and people have several potential reactions to being startled, assaulted, or threatened. One reaction to danger is to **freeze**. You may have seen a cat that is being approached by a dog crouch down and be very still when it is afraid. A second possible reaction to being threatened is to **run away** or **flee**. A third reaction is to **fight**. The fleeing or fighting responses require a burst of adrenaline to mobilize your body and help it respond adequately to a dangerous situation.

As a result of the traumatic event, you have realized that there is danger in the world and you want to be ready for it. Your body is in a constant state of preparedness and arousal, so you can feel pumped and ready to respond immediately to a dangerous situation.

5. You may find that you are physically or emotionally **avoiding** people, places, or things that remind you of the traumatic event. This avoidance is a strategy to protect yourself from situations that you may feel have become dangerous and thoughts and feelings that are overwhelming and distressing.

Sometimes the desire to avoid memories and feelings about the traumatic event may be so intense that you might find that you have forgotten important aspects of what happened during the traumatic event. Another common strategy to avoid painful feelings and thoughts about the event is **emotional numbness**, where you find it difficult to have both fearful and pleasant or loving feelings.

6. Another common reaction to traumatic events is **sadness** and a **sense of feeling down** or **depressed**. You may have feelings of hopelessness and despair, frequent crying spells, and sometimes even thoughts of hurting yourself and suicide. A **loss of interest** in people and activities that you once found pleasurable is often associated with experiencing a traumatic event. Nothing may seem fun to you anymore. You may also feel that life isn't worth living and that plans you had made for the future do not seem important any longer.

7. During the traumatic event, you may have felt threatened and been scared for you life. During the events that lead to the trauma, you may have felt as if you had **no control** over your feelings, your body and your life. Sometimes the feelings of loss control may be so intense that you may feel as if you are "**going crazy**" or "**losing it**."

8. Feelings of **guilt** and **shame** may be present. Guilt and shame may be related to something you did or did not do during the traumatic event. It is common to second guess your reactions and blame yourself for what you did or did not do.

Feeling guilty or ashamed about what happened to you means that you are holding yourself responsible for the effects of the traumatic event. These feelings of guilt can lead to feelings of helplessness, depression and negative thoughts about yourself.

Blame can also come from society, friends, family and acquaintances because many times, people place responsibility on the person who has been hurt and victimized.

9. A feeling of **anger** is also a common reaction to a traumatic event. Feelings of anger may be stirred up in the presence of people who remind you of the event. Anger can also surface in the absence of any reminders of the traumatic event.

Sometimes, you may find that you are so **angry** that you want to hit someone or swear; and if you are not used to feeling angry, you may not recognize or know how to handle these angry feelings.

Many people direct the anger toward themselves for something that they did or did not do during the traumatic event. These feelings of anger directed at the self may lead to feelings of blame, guilt, helplessness and depression.

Many people also find that they are experiencing anger and irritability toward those people that they love the most: caretakers, family, friends, their partners and their children.

Sometimes you might **lose your temper** with your loved ones. This may be confusing since you may not understand why you are most angry and irritable with those you care about most. While closeness with others may feel good, it also increased the opportunity

for feelings of dependency, vulnerability, helplessness and intimacy. Having those feelings may make you feel angry and irritable because they may remind you of the traumatic event.

10. **Self-image** can also suffer as a result of a traumatic event. You may tell yourself, "I am a bad person and bad things happen to me," or, "If I had not been so weak or stupid, this would not have happened to me," or, "I should have been tougher."

11. People who experience a traumatic event can develop **negative thoughts** about other people and life events. For many people, the safe and rewarding world that they have been familiar with suddenly becomes a very dangerous place. They may feel that they **cannot trust anyone or feel safe anywhere.** You may feel this way yourself. Or, if you have had previous negative experiences and thoughts about the world, the traumatic event may confirm your notion that "the world is a dangerous place" and "no one can be trusted."

We often hear people who tell us that the traumatic event has changed them completely. They say, "Before the event, I was not afraid of anything. I could cope with any kind of stress, no matter how difficult the situation was, and get along with others. And now I am afraid of my own shadow and I cannot cope even with minor problems."

Some people tell us that "the event was the last straw," or, "I knew I always felt that I could not trust myself," or "I am the kind of person that cannot handle even the slightest difficulties."

12. **Sexual relationships** may also suffer after a traumatic experience. Many people find it difficult to feel sexual or have sexual relationships.

13. Some people increase their **use of alcohol or other substances** after trauma. There is nothing wrong with responsible drinking, but if your use of alcohol or drugs changed as a result of your traumatic experience, it can slow down your recovery and cause problems of its own.

14. Finally, as a result of this recent traumatic event, you may be reminded of your **past experiences**. These negative memories may be stirred up as a result of the recent traumatic event and it may be difficult for you to think of any other situations or experiences that are not negative. In fact, it may be very difficult to believe that you will ever feel happy again or have pleasant experiences, but you will. It is important for you to know that our memories are associated because of the way our minds organize information.

You may also suddenly recall memories that you had forgotten. These new memories may be as disturbing to you as the memory of the recent traumatic event. But it is possible to put these negative experiences behind you.

Some of these common reactions to traumatic events are connected with each other. For some people, having a flashback may increase their concern about losing control of their lives and may even intensify their fears. In other words, the responses to traumatic events often interact with one another and cause the overall response to be more intense. Of all these normal reactions to traumatic events, fear is probably the most common and appears to be the most debilitating. In this program, we are going to focus on the fears and negative thoughts that you are having and that are directly related to the traumatic event.

Therapist Exposure Recording Form

Client Initials and Number		Date		
Name of Therapist	_Session #	Exposure #	:	
Description of exposure being descr				
Virtual Environment and Cues used:				
Start Time: Beginning SUDS score (0-100):			
End Time:				
End SUDS rating:				
Peak SUDS rating:				
Number of minutes of exposure:				
Number of repetitions:				
Hot Spot?YesNo				
Notes:				

"Enhancing Exposure Therapy for PTSD: Virtual Reality and Imaginal Exposure with a Cognitive Enhancer"

DoD Psychophysiological Assessment and Startle Manual

Revised October 2012

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Contact Information

If you have any questions, please contact the following people.

For Troubleshooting or Related Issues: Dr. Tanja Jovanovic

Dr. Seth Norrholm

For REDCap Issues: Katarzyna Wyka

For All Other Issues: Brittany Mello

Kathy Rosenberg

Psychophysiological Assessment Overview

Completing the psychophysiological assessment will take approximately 2-2¹/₂ hours. The other assessments should be completed prior to the psychophysiological assessment. If the assessments are all being conducted on the same day, it is likely that the patient will need a break for lunch and/or a snack. Assessors should discuss the availability of funds for providing a snack and/or lunch.

Since cortisol is collected, it is best to run all subjects through this assessment at approximately the same time of day. <u>The psychophysiological task should be</u> <u>completed in the afternoon, after 1pm is best</u>.

This behavioral task will also be done at post-treatment assessment and 3-month follow-up assessments. Compensation will be provided after all completed assessments that include the psychophysiological piece (pre-treatment, post-treatment, and 3-month follow-up). Assessors should work with their site's coordinator to arrange for the compensation to be provided.

Order of Tasks

- 1. Set up preparation table before participant arrives.
- 2. Have patient prepare for task by using the bathroom, washing hands, and drinking water.
- **3.** Read the "Introduction" script.
- 4. Cortisol Sample #1
- 5. Impedance Test Form
- 6. Electrode Preparation
- 7. Cortisol Sample #2
- 8. Read the "AXBX Session" script.
- 9. AXBX Session
- 10. Exit Interview Form
- 11. 10 min break
- 12. Cortisol Sample #3 (during break)
- 13. Read the "EXT Session" script.
- 14. Extinction (EXT) Session
- 15. Read the "VR Session" script.
- 16. Virtual Reality (VR) Session
- 17. Cortisol Sample #4
- 18. Remove electrodes and coordinate reimbursement.

Cortisol Sampling Procedure

There will be 4 saliva samples collected at the following timepoints:

- 1. Prior to prepping participant and putting on electrodes (Sample 1, baseline record the time)
- 2. After finishing the participant prep, immediately before beginning the AXBX task (Sample 2 record the time)
- 3. After finishing the AXBX session and the Exit Interview form during the 10-minute break (Sample 3 record the time)
- 4. After finishing the VR session (Sample 4 record the time)

Be sure to record the time of each sample on the <u>Cortisol Form</u> (see Appendix).

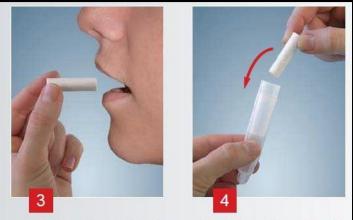
Salivette tubes used for saliva collection for cortisol should be clearly marked with the SCREEN ID and with the timepoint of collection. The cortisol samples need to be stored in a -80 degree freezer and so arrangements should be made for the use of a freezer for the duration of the protocol. If need be, the samples can be placed in a regular refrigerator for up to 24 hours before moving them to the -80 degree freezer.

Figure 1. How to collect saliva for cortisol samples.





The patient removes the swab from the Salivette[®] (see Figs. 1 and 2)...



...and places the swab in the mouth and chews it for about 45 seconds to stimulate salivation (see Fig. 3).

Now the patient returns the swab with the absorbed saliva to the Salivette[®] (see Fig. 4)...



.and replaces the stopper (see Fig. 5).

Cortisol Shipping Instructions

All cortisol samples should be sent directly to Weill Cornell's CTSC lab using FedEx or UPS.

1) Samples are stable for at least a year when frozen at -80, so samples should be shipped when you have 40 samples or at 1 year, whichever comes FIRST.

2) Samples should be shipped in a styrofoam box filled with dry ice. The styrofoam box should be an inch thick and have a few inches of ice surrounding the sample boxes.

3) Samples should be shipped via FedEx or UPS, for Monday to Friday delivery (last shipments accepted at 5 PM) to:

Mr. Drury Philip CTSC Core Laboratory @ Weill Cornell Medical College 525 East 68th Street Room F-265 New York, NY 10065

All shipments should include the <u>Clinical & Translational Science Center (CTSC)</u> <u>Core Laboratory Assay Request Form</u> (see Appendix). The lab is closed on Saturdays and Sundays. If given the option from your carrier, please ensure the samples arrive early in the day (no earlier than 7am). Samples will not be accepted after 5pm.

Please alert Kathy Rosenberg (212-821-0669; <u>kar2015@med.cornell.edu</u>) when preparing a batch of cortisol samples for shipment to verify that this information is up to date.

Before the participant arrives...

You'll need to set up the computers and preparation table according to the instructions below.

- 1. Turn on and log on to the ACQ and SuperLab computers
 - Write site-specific log-in information here:

Username: _____

Password: _____

- 2. Ensure you have a copy of each of the required forms (see Appendix):
 - One copy of the Impedance Test Form
 - One copy of the Exit Interview Form
 - One copy of the Cortisol Form
- 3. Set up preparation table (see Figures 2-5)

Items to include:

- Isotonic paste (white lotion)
- Lemon prep*
- Green Electrolyte gel*

*Place a small amount of gel and lemon prep on sterile gauze paper so it's easily accessible.

- 2 Snap-on EMG Electrodes (0.875 in square cloth, **pre-cut**)
- 2 Snap-on GSR Electrodes (1.5 x 1.0 in rectangular foam)
- 2 Snap-on round ECG electrodes
- 2 Alcohol Prep pads
- 2 Q-tips
- Gauze

Figure 2. EMG electrodes (pre-cut) Figure 3. GSR electrodes

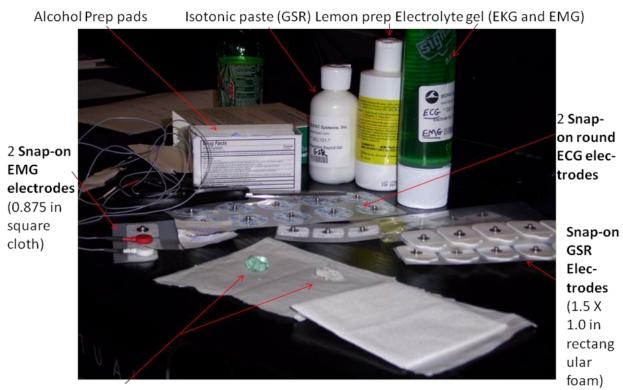
Figure 4. ECG electrodes







Figure 5. Preparation Table Setup



Gel and lemon prep for *orbicularis* muscle (use Q-tip)

Electrode Gel Isotonic Paste

2 BIOPAC S

GEL100 *

FEERMANN

Lemon Prep

Witch Hazel













2 swan.

WITCH

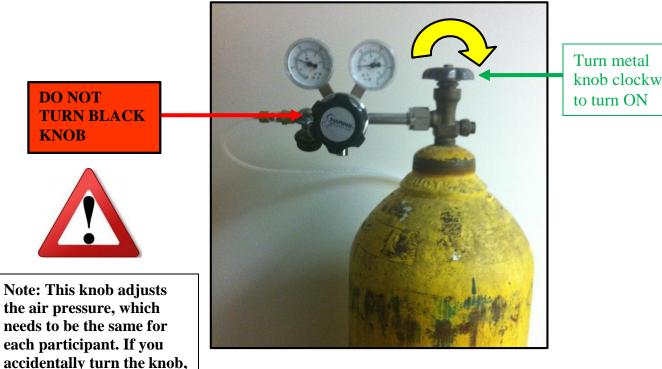
elief of Min

F7=

16 FL OZ (I PT)

4. Turn on the air tank and test it to make sure it is working properly.

Figure 6. How to turn on the air tank



knob clockwise

To test the air tank...

please alert Tanja and ask how to recalibrate it.

- a) Open the "DOD AXBXSESSION1" session on the SuperLab computer
- b) Scroll down the list of events on the right-hand side of the menu
- c) Double-click on "AIRBLAST"
- d) A new window will pop up. Click the "Test Now" button. An air blast should occur if everything is working properly.

Tip: Testing the air blast ahead of time will prevent the initial blast of air when you first start the patient's AXBX session, and ensure it's working before the participant begins the assessment.

When the participant arrives...

- 1. Ask the participant to wash their hands with soap and water and to dry them completely.
- 2. Ask the participant to use the restroom (even if they don't think they need to).
- 3. Ask the participant to rinse their mouth out with water to clean their mouth for the cortisol samples, and record the time that they drank water on the <u>Cortisol Form</u>.
- 4. Have participant sit so you can begin the assessment.
- 5. Read the "Introduction" script (refer to pg. 25).
- 6. Collect Cortisol Sample #1 according to instructions above (pg. 6) and record the time.
- 7. Complete the <u>Impedance Test Form</u> (form administered to ensure participant can hear startle cues).
- 8. Begin electrode preparation according to the instructions below.

Instructions for Startle Task Preparation

Order of Tasks:

- 1. Prep "blink" muscle with scrub and gel
- 2. Attach ECG electrodes (wait to connect red lead until Step 8)
- 3. Attach GSR electrodes (wait to connect the leads until Step 8)
- 4. Remove gel from under the eye
- 5. Attach EMG electrodes and connect the leads
- 6. Put on respiration band
- 7. Put on air blast vest
- 8. Connect red lead for ECG (pg. 18) and both leads for GSR (pg. 20)
- 9. Give patient response pad
- 10. Put headphones on patient

ELECTROMYOGRAM (EMG) SET-UP (Eye):

Materials Needed: White and Red electrode EMG snap-on leads

2 **Snap-on EMG electrodes** (0.875 in square cloth) Lead Receptacle Alcohol Prep pads Lemon prep Electrode gel (green) Q-tips Tissues Medical adhesive tape







Skin Preparation:

1.1 Instruct the subject to close his eyes. Use an alcohol pad to scrub the area under the right eye to target the *orbicularis oculi* "blink" muscle.



Figure 7. Scrubbing under the eye

- 1.2 After alcohol dries, dip a Q-tip into the Lemon Prep that you put onto the gauze paper and apply a small amount under the eye.
- 1.3 Using a brisk side-to-side motion, apply moderate pressure to scrub the area under the eye for at least 1 minute, up to 2 minutes (shorter for fair skin, more time for darker complexions). The subject may experience some degree of discomfort due to the abrasive movement, but this is temporary.
- 1.4 Instruct the subject to open eyes and look up. Gently wipe off the Lemon Prep with a gauze pad. It is normal for skin to appear reddened after scrubbing procedure.
- 1.5 Using a clean Q-tip, dip the Q-tip into the green gel that you put onto the gauze paper and apply a generous layer of electrode gel over the scrubbed area under the eye. Rub the gel in, and leave it on the skin while preparing the electrodes in order to improve the impedance.

Tip: The longer the electrode gel is absorbed into the skin, the better the electrode impedance!

- 1.6 To give the gel more time to be absorbed into the skin, proceed to pg. 17-19 to set up the ECG and GSR electrodes. After these electrodes are in place, return to this page to complete the steps below.
- 1.7 After waiting for the gel to be absorbed, use a gauze pad or tissue to wipe off excess gel before positioning the electrodes.

Preparing and Positioning Electrodes:

- 2.1 Snap the leads onto the electrodes.
- 2.2 Use a Q-tip to add a small amount of green gel to the electrodes and then place them on the face:
 - The WHITE electrode should be placed directly under the pupil onto the "blink" muscle. To locate the center of the pupil, have the participant look directly at you and then place the electrode below the center of the pupil.
 - The RED electrode is placed directly to the side of the white electrode, also on the "blink" muscle.

Figure 8. Placement of EMG electrodes



• Note: The white electrode pads should slightly overlap, but be sure that the metal discs of the electrodes are <u>not</u> touching, or they will cause interference.

Tip: Have the participant blink a few times before placing the electrodes to help you locate their "blink" muscle.

- 2.3 Loosely tuck the lead wires around the right ear to keep them from pulling at the eye. Tape the leads to the participant's chest or neck to keep them in place.
- 2.4 Test the impedance between the electrodes using the Checktrode meter (see detailed instructions below).
- 2.5 Record the impedance and offset values on the <u>Impedance Test Form</u> for each trial.



Instructions for Using the Checktrode Meter

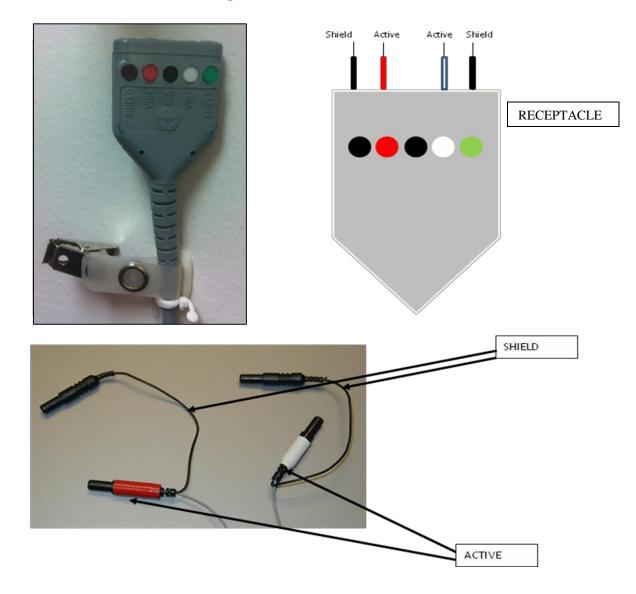
- a) Turn Checktrode on.
- b) Turn dial to "50 K Ω test" if it is not already in this position. Display should read 50 with a margin of error of ± 1 (e.g., 49.3, 50.8).
- c) Plug red and white electrode leads into the black and red ports on the bottom of the Checktrode (color does not matter).
- d) Turn dial to "contact (K Ω)" position. Display should read less than 6.0 K Ω .
 - If between 6 and 8, leave the electrodes in place and impedance should drop to an acceptable level over the next few minutes.
 - If > 8, re-scrub the participant to lower the impedance. If the display fluctuates or displays an "odd" reading (e.g., -----1), re-check your connections to the bottom of the Checktrode and if necessary, replace the 9V battery in the back of the Checktrode.
- e) Turn dial to "offset (mV)" position. Display should read between + 10 to -10. If outside this range, the leads may be of too poor quality to proceed and should be replaced.
- f) For each trial, write the impedance value in the "Trial" box on the <u>Impedance Test Form</u>, along with the offset value beside it.

Tip: If the offset is poor, but the impedance is under 6, proceed with the assessment, but be sure to note the offset value. CKTRODE® model 1089 mk III **Connect Active Leads** electrode tests offset(mV) battery 50 KO est (V) Offset: Should read between -10 Test: Should read 50 (test to +10 (test of box quality) oflead quality)

Contact: Impedance should be less than 6 *this is the crucial number*

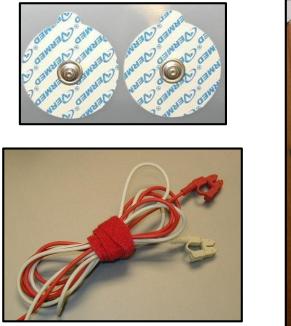
Connecting the Lead Wires:

3. Connect black shield wires to the outer plugs, and the active wires to the inner plugs. **Be sure to match the colors on the receptacle: red-red, white-white!**



ELECTROCARDIOGRAM (ECG) SET-UP (Neck/Wrist):

Materials Needed:White and Red electrode ECG pinch leads (alligator clips)2 Snap-on round ECG Electrodes (1.5 in diameter vinyl)Lead Receptacle with leads plugged into BiopacAlcohol pad(s)





Electrode Preparation:

- 1.1 Take their left hand and place it palm up.
- 1.2 Rub alcohol pad on the right side of the collarbone and on left side of their wrist.
- 1.3 Add a small amount of green gel to the electrodes.
- 1.4 Place one electrode (or have the subjects place the electrodes) on the RIGHT side of the neck just below the collarbone. Place the other electrode just above the LEFT wrist (see Figure 9).
- 1.5 Attach the **WHITE** lead to the electrode below the collarbone on the **RIGHT** side. **Remember: "white on the right"** (see Figure 9).
 - Tape directly under the lead joint (where the wire leaves the clip) and tape the lead wire to the participant, making a small loop to help prevent the leads from moving.

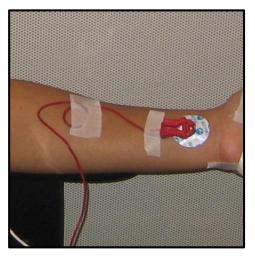
Tip: Because the red (wrist) lead wire may get in the way when you are putting on the air-blast vest, it's easier to wait until the belt and vest are on before attaching this lead.

- 1.6 So that the red lead wire doesn't get in the way, proceed to attaching the GSR electrodes, the EMG electrodes, and put on the respiration belt and air-blast vest before attaching the red lead wire.
- 1.7 After finishing these intermediate steps, attach the red lead wire to the correct location (see Figure 9).
 - Attach the **RED** lead to the electrodes on the wrist on the **LEFT** side. **Remember: "red wrist"**.
 - Tape directly under the lead joint (where the wire leaves the clip) and tape the lead wire to the participant, making a small loop to help prevent the leads from moving.

Tip: Have the lead on the wrist go down the arm lengthwise instead of down the side to lessen the chances that the wire will be pulled.

Figure 9. ECG Placement of Electrodes and Leads

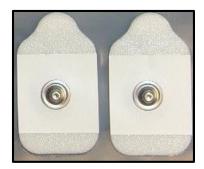




- 1.8 If the leads are not already plugged in, plug the electrode leads into the corresponding receptacle that is plugged into the front of the BIOPAC unit (i.e., white VIN- and its adjacent shield, red VIN+ and its adjacent shield; Note: you do not need a GND for ECG). (These leads should already be connected unless you are using the equipment for another task.)
- 1.9 Clip receptacle to subject's clothing.

GALVANIC SKIN RESPONSE (GSR) SET-UP (Palm):

Materials Needed: 2 Black GSR pinch leads (alligator clips) 2 Snap-on GSR Electrodes (1.5 X 1.0 in rectangular foam pads) Isotonic paste (white lotion)







Electrode Preparation:

- 1.1 Ask the participant which hand is their dominant hand.
- 1.2 Have the participant hold out their **<u>non-dominant hand</u>** (i.e., if they're right-handed, take their left hand), and place it palm side up.
- 1.3 Add a small amount of paste to the foam electrodes.
- 1.4 Place electrodes directly next to each other on the outside of the palm of the non-dominant hand (see Figure 10).
- 1.5 Tape down the outer edge of the foam electrodes to the palm.
- 1.6 Again so the lead wires don't get in the way, proceed to attaching the EMG electrodes, and put on the respiration belt and air blast vest before attaching the GSR lead wires.

- 1.7 After finishing the intermediate steps, attach the lead wires to the foam electrodes (it doesn't matter which lead connects to which electrode; they are interchangeable).
- 1.8 Tape down the lead wires at the base of the clip and over the palm to ensure they stay in place.

Figure 10. GSR Electrode and Lead Placement



Tip: Make sure the lead wires face away from the foam pads and go over the rest of the hand to prevent them from being pulled.

RESPIRATION SET-UP (Belt):

Materials Needed: Black velcro chest strap with 'Biopac Systems' sensor attached



Belt Placement:

- 1. Loosely wrap strap around upper torso at approximately the level of the armpits so that it sits below the ECG electrodes and the sensor is right over the sternum the middle of the chest (see Figure 11).
- 2. Put the loose end of the strap into the opening coming toward you, so you will be able to pull the loose end to tighten the belt.
- 3. Instruct subject to exhale completely and tighten the strap—it should be slightly tight when the subject fully exhales (i.e., it should be snug like a hug, but not uncomfortable).
- 4. Press the leftover length of the strap onto the belt to secure it firmly.



Figure 11. Correctly placed respiration belt

AIR BLAST VEST PLACEMENT:

Materials Needed: "Camelbak" backpack with air nozzle connected to air tank



- Ask the participant to lean forward and put their arms through the straps with the vest on the front of the participant.
 Note: This will be easier if the red (wrist) ECG lead and GSR leads are not yet attached.
- 2. Snap the vest in the back and adjust the strap length to fit the participant.
- 3. The air delivery nozzle should sit right below the larynx of the participant. Adjust the pack and straps as needed to position the nozzle properly (see Figure 12). <u>Note: The nozzle should NOT touch the skin.</u>
- 4. Once the vest is securely in place, return to the instructions above to finish connecting the red ECG lead on the wrist and both GSR leads on the palm.

Figure 12. Placement of air vest and correct distance of nozzle from larynx.



RESPONSE PAD:

- 1. When you are about to begin the AXBX Session, show the participant the response pad and place it under their dominant hand.
- 2. Show them the finger placement for the +, 0, and keys.
- 3. When you read the AXBX Session instructions to the participant, it will explain how to use the response pad.

Figure 13. Controller response pad



Final Checklist Before Beginning Assessment...

Before beginning the startle task, review this checklist to make sure everything is in place.

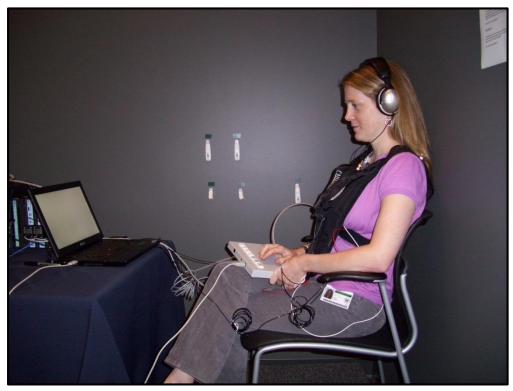
Remember to collect Cortisol Sample #2 after you finish electrode preparation, but before you start the AXBX Session. Be sure to record the time on the Cortisol Form.

Double-check that you have connected all the leads (especially the red ECG wrist lead and two GSR hand leads).

	Are the participant's headphones on? Did you give them the
respo	onse pad? Did you face the monitor toward them?

Remember to read the instructions before beginning each task.

Figure 14: Example of Participant Ready to Begin the Assessment



INSTRUCTIONS FOR PARTICIPANT (Script):

Read the below instructions to the participant **verbatim**. Copy the instruction sheet and keep it close to the startle setup for easy access.

Additional Notes:

- Ask participants not to talk to you during the experiment (unless they are asking to stop the experiment) because you cannot answer any of their questions.
- Ask participants to stay awake with their eyes open.
- Ask participants to stay as still as possible and to avoid smiling or fidgeting as these can affect the readings.
- Ask participants to tell you when the SuperLab experiment ends (you will not be able to see the screen since it faces the participant).
- Ask participants not to attempt to dodge the air blast at any time.
- It may help participants feel more comfortable if you point to where the electrodes will be placed on yourself before attaching them to participants.
- You may also want to note that it's common for people to experience some arousal/anxiety/stress during these procedures.

Introduction

"Today's assessment also includes a psychophysiological assessment, which involves having us connect some electrodes and other measuring devices to assess your physiological responses to a clicking sound and an air blast while participating in a computer-based learning task of looking at shapes and seeing some virtual scenes of combat in Iraq. The assessment takes approximately 2 hours total and is a way for us to better understand your body's physical responses to stress, including how strongly you startle, your breathing, eye blink, heart rate, and sweating response. This will allow us to get an objective baseline on some of the physical aspects of your PTSD symptoms now so that after treatment we can measure how much these symptoms have improved. The task is somewhat unpleasant, but has been well tolerated by most of our participants."

AXBX SESSION:

"During this experiment, you will hear some sudden tones and noises and see several colored shapes appear on the computer screen. The tones are there to elicit startle and occur every time something happens. Some of the shapes will be followed by a blast of air, while other shapes will not.

Throughout the experiment, please press the button on the keypad to tell us whether you think a shape WILL BE followed by air by pressing a plus (+) sign, or WILL NOT BE followed by air by pressing the minus (-) sign. If you do not know, press the zero (0) sign. You should press a button for each shape. You will have 3 seconds from the time the shape appears to press the button. If you miss a shape, please move on to the next one.

If at any time you want to stop the experiment, just let me know, and we will stop the session immediately.

Do you have any questions?"

EXT SESSION:

"Just like in the last experiment, you will hear tones and see shapes. Just like last time, when you see a shape appear on the screen, press the plus (+) sign if you think the shape WILL BE followed by air, the minus (-) sign if you think it WILL NOT BE followed by air, and the zero (0) sign if you don't know.

Do you have any questions?"

VR SESSION:

"Just like in the last experiment, you will hear tones through earphones. This time you will see some virtual scenes of combat in Iraq appear on the screen in front of you and hear noises of gunfire and explosions. You do not need to press any buttons this time.

Do you have any questions?"

Instructions for Data Collection

The Assessor should turn on the ACQ and SuperLab computers prior to prepping the participant. Troubleshoot areas where common errors occur (e.g., make sure the air blast and solenoid box are working properly) before participant is scheduled to begin.

ACQUISITION (AXBX) STARTLE SESSION:

ACQKNOWLEDGE COMPUTER SOFTWARE:

- 1. Open the DOD Session file.
- 2. With the AcqKnowledge file open, save the file according to the following naming convention: DOD_site_AXBX1 (or AXBX2)_SubID#_date

Ex. DOD_Cornell_AXBX1_0001_11.09.11

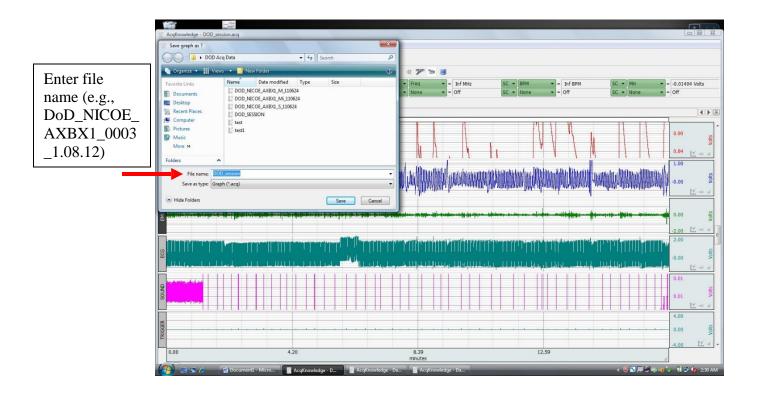
Ex. DOD_NICOE_AXBX2_0002_11.10.11

Ex. DOD_VALB_AXBX1_0003_11.11.11

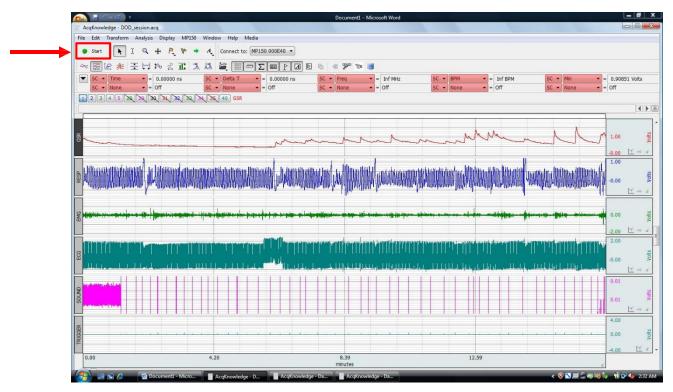
***Use AXBX1 for the baseline assessment; AXBX2 for the post-treatment; and

AXBX1 for the 3-month follow-up assessment.***

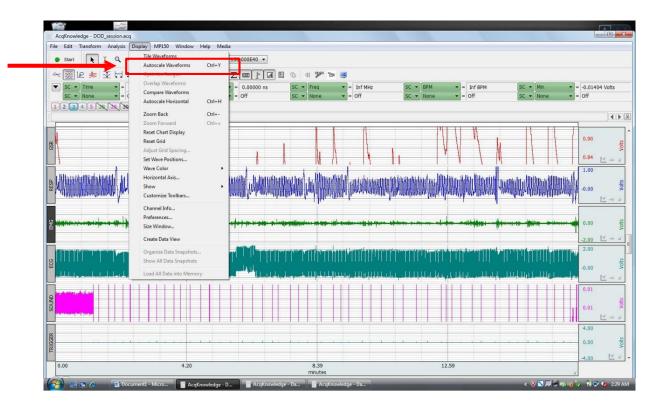
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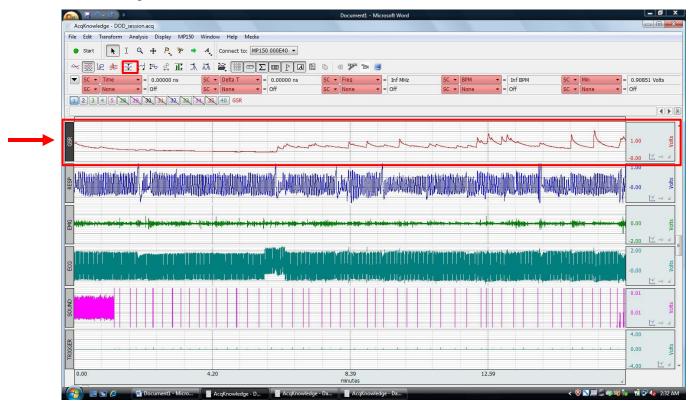
3. Click on 'Start' in the upper left corner of the window.



- 4. When prompted to overwrite existing data, select 'OK'.
- 5. To view data, select Display, "Autoscale Waveforms."



6. GSR: Changes the most, thus select channel, then autoscale (boxes in red below).



SUPERLAB COMPUTER SOFTWARE:

Tip: Make sure ACQ Computer is started before starting the SuperLab computer.

7. Open "DOD AXBX Session 1" (or 2) file on the desktop.

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Registered To: Seth Norrholm, Emory University SuperLab Send Us Feedback							

- 8. Place the **response keypad** under the participant's dominant hand and show them the +, 0, and keys.
- 9. Read "AXBX SESSION" Instructions to the subject (on pg. 26).
- 10. Under the Experiment drop down menu select 'Run'.
- 11. Put in subject's filename, copy the filename (to paste in the next step), and <u>double-check that</u> <u>'Save collected data' is checked</u>.

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12. Another window will pop up, repeat the same filename as above by pasting it in the field, and click 'Save' (Save to "DOD SuperLab Data" folder on desktop).

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- 13. Rotate the laptop so that the monitor faces the subject.
- 14. Flip the switch on the solenoid control box UP to enable.

Tip: Flip UP to enable the solenoid box, and flip DOWN to switch to standby mode.

- 15. Ensure the air tank is on.
- 16. Place the headphones on the participant.
- 17. When the SuperLab session ends, click 'Stop' on the AcqKnowledge session, then save the file.
- 18. Remove the headphones from the participant and take the response pad.
- 19. Flip the switch on the solenoid controller DOWN (standby mode).
- 20. Perform Exit Interview Form.
- 21. There is now a 10-minute break. Have the participant just sit quietly and rest.
- 22. Collect <u>Cortisol Sample #3</u> and record the time.

EXTINCTION (EXT) STARTLE SESSION:

ACQKNOWLEDGE COMPUTER SOFTWARE:

- With the AcqKnowledge file still open, save the file as "DOD_site_EXT1 (or 2)_ SubID#_Date" in the "DOD Acq Data" folder on the desktop.
 NOTE: The number of the Extinction session has to match the AXBX session! (i.e., AXBX2 then use EXT2)
- 2. Click on 'Start' in the upper left corner of the window.
- 3. When prompted to overwrite existing data, select 'OK'.

SUPERLAB COMPUTER SOFTWARE:

- 4. Open "DOD EXT Session 1" (or 2) file on the desktop.
- 5. Read the "EXT SESSION" Instructions to the subject.
- 6. Put on the subject's **headphones** and return the **response keypad** under the participant's dominant hand.
- 7. Under the Experiment drop down menu select 'Run'.
- 8. Put in subject's filename and check that 'Save collected data' is checked.
- Another window will pop up, repeat the same filename as above and click 'Save' (Save to "DOD SuperLab Data" folder on desktop).
- 10. Rotate the laptop so that the monitor faces the subject.
- 11. When the SuperLab session ends, click 'Stop' on the AcqKnowledge session, then save the file.
- 12. Remove the headphones from the participant and take the response pad back.

VIRTUAL REALITY (VR) STARTLE SESSION:

ACQKNOWLEDGE COMPUTER SOFTWARE:

 With the AcqKnowledge file still open, save the file as "DOD_site_VR_ SubID#_Date" in the "DOD Acq Data" folder on the desktop.

Note: There is only one VR file for all assessments.

- 2. Click on 'Start' in the upper left corner of the window.
- 3. When prompted to overwrite existing data, select 'OK'.

SUPERLAB COMPUTER SOFTWARE:

- 4. Open "DOD VR Session" file on the Desktop.
- 5. Read "VR SESSION" Instructions to the subject.
- 6. Place the headphones on the participant.
- 7. Under the Experiment drop down menu select 'Run'.
- 8. Put in subject's filename and check that 'Save collected data' is checked.
- Another window will pop up, repeat the same filename as above, and click 'Save' (Save to "DOD SuperLab Data" folder on desktop).
- 10. Rotate the laptop so that the monitor faces the subject.
- 11. Dim or turn off the lights in the room.
- 12. When the SuperLab session ends, click 'Stop' on the AcqKnowledge session, then save the file.
- 13. Turn the lights back on in the room.
- 14. Collect <u>Cortisol Sample #4</u> and record the time.
- 15. Remove participants' setup in the reverse order of how you prepared them, as follows:
 - Headphones
 - GSR leads and electrodes from hand
 - Red ECG lead from wrist
 - Air blast vest
 - White ECG lead and electrode from collarbone
 - EMG leads and electrode from underneath the eye
 - <u>Turn off air tank</u>

Tip: Give participants tissues to wipe their hands and face.

Tip: Be sure to place all equipment back in the same spot where you found them, so they will be ready for the next participant.

Uploading Data into REDCap:

Once you have completed the psychophys. assessment, you will need to upload all of the files into REDCap, the online data capture program.

- If your psychophys. computers have internet access, you can access REDCap directly. Otherwise, copy the files onto a USB drive and move to a computer with an internet connection. Important: Do not cut or delete the files from the psychophys.computers!
- 2. Follow the links below to REDCap:

You may open the survey in your web browser by clicking the link below: DOD Psychophysiological Assessment

If the link above does not work, try copying the link below into your web browser: https://ctscd22.ctsc.med.cornell.edu/redcap_protocols/surveys/?s=bPDyGt

DOD	Psychophysiological Assessment	Resize font:	C Returning?
1)	Site: * must provide value	WCMCNICOEVALB	reset
2)	Participant ID * must provide value		
3)	Assessment date * must provide value	Today Y-M-D	
4)	Session Type * must provide value	 Baseline Assessment Post-treatment assessment 3-month follow-up 	reset

3. When you follow the link, you'll see this screen.

4. Choose your site, enter the Participant ID number (e.g., V003), choose the date of the assessment, and which type of assessment you conducted (e.g., Baseline). You are now ready to upload the files.

- 5. There are a total of 9 files to upload for each assessment:
 - Three ACQ files (".acq") Questions 5-7
 - Three SuperLab files to upload (".txt") Questions 10-12
 - Three forms Impedance Test Question 8 Exit Interview - Question 9 Cortisol Sample - Question 13

Note: If you completed the forms by hand, you will first need to scan them and create a separate pdf for each file. Since the Impedance Test, Exit Interview, and Cortisol Sample forms are <u>not</u>, the hard copies can be kept in the psychophys. room or other predetermined location.

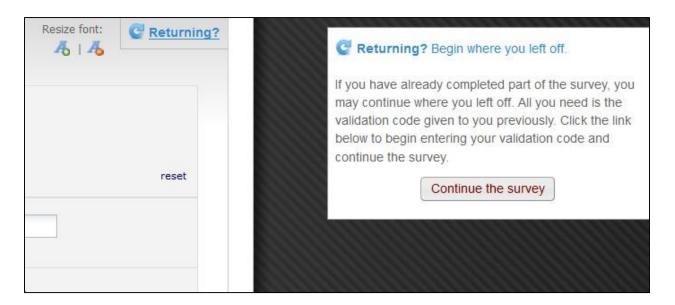
- 6. If there are any additional notes from the assessment, please enter them in Question 14.
 - Ex. "There was a loud noise in the building due to construction at 2:25pm." "Someone accidentally walked into the psychophys. room at 4:12pm during the VR portion."

5)	Upload Acq AXBX file here	
6)	Upload Acq EXT file here	
7)	Upload Acq VR file here	
8)	Upload Impedance Test file here	
9)	Upload Exit Interview file here	
10)	Upload Superlab AXBX file here	O Upload document
11)	Upload Superlab EXT file here	O Upload document
12)	Upload Superlab VR file here	O Upload document
13)	Upload cortisol sample log here	Upload document
14)		

7. Before hitting submit, double-check that you have uploaded the correct files, and that all files are accounted for.



8. If you have started the upload process but are unable to finish in one sitting, click "Save & Return Later." You will be given a validation code on the screen. To finish the survey at a later time, click the REDCap link and then the "Returning?" icon on the upper-right hand side (see image below). Enter your validation code and return to where you left off.



<u>Take care not to lose the validation code!</u> However, if you lose it, e-mail Kasia Wyka and she will assist you.

For any questions regarding REDCap, call Katarzyna (Kasia) Wyka at 212-821-0869 or email her at <u>kew2008@med.cornell.edu</u>.

Things to Remember

- The participant can decide to stop the task at any time for any reason! Pay attention to how they are faring, especially after the first few air blasts and when the VR session starts, as the participant may find the VR scenes troubling.
- Always press "Save" then "Save As" before starting the next task or you will overwrite your data!
- Make any and all notes about your participant in the appropriate notebook and add them in REDCap. If you have any major concerns, speak with Tanja as soon as possible.

Troubleshooting Tips

Problem	Solution				
The EMG readout doesn't seem to be	You may have bad leads, or they could be				
responding to the patient's eye blink/the	dirty.				
readout is a solid green bar (not a line).	- Un-snap the leads and wipe the metal discs				
	with an alcohol pad				
	- Remove and replace the leads (you may				
	need to re-scrub the participant's skin)				
The GSR readout is bouncing up and down	The GSR electrodes may be loose. Try re-				
very rapidly, and not corresponding to the	attaching them securely, or get a new pair.				
participant's response.					
I can't see the GSR or RESP readouts	Select the gray bar to the left of the readout in				
anymore.	question. On the menu bar, click the button				
	labeled "Autoscale Waveforms."				
SuperLab will not run, and a text box	Pick up the response pad and disconnect the				
popped up saying there is no response pad	cord. Wait a few seconds, then plug it back in.				
connected.					
My participant needs glasses to see the	As long as the frames can sit on top of the				
booth monitor.	electrodes, there should be no problem to have				
	the participant wear them.				
My participant waits until after the air	Remind them that they are supposed to be				
blast/no air blast before pressing a button	"predicting" the outcome before it actually				
on the response pad.	happens, so they need to press a button before				
	the shape disappears.				

Appendix

Cortisol Sample Form	
Impedance Test Form	
Exit Interview Form	
CTSC Core Laboratory Assay Request Form	
Instructions for Computer and Hardware Set-up	
Glossary of Terms	
Equipment connections	

Date:	Psychophys. Assessor:
Participant Screening ID:	Assessment Type:

Cortisol Form

Saliva Cortisol Sampling

There will be 4 saliva samples collected for cortisol at the following timepoints:

Have participant rinse mouth out with water.

- 1. Prior to prepping participant and putting on electrodes (Sample 1, baseline—record the time)
- 2. After finishing the participant prep (Sample 2—record the time)
- 3. After finishing the AXBX session and the exit report (Sample 3—record the time)
- 4. After finishing the VR session (Sample 4—record the time)

Event	Time
Water	
Sample 1	
Sample 2	
Sample 3	
Sample 4	

Notes:

Tube labels:

Screen ID: Site Name_SubID (e.g., WCMC_0001)

Tube #:1, 2, 3, 4

Other: Date, Assessment Type (baseline, posttreatment, 3-month follow-up)

Filename:		-	Date:	Assessor:		
		Imp	edance Test F	orm		
<u>Hearing:</u>						
Any history o	of exposure t	o loud noise	? No	Yes	_	
If yes, explain	:					
Any perceive	ed difficulty	with hearing	? No	Yes	_	
If yes, explain	:					
<u>Menstrual Cy</u>	vcle:					
For Females o	only - First Da	ay of Last Men	strual Cycle: _			
Contraception	:	; Meno	pause:	; Surg	gery:	
Impedance:						
Electrodes	Trial 1	Offset	Trial 2	Offset	Trial 3	Offset
R & W						

Fil	ename:

Date: _____Assessor: _____

Exit Interview Form

Session: AXBX1

_AXBX2

1. Which shapes were followed by the air blast?

2. Which shapes were <u>not</u> followed by the air blast?

- 3. How much did the air blast bother you? (On a scale from 1-5, where 1=Not at all and 5=Really badly):
- 4. How much did the sounds in your ears bother you? (On a scale from 1-5, where 1=Not at all and 5=Really badly):

Notes:

(212)746-8348
6-3480
6-7698

Clinical & Translational Science Center (CTSC)							
Core Laboratory Assay Request Form (A separate copy of this submittal form is required to accompany each sample or time series. For batches of identical assays, fill in one form and attach a list of samples)							
Requestor: Dr. JoAnn Difede	Phone number: _212-746-3079						
	E-mail address: jdifede@med.cornell.edu						
Department/Institution:Psychiatry/WCM	C						
Principal Investigator: JoAnn Difede	IRB#:1005011047 (required)						
Project Title: Enhancing Exposure Therapy for PTSD: Virtuenhancer.							
Sample:	Submission date: / /						
Sample ID #: (Requestor's reference number)*	[] Male [] Female						
	Investigation date: / /						

If time series, list all time points:

Assays Requested:

Tube Type (e.g. red-top, blue-top, etc)	# of Tubes	Volume/ tube (ml)	Sample Type (e.g. blood, urine, etc)	Assays Requested (e.g. total testosterone, TNFα, etc)	Special Procedures, if any (sample preparation, extra aliquots, etc)
Cotton for Saliva collection		0.2 ml	Saliva	Cortisol	Squeeze cotton to release saliva into a vial, freeze @ -20*C.

Identify unusual biological hazards:

Received by _____ Date __/ /

* Note: Privacy regulations require that the samples be identified by reference numbers (and investigator's name) only. The Core Lab *cannot accept* samples for assays labeled with the *subjects' names*.

Instructions for Computer and Hardware Set-up:

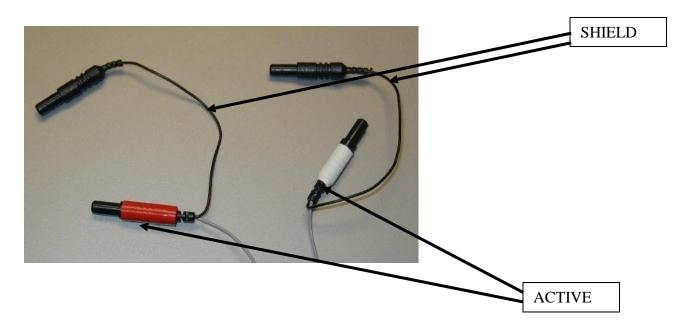
Turn on **Biopac Systems MP150**, black push button on the rear—check for green light under POWER.

See connection diagram (pg. 52).

- 1. Turn on AcqKnowledge computer (ACQ).
- 2. Check that the **ethernet** cable is plugged into the ethernet port on the back of the computer.
- 3. Select the serial number of the MP150 in the "hardware" window. If window is empty, click on "refresh list" until the number appears. This may take several tries for the system to find the Biopac hardware.

Glossary of Terms:

Active electrodes/lead: the wire that carries the signal to Biopac. There are 2 active leads with the colored tape on the plug (red and white, also labeled VIN+ and VIN-).



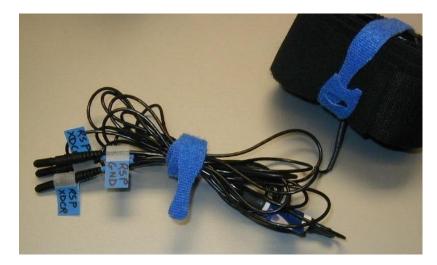
AcqKnowledge: the software that measures psychophysiological data via the Biopac System, loaded on the AcqKnowledge (ACQ) computer.

Audiometer: instrument used to test hearing

FPS: abbreviation for fear-potentiated startle paradigm

Biopac System MP150: the hardware that collects psychophysiological data

Chest strap: black velcro band used to measure respiration



- ECG: Electrocardiogram, used to measure heart-rate
- **ECG pinch leads**: the red and white shielded wires with clamps at the end that plug into the ECG receptacle on the other end



ECG snap-on electrodes: round vinyl electrodes 1.5 in. in diameter with snap-on attachment



- EMG: Electromyogram, used to measure muscle contraction
- **EMG snap-on leads**: the wires that attach to the EMG electrodes via snaps on one end and plug into the EMG receptacle on the other end



EMG snap-on electrodes: square cloth electrodes 0.875 by 0.875 inches with snap-on attachment for the leads



Ethernet: Yellow cable with phone-jack attachment

- **Ground**: the wire with no shield that grounds the electricity to prevent short circuits. Only one ground electrode is necessary for each subject, i.e., all electrodes on one subject can use the same ground wire.
- GSR: galvanic skin response, a measure of perspiration
- **GSR pinch leads:** black, unshielded wires with clamps on one end that plug into the GSR module on the Biopac on the other end



GSR snap-on electrodes: rectangular snap-on electrodes with foam backing



Impedance: the amount of resistance between the electrodes due to skin, oils, and dead skin cells

Samson mixer: S Monitor mixes the sounds going to the headphones

Shield: a 'net' of wires surrounding the active wires that shields the signal from electronic noise, such as produced by lights or other electrical equipment in the room.

Sternum: breastbone in center of ribcage

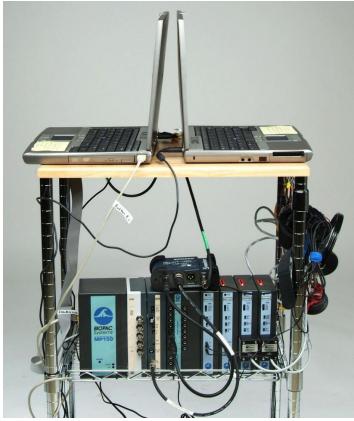
SuperLab: the software that presents the visual and acoustic stimuli

Receptacle: the flat portion at the end of the gray wires where the leads are plugged in



Equipment Connections:

OVERALL SET-UP OF ACQKNOWLEDGE AND SUPERLAB COMPUTERS (FRONT):



OVERALL SET-UP OF ACQKNOWLEDGE AND SUPERLAB COMPUTERS (REAR):



REAR VIEW OF ACQKNOWLEDGE (ACQ) AND SUPERLAB COMPUTERS:



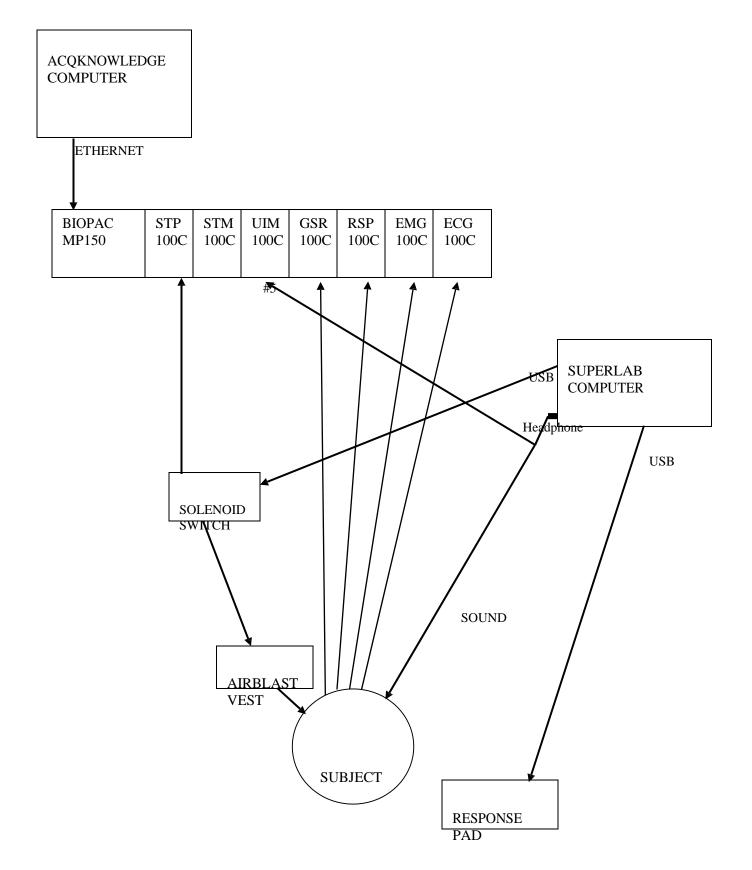
BIOPAC FRONT:



BIOPAC BACK:



CONNECTION DIAGRAM:





Virtual Reality Exposure Therapy Application for Post-Traumatic Stress Disorder

"Bravemind"

User Manual

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Version 1.0.3 June 2014



Sponsors



Development

USC Institute for Creative Technologies

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Release Notes

Version 1.0.3

- 1. New Functionality
 - a. Scenarios, global
 - i. Added new clips to sound library of Air Raid Siren, Bullet By 1 & 2, Baby Crying, Bullet Hits Aluminum, Bullets Hit Aluminum, Incoming Alert, Motor Pool 1 & 2, Phalanx Firing, and Radio 1 & 2. Note, not all scenario sound button panels in the Controller will have these sounds available by default.
 - b. Scenarios, Driving global
 - i. Create distant smoke of varying types and severity with Distant Effects controls.
 - c. Afghanistan Rural Driving and Afghanistan Bagram AB
 - i. Enabled medevac event content. Note, content still under development and may
 - have active issues. Feedback is welcome for ways to improve medevac content.
- 2. Improvements
 - a. Scenarios, global
 - i. Improved various system sounds for rumblefloor bass shaker actuation.
 - ii. Adjusted RPG Ambush explosion audio to be significantly louder.
 - iii. A-10 Flyover sound effect delay now timed properly.
 - iv. Added head shadow to avatar.
 - v. Increased Directional IED smoke duration.
 - vi. Shortened audio clip length and renamed "M2" Bursts 1 & 2 to ".50 Caliber."
 - b. Scenarios, Driving global
 - i. Vehicle Damage set to Moderate and Severe will dynamically cause the Humvee vehicle suspension to collapse in the direction of the IED hit.
 - 1. Vehicle will automatically slow to a stop under Moderate and Severe.
 - 2. Note, review damage states before use.
 - ii. Added dust effects to Black Hawk Landing/Takeoff.
 - iii. Removed ejected soldier on ground from Vehicle Flip encounter.
 - c. Afghanistan Rural Driving
 - i. Improved interior of Helicopter Ride model.
 - d. Afghanistan and Iraq Rural Driving
 - i. Added Black Hawk Landing/Takeoff instance near checkpoint location.
 - e. Iraq Rural Driving
 - i. Increased draw distance and appearance of palm trees.
 - f. Afghanistan Bagram AB
 - i. Adjusted animation of idle medics.
 - g. Afghanistan FOB
 - i. Barracks collision adjusted so avatar can naturally enter through doorway.
 - ii. Added idle soldiers and medics to the base interior.
 - iii. Added toggle visibility of soldiers and medics.
 - h. Afghanistan/Iraq Markets
 - i. Reduced firing time of RPG Ambush insurgents.
 - ii. RPG Ambush insurgents now reliably complete projectile firing sequence.
 - iii. Animals now toggle visibility.
 - iv. Added blue barrels to help denote navigable entryways and stairways.

- i. Afghanistan Market and Afghanistan Village
 - i. Randomized traditional clothing textures for men, women and children civilians.
- j. Afghanistan Village
 - i. Reduced walking civilians, minimizing their chances of becoming stuck in place.
 - ii. Added Black Hawk Landing/Takeoff instance near south west location.
 - iii. South West AK-47 Ambush insurgent now reliably completes attack sequence.
 - iv. Added Foothills teleport location.
 - v. Increased doorway heights.
 - vi. Animals now toggle visibility.
- k. Iraq Industrial
 - i. All NPCs now toggle visibility.
- 1. Iraq Residential
 - i. Added navigable mosque interior.
- m. Controller Application
 - i. Added blue background to the sound button panels to more clearly separate and define columns of the interface.
 - ii. The first teleport location of each scenario is now labeled "Starting Location" and corresponds to the initial spawn point of the avatar upon load of a scenario.
 - iii. Adjusted and updated sound button panel layouts.
 - iv. Rural Driving Scenarios, adjusted grouping of features in button layout.
 - v. Map Peek images now display all the same icons for locations, explosions, insurgents, soldiers, wounded, entryways and stairways found in images of the Guide Maps section of this manual.
- 3. Notable Issues
 - a. Scenarios, Driving global
 - i. Roadside Ambush and certain triggers may not recognize the switched second vehicle.
 - ii. Front vehicle may swerve or become stuck after terrain loops to starting point.1. Tip Click the Palm Grove location or another location to correct.
- 4. Other Notes
 - a. Iraq Rural Driving
 - i. Fixed issue with Roadside Debris set to Severe and Burning checked that caused soldier audio responses for IEDs and ambushes to not be heard.
 - b. Scenarios, Driving global
 - i. Front vehicle will slow down and brake at City intersection.
 - 1. Tip Slow avatar vehicle using gamepad to avoid ramming the vehicle.
 - ii. Vehicle Damage textures will not appear on the MRAP; as designed.
 - iii. Terrain fails to loop under Driver Control Full.
 - 1. Tip Teleport avatar vehicle manually after Checkpoint location.
 - c. Scenarios, Walking global
 - i. Crowd/NPCs fail to react to Directional IED trigger.
 - 1. Tip Hide civilians first or trigger a separate ambush simultaneously.
 - d. Device Drivers
 - i. InterSense InertiaCube 4 compatible through manual copy/paste/replace of isense.dll from C:\InterSense\InertiaCube Software\SDK\Windows\x86_32 to C:\Bravemind\PatientApplication\PatientApplication_Data\Plugins\
 - ii. Download Logitech Gamepad software from the manufacturer <u>website</u> or install the drivers from the disc bundled with the gamepad package.

Version 1.0.2

- 1. Improvements
 - a. Scenarios, global
 - i. Smoothed smoke transparency fade out effect for IED explosions.
 - b. Scenarios, Driving global
 - i. Added dynamic switch to avatar-centric Directional IED orientation after vehicle exit.
 - ii. MRAP engine sound level increased.
 - c. Afghanistan Village, Afghanistan FOB and Iraq Industrial
 - i. Changed sound of Mortar Attack incoming fire.
 - d. Iraq City Checkpoint
 - i. Reduced Rolling VBIED sequence detonation to 10 seconds from trigger.
 - ii. Added driver to Rolling VBIED sedan.
 - iii. Adjusted behaviors and placement of reacting soldiers.
- 2. Notable Issues
 - a. Iraq Rural Driving
 - i. With Roadside Debris set to Severe and Burning checked, soldier audio responses for IEDs and ambushes fail to emit.
 - 1. Tip Use Moderate with Burning checked instead to hear the audio.

Version 1.0.1

- 1. Bravemind now supports multiple HMD resolutions selectable from the Bravemind Configuration window Resolution dropdown at launch of the Patient Application.
- 2. Currently Supported Devices
 - a. InterSense InertiaCube 2 and 2+ motion trackers; 3 model untested
 - b. EnviroScent Scent Palette olfactory delivery machine
 - c. Logitech Rumblepad 2
 - d. Logitech Gamepad F310, F510, and F710
 - e. Ion GoPad and Genius MaxFire Pandora Pro mini-gamepads
- 3. Testable Motion Tracking Devices Requiring Manual Workaround to Enable Please contact us if you wish to use any of the below devices. Separate installer and/or .dll files are required to activate. Compatibility may vary by system.
 - a. InterSense InertiaCube 4 USB motion tracker
 - b. eMagin built-in motion tracker; drivers beta
 - c. Hillcrest FSRK-6 or FSM-6 motion trackers; drivers beta
- 4. Testable HMDs Requiring Adjustments to Configuration Please contact us if you wish to use the below device. Internal evaluation is underway and

considerations with regard to battery and external headphones are necessary.

- a. Sony HMZ-T3W HMD
- 5. Unsupported Devices
 - a. NVIS nVisor SX
- 6. Unsupported Operation Systems
 - a. Windows 7 32-bit
 - b. Windows 7 Home
 - c. Windows Vista 32-bit and 64-bit
 - d. Windows XP 32-bit and 64-bit

- 7. New Functionality
 - a. Scenarios, global
 - i. Addition of Fog and Sandstorm effects.
 - ii. Added new model of VBIED.
 - iii. Added new preset sound panels with updated button configurations.
 - iv. Replaced and improved many system sounds.
 - b. Scenarios, Driving global
 - i. Dynamic switching of MRAP and Humvee vehicles.
 - ii. Toggle on/off soldier IED reaction audio.
 - iii. Replaced soldier reaction audio for IED and ambushes.
 - c. Scenarios, Walking global
 - i. Addition of Directional IED triggers.
 - ii. Added new model of mosque.
 - d. Afghanistan Driving
 - i. Added Farm teleport location.
 - e. Afghanistan FOB
 - i. Edited avatar teleport locations.
 - f. Afghanistan/Iraq Markets
 - i. Edited avatar teleport locations.
 - ii. Added more parked vehicles to East/West zones.
 - g. Afghanistan/Iraq Markets and Afghanistan Village
 - i. Multiple Building Rooftop and Interior avatar teleport locations.
 - h. Afghanistan Village
 - i. Added Mortar Attack trigger.
 - i. Iraq City Checkpoint
 - i. Reduced Rolling VBIED sequence detonation to 25 seconds from trigger.
 - j. Iraq Industrial
 - i. Added break in rear of perimeter fence for river access.
 - ii. Added Military, Police, and Civilian NPCs.
 - iii. Added Mortar Attack trigger event.
 - k. Controller Application
 - i. Adjusted order of scenario buttons in main menu.
 - ii. Version number added to lower right of main menu.
 - iii. Added 60+ varieties of sound files for use with sound button panels.
 - iv. Map Peek; hover cursor over text to reveal top-down view of the current map.
 - v. Sound Configuration Editor; Edit, Load, and Save custom sound button panels for use within any scenario.
 - vi. Customize Scenario; click button to open dialog that allows loading of saved sound button panel configurations. Selection will persist between sessions.
- 8. Notable Issues
 - a. Scenarios, Driving global
 - i. Roadside Ambush and certain triggers may not recognize the switched second vehicle.
 - ii. Front vehicle may swerve or become stuck after terrain loops to starting point.
 - 1. Tip Click the Palm Grove location or another location to correct.
 - b. Scenarios, Walking global
 - i. RPG Insurgents may become stuck unable to fire from rooftops.
 - 1. Tip Move the avatar to a different location and try the ambush again.

- c. Afghanistan Bagram AB
 - i. Medics visible with rough animation idle.
- d. Afghanistan Village
 - i. Fleeing civilians become stuck running in place.
 - 1. Tip Uncheck Civilians to hide them before AK-47 or RPG Ambush.
 - ii. Certain civilians fail to react to VBID or toggle of visibility.
 - iii. Squad Foot Patrol soldiers stray or can become stuck against walls.
 - 1. Tip Reset and toggle again.
 - iv. Squad Foot Patrol soldiers weapons disappear after toggle of visibility.
- e. Iraq City Checkpoint
 - i. Rolling VBIED fails to complete after multiple toggles.
 - 1. Tip Toggle the event once to enable it until completion. Do NOT immediately toggle the event mid-sequence.
- 9. Other Notes
 - a. Scenarios, Driving global
 - i. Front vehicle will slow down and brake at City intersection.
 - 1. Tip Slow avatar vehicle using gamepad to avoid ramming the vehicle.
 - ii. Vehicle Damage textures will not appear on the MRAP; as designed.
 - iii. Terrain fails to loop under Driver Control Full.
 - 1. Tip Teleport avatar vehicle manually after Checkpoint location.
 - b. Scenarios, Walking global
 - i. Crowd/NPCs fail to react to Directional IED trigger.
 - 1. Tip Hide civilians first or trigger a separate ambush simultaneously.
 - c. Device Drivers
 - i. InterSense InertiaCube 4 compatible through manual copy/paste/replace of isense.dll from C:\InterSense\InertiaCube Software\SDK\Windows\x86_32 to ...\PatientApplication\PatientApplication_Data\Plugins\
 - ii. Download Logitech Gamepad software from the manufacturer <u>website</u> or install the drivers from the disc bundled with the gamepad package.
- 10. Postponed Improvements
 - a. Scenarios, Driving global
 - i. Randomize soldier reaction audio for IED trigger.
 - 1. Tip Click appropriate custom sound buttons for alternative reactions.
 - ii. Redistribute placed instances of Roadside Debris.
 - 1. Tip Use Moderate or Severe for best placement.
 - iii. Dynamic switch to avatar-centric Directional IED orientation after vehicle exit.
 - 1. Tip Reference the avatar vehicle orientation while dismounted.
 - b. Afghanistan Driving
 - i. Add vehicle traffic and "jingle" trucks.
 - c. Afghanistan/Iraq Markets
 - i. Additional stall vendors.
 - ii. Additional static vehicles.
 - iii. Toggle visibility of center stalls.
 - iv. Walking behavior of NPC civilians.
- 11. General
 - a. Other issues may still be present in the software and minor inconsistencies between the manual and software may exist.

VRET System Requirements

Desktop PC and Laptop Computer Specifications

Desktop Recommended Specs

- Operating System (OS): Windows 7 Pro/Ultimate/Enterprise 64-bit, w/latest service pack
- Processor (CPU): Intel Core i7, 3.5GHz processor or faster
- Memory (RAM): 8GB or greater
- Hard disk drive (HDD) free space: 15GB
- Graphics card: nVidia GTX 680 w/2GB VRAM or better card
- Other: HDMI output from graphics card for using Sony HMZ-T1 HMD.

Desktop Minimum Specs

- Operating System (OS): Windows 7 Pro/Ultimate/Enterprise 64-bit, w/latest service pack
- Processor (CPU): Intel Core Duo, 2.5GHz processor or equivalent
- Memory (RAM): 4GB
- Hard disk drive (HDD) free space: 15GB
- Graphics card: nVidia GTX 650 w/2GB VRAM or better card
- Other: HDMI output from graphics card for using Sony HMZ-T1 HMD.

Laptop Recommended Specs

- Operating System (OS): Windows 7 Pro/Ultimate/Enterprise 64-bit, w/latest service pack
- Processor (CPU): Intel Core i7, 2.7GHz processor or faster
- Memory (RAM): 8GB or greater
- Hard disk drive (HDD) free space: 15GB
- Graphics card: nVidia GTX 680M w/2GB VRAM or better card
- Other: HDMI output from laptop for using Sony HMZ -T1 HMD.

Laptop Minimum Specs

- Operating System (OS): Windows 7 Pro/Ultimate/Enterprise 64-bit, w/latest service pack
- Processor (CPU): Intel Core i7, 2.0GHz processor or faster
- Memory (RAM): 4GB
- Hard disk drive (HDD) free space: 15GB
- Graphics card: nVidia GTX 570M w/2GB VRAM or better card
- Other: HDMI output from laptop for using Sony HMZ-T1 HMD.

Note: GeForce cards recommended over Quadro for better real-time performance.

Note: AMD/ATI cards likely compatible, but not tested internally.

Desktop PC and Laptop Computer Equipment Configurations

Configuration is determined by choice of Head Mounted Display (HMD). The latest model is from Sony, the HMZ-T1, which utilizes HDMI at a resolution of 1280 x 720. The other option is the legacy eMagin Z800 3DVisor which uses VGA for lower quality 800 x 600 resolution.

Desktop – Sony HMZ-T1 HMD

- 1. Desktop PC with DVI and HDMI output from graphics card.
- 2. Monitor 1): DVI/HDMI input preferred. Displays the Controller application which is used by the Therapist to trigger and modulate stimuli in the virtual environment.
 - a. Appropriate video cable for connecting to PC; often included with monitor.
- 3. Monitor 2): Must have DVI or HDMI input. Used to mirror the patient's view of the virtual environment in the HMD. Small-medium sized HDTV also acceptable.
- 4. <u>Sony HMZ-T1</u> HMD. Displays virtual environment to patient.
- 5. Sony HMZ-T1 HMD video components:
 - a. <u>HDMI Matrix Splitter w/RCA Output</u>. For Sony HMD, secondary monitor, and amp.
 - b. 3qty. <u>High-Speed HMDI Cables</u>, 6ft. For HDMI Matrix Splitter, Sony HMD processer, and 2nd monitor.
 - i. <u>HDMI to DVI cable</u>, 6ft. If monitor DVI only. Replaces 1qty HDMI cable.
- 6. Sony HMZ-T1 HMD audio components:
 - a. <u>Behringer HA400 Headphone Amplifier</u>. Connects HDMI Matrix Splitter to audio output devices.
 - b. 2qty. <u>RCA Audio Cable</u>, 6ft. For connecting HDMI Matrix Splitter to headphone amplifier, then out to stereo-receiver.
 - c. 3qty. <u>6.35mm (1/4 Inch) Stereo Plug to 3.5mm Stereo Jack Adapter</u>. For headset output connecting from headphone amplifier. 2qty used, extras on-hand for replacement.
 - d. 4qty. <u>6.35mm (1/4 Inch) Stereo Plug to 2 RCA Jack Splitter Adapter</u>. For stereo-receiver connecting from headphone amplifier. 2qty used, extras on-hand for replacement.
 - e. <u>3.5mm F to M extension cable</u>, 6ft. For headset mic input connecting to PC.
- 7. <u>Vibrotactile Platform and Stereo Receiver</u>. Bass shaker speakers mounted underneath allow patient to feel sounds from the virtual environment. See section for options and construction. Receiver used to power speakers.
- 8. Microphone Headset. Allows clinician to speak to patient and hear VR environment.
- 9. Motion tracker device. Allows patient head movement to manipulate camera orientation in virtual environment. Choose an option:
 - a. Option #1 (high-cost) <u>InterSense InertiaCube 2+</u>. Requires add-on <u>serial/USB converter</u> <u>cable</u>.
 - b. Option #2 (mid-cost) <u>InterSense InertiaCube 4 USB</u>. Requires installation of specific drivers then manual file copy.
 - c. Option #3 (low-cost) <u>Hillcrest FSM-6</u>. Requires enclosure and cable. <u>See recommendations</u>.
- 10. <u>Logitech Gamepad</u>. Used for vehicle movement within the virtual environment. Models currently supported:
 - a. Rumblepad 2.
 - b. Rumble Gamepad F510.
 - c. Gamepad F310.
 - d. Wireless Gamepad F710 w/rumble.
 - e. Note: Be sure to switch the mode on the back of the gamepad to "D" instead of "X".

- 11. <u>M4 Training Rifle</u> (Inert; plastic polyurethane with the same weight as a real rifle). For use with mini-gamepad for dismounted movement within the virtual environment. Choose the black color option instead of blue to increase the immersive effect.
 - a. Alternate vendor: <u>http://www.inertproducts.com/inc/sdetail/1339/6963</u>
- 12. <u>Ion Go Pad</u>. Mini-gamepad for use with the M4 Training Rifle.
 - a. <u>Short mini-USB cable to connect to USB extension cable.</u>
 - b. Note: Legacy model supported, Genius MaxFire Pandora Pro.
- 13. 2qty. <u>USB extension cables</u>, 10ft. For connecting the Logitech Gamepad and mini-gamepad to the PC.
- 14. <u>Cable-ties</u> and <u>Velcro tape</u> for mounting motion tracker device to the HMD and the minigamepad to the training rifle.
- 15. Standard keyboard & mouse.
- 16. <u>Power strip</u> with at least 7 outlets.
- 17. Optional Components.

Desktop – eMagin Z800 HMD

- 1. Desktop PC with DVI and/or VGA output from graphics card.
- 2. Monitor 1): DVI input preferred. Displays the Controller application which is used by the Therapist to trigger and modulate stimuli in the virtual environment.
 - a. Appropriate video cable for connecting to PC; often included with monitor.
- 3. Monitor 2): Must have VGA input. Used to mirror the patient's view of the virtual environment in the HMD. Small-medium sized HDTV also acceptable.
- 4. <u>eMagin Z800 HMD</u>. Displays virtual environment to patient.
- 5. eMagin Z800 HMD Audio/Video components:
 - a. <u>DVI to VGA cable</u>, 6ft. If connecting from graphics card DVI output to eMagin Z800 HMD control box.
 - b. <u>VGA cable</u>, 6ft. For connecting secondary monitor to eMagin Z800 HMD control box.
 i. 2qty if output from graphics card VGA. Replaces DVI to VGA cable.
 - c. <u>USB A to B (straight) cable</u>, 6ft. Allows eMagin Z800 HMD control box to be conveniently placed on desk.
 - d. 2qty. <u>3.5mm Headphone Splitter</u>, 6in. For splitting audio to headphones, headset and Vibrotactile Platform.
 - e. <u>3.5mm M to RCA M Stereo cable</u>, 6ft. Connects to Receiver from splitter.
 - f. Note: See <u>recommended audio components</u> using headphone amplifier if sound levels too low in patient headphones, headset, and Vibrotactile Platform.
- 6. <u>Vibrotactile Platform and Stereo Receiver</u>. Bass shaker speakers mounted underneath allow patient to feel sounds from the virtual environment. See section for options and construction. Receiver used to power speakers.
- 7. <u>Microphone Headset</u>. Allows clinician to speak to patient and hear virtual environment.
- 8. <u>Headphones</u>. For patient audio in virtual environment; high-quality and over-ear recommended.
- 9. Motion tracker device. Allows patient head movement to manipulate camera orientation in virtual environment. Choose an option:
 - a. Option #1 Built-in, internal motion tracker to eMagin Z800 HMD.
 - b. Option #2 (high-cost) <u>InterSense InertiaCube 2+</u>. Requires add-on <u>serial/USB converter</u> <u>cable</u>.
 - c. Option #3 (mid-cost) <u>InterSense InertiaCube 4 USB</u>. Requires installation of specific drivers then manual file copy.
 - d. Option #4 (low-cost) <u>Hillcrest FSM-6</u>. Requires enclosure and cable. <u>See</u> recommendations.

- 10. <u>Logitech Gamepad</u>. Used for vehicle movement within the virtual environment. Models currently supported:
 - a. Rumblepad 2.
 - b. Rumble Gamepad F510.
 - c. Gamepad F310.
 - d. Wireless Gamepad F710 w/rumble.
 - e. Note: Be sure to switch the mode on the back of the gamepad to "D" instead of "X".
- 11. <u>M4 Training Rifle</u> (Inert; plastic polyurethane with the same weight as a real rifle). For use with mini-gamepad for dismounted movement within the virtual environment. Choose the black color option instead of blue to increase the immersive effect.
 - a. Alternate vendor: <u>http://www.inertproducts.com/inc/sdetail/1339/6963</u>
- 12. <u>Ion Go Pad</u>. Mini-gamepad for use with the M4 Training Rifle.
 - a. <u>Short mini-USB cable</u> to connect to USB extension cable.
 - b. Note: Legacy model supported, Genius MaxFire Pandora Pro.
- 13. 2qty. <u>USB extension cables</u>, 10ft. For connecting the Logitech Gamepad and mini-gamepad to the PC.
- 14. <u>Cable-ties</u> and <u>Velcro tape</u> for mounting motion tracker device to the HMD and the minigamepad to the training rifle.
- 15. Standard keyboard & mouse.
- 16. <u>Power strip</u> with at least 5 outlets.
- 17. Optional Components.

Laptop – Sony HMZ-T1 HMD

- 1. Laptop must have HDMI output.
- 2. Laptop screen: Displays the Controller application which is used by the Therapist to trigger and modulate stimuli in the virtual environment.
- 3. Monitor: Must have DVI or HDMI input. Used to mirror the patient's view of the virtual environment in the HMD. Small-medium sized HDTV also acceptable.
 - a. **Note:** For portability and travel, the <u>Xenarc 700YH</u>7" LCD monitor has been tested compatible with the software and Sony HMZ-T1.
- 4. <u>Sony HMZ-T1</u> HMD. Displays virtual environment to patient.
- 5. Sony HMZ-T1 HMD video components:
 - a. <u>HDMI Matrix Splitter w/RCA Output</u>. For Sony HMD, secondary monitor, and amp.
 - b. 3qty. <u>High-Speed HMDI Cables</u>, 6ft. For HDMI Matrix Splitter, Sony HMD processer, and 2nd monitor.
 - i. <u>HDMI to DVI cable</u>, 6ft. If monitor DVI only. Replaces 1qty HDMI cable.
- 6. Sony HMZ-T1 HMD audio components:
 - a. <u>Behringer HA400 Headphone Amplifier</u>. Connects HDMI Matrix Splitter to audio output devices.
 - b. 2qty. <u>RCA Audio Cable</u>, 6ft. For connecting HDMI Matrix Splitter to headphone amplifier, then out to stereo-receiver.
 - c. 3qty. <u>6.35mm (1/4 Inch) Stereo Plug to 3.5mm Stereo Jack Adapter</u>. For headset output connecting from headphone amplifier. 2qty used, extras on-hand for replacement.
 - d. 4qty. <u>6.35mm (1/4 Inch) Stereo Plug to 2 RCA Jack Splitter Adapter</u>. For stereo-receiver connecting from headphone amplifier. 2qty used, extras on-hand for replacement.
 - e. <u>3.5mm F to M extension cable</u>, 6ft. For headset mic input connecting to PC.
- 7. <u>Vibrotactile Platform and Stereo Receiver</u>. Bass shaker speakers mounted underneath allow patient to feel sounds from the virtual environment. See section for options and construction. Receiver used to power speakers.

- 8. <u>Microphone Headset</u>. Allows clinician to speak to patient and hear VR environment.
- 9. Motion tracker device. Allows patient head movement to manipulate camera orientation in virtual environment. Choose an option:
 - a. Option #1 (high-cost) <u>InterSense InertiaCube 2+</u>. Requires add-on <u>serial/USB converter</u> <u>cable</u>.
 - b. Option #2 (mid-cost) <u>InterSense InertiaCube 4 USB</u>. Requires installation of specific drivers then manual file copy.
 - c. Option #3 (low-cost) <u>Hillcrest FSM-6</u>. Requires enclosure and cable. <u>See recommendations</u>.
- 10. <u>Logitech Gamepad</u>. Used for vehicle movement within the virtual environment. Models currently supported:
 - a. Rumblepad 2.
 - b. Rumble Gamepad F510.
 - c. Gamepad F310.
 - d. Wireless Gamepad F710 w/rumble.
 - e. Note: Be sure to switch the mode on the back of the gamepad to "D" instead of "X".
- 11. <u>M4 Training Rifle</u> (Inert; plastic polyurethane with the same weight as a real rifle). For use with mini-gamepad for dismounted movement within the virtual environment. Choose the black color option instead of blue to increase the immersive effect.
 - a. Alternate vendor: http://www.inertproducts.com/inc/sdetail/1339/6963
- 12. <u>Ion Go Pad</u>. Mini-gamepad for use with the M4 Training Rifle.
 - a. <u>Short mini-USB cable</u> to connect to USB extension cable.
 - b. Note: Legacy model supported, Genius MaxFire Pandora Pro.
- 13. 2qty. <u>USB extension cables</u>, 10ft. For connecting the Logitech Gamepad and mini-gamepad to the PC.
- 14. <u>Cable-ties</u> and <u>Velcro tape</u> for mounting motion tracker device to the HMD and the minigamepad to the training rifle.
- 15. Built-in keyboard & trackpad or external keyboard & mouse.
- 16. <u>Power strip</u> with at least 6 outlets.
- 17. Optional Components.

Laptop – eMagin Z800 HMD

- 1. Laptop with Mini DisplayPort, DVI or VGA output.
- 2. Laptop screen: Displays the Controller application which is used by the Therapist to trigger and modulate stimuli in the virtual environment.
- 3. Monitor: Must have VGA input. Used to mirror the patient's view of the virtual environment in the HMD. Small-medium sized HDTV also acceptable.
 - a. **Note:** For portability and travel, <u>Xenarc 800YV</u> 8" LCD monitor has been tested compatible with the software and eMagin Z800.
- 4. <u>eMagin Z800 HMD</u>. Displays virtual environment to patient.
- 5. eMagin Z800 HMD Audio/Video components:
 - a. <u>DVI to VGA cable</u>, 6ft. If connecting from laptop DVI output to eMagin Z800 HMD control box.
 - b. <u>Mini DisplayPort to VGA cable</u>, 6ft. If connecting from laptop Mini DisplayPort output to eMagin Z800 HMD control box.
 - c. <u>VGA cable</u>, 6ft. For connecting secondary monitor to eMagin Z800 HMD control box.
 - i. 2qty if laptop direct output VGA. Replaces DVI to VGA cable and Mini DisplayPort to VGA cable.

- d. <u>USB A to B (straight) cable</u>, 6ft. Allows eMagin Z800 HMD control box to be conveniently placed on desk.
- e. 2qty. <u>3.5mm Headphone Splitter</u>, 6in. For splitting audio to headphones, headset and Vibrotactile Platform.
- f. <u>3.5mm M to RCA M Stereo cable</u>, 6ft. Connects to Receiver from splitter.
- g. Note: See <u>recommended audio components</u> using headphone amplifier if sound levels too low in patient headphones, headset, and Vibrotactile Platform.
- 6. <u>Vibrotactile Platform and Stereo Receiver</u>. Bass shaker speakers mounted underneath allow patient to feel sounds from the virtual environment. See section for options and construction. Receiver used to power speakers.
- 7. <u>Microphone Headset</u>. Allows clinician to speak to patient and hear virtual environment.
- 8. <u>Headphones</u>. For patient audio in virtual environment; high-quality and over-ear recommended.
- 9. Motion tracker device. Allows patient head movement to manipulate camera orientation in virtual environment. Choose an option:
 - a. Option #1 Built-in, internal motion tracker to eMagin Z800 HMD.
 - b. Option #2 (high-cost) <u>InterSense InertiaCube 2+</u>. Requires add-on <u>serial/USB converter</u> <u>cable</u>.
 - c. Option #3 (mid-cost) <u>InterSense InertiaCube 4 USB</u>. Requires installation of specific drivers then manual file copy.
 - d. Option #4 (low-cost) <u>Hillcrest FSM-6</u>. Requires enclosure and cable. <u>See</u> recommendations.
- 10. <u>Logitech Gamepad</u>. Used for vehicle movement within the virtual environment. Models currently supported:
 - a. Rumblepad 2.
 - b. Rumble Gamepad F510.
 - c. Gamepad F310.
 - d. Wireless Gamepad F710 w/rumble.
 - e. Note: Be sure to switch the mode on the back of the gamepad to "D" instead of "X".
- 11. <u>M4 Training Rifle</u> (Inert; plastic polyurethane with the same weight as a real rifle). For use with mini-gamepad for dismounted movement within the virtual environment. Choose the black color option instead of blue to increase the immersive effect.
 - a. Alternate vendor: <u>http://www.inertproducts.com/inc/sdetail/1339/6963</u>
- 12. <u>Ion Go Pad</u>. Mini-gamepad for use with the M4 Training Rifle.
 - a. <u>Short mini-USB cable to connect to USB extension cable.</u>
 - b. Note: Legacy model supported, Genius MaxFire Pandora Pro.
- 13. 2qty. <u>USB extension cables</u>, 10ft. For connecting the Logitech Gamepad and mini-gamepad to the PC.
- 14. <u>Cable-ties</u> and <u>Velcro tape</u> for mounting motion tracker device to the HMD and the minigamepad to the training rifle.
- 15. Built-in keyboard & trackpad or external keyboard & mouse.
- 16. <u>Power strip</u> with at least 4 outlets.
- 17. Optional Components.

Optional Components

- 1. Scent machine with compressor and set of scent vials. See the <u>Scent Machine</u> section for the components and proper use of the machine to simulate different scents during the simulation.
- 2. <u>Mic/light stand with boom</u>. For cable management, allowing cables to be off the ground and strung overhead.
 - a. <u>Carabiner or mic clip</u> attached to end of boom to run cables through.

- b. Note: See cable management for details.
- 3. <u>Comfort Pads</u> for the Sony HMZ-T1 HMD.
- 4. <u>Forehead Pad and Light Blocker</u> for the Sony HMZ-T1 HMD.

Comfort and Forehead Pads - Sony HMZ-T1 HMD

Outfit the comfort pads and forehead pads as shown below to significantly improve comfort of the Sony HMZ-T1 HMD. Alternative, per-site modifications welcome, if patient comfort will further improve.



InterSense InertiaCube 2/2+ Serial/USB Adaptor

Pictured below is the serial/USB adaptor required for the InertiaCube2/2+. Request it when ordering through InterSense. The other serial+A/C power adaptor piece shipped with the device will not be used with the system.



Hillcrest FSM-6 Enclosure Recommendations

- 1. <u>Micro-USB cable</u>, 15ft. For connecting FSM-6 to PC.
- 2. <u>Mini Project Box</u>. Protects device and allows it to be mounted on HMD.
- 3. Hardware and tools for securing device inside enclosure. See <u>assembly steps</u>.

Hardware Configuration

Desktop Connection Process w/Recommended Audio – Sony HMZ-T1 HMD

The below steps detail the process to connect the Sony HMZ-T1 HMD and Desktop PC with all peripherals. This includes steps to connect the recommended audio components. Diagrams for device and audio connections follow.

- 1. HDMI Matrix Splitter and Analog Audio
 - a. Plug in HDMI cable to Input #1 that will go to Desktop.
 - b. Plug in HDMI cables to Output A for the Sony HMD, and Output B for the secondary monitor.
 - c. Plug in red end of RCA cable to red connector on HDMI splitter.
 - d. Plug in white end of RCA cable to white connector on HDMI splitter.
 - e. Plug in power adaptor for HDMI splitter.
 - f. Power on HDMI splitter.
- 2. Headphone Amplifier
 - a. Ensure all volume level knobs at 0.
 - b. Plug in the RCA cable red and white ends from HDMI splitter box to RCA side of 6.35mm stereo plug to RCA adapter.
 - c. Plug in 6.35mm stereo plug end of adapter to Input port on headphone amplifier.
 - d. Plug in power adaptor for headphone amplifier.
- 3. Headset and Headphone Amplifier
 - a. Plug in green (output) end of headset to connector of 3.5mm F to M extension cable.
 - b. Plug in 3.5mm F to M extension cable to 6.35mm M to 3.5mm F adapter.
 - c. Plug in end of the 6.35mm M to 3.5mm F adapter to #1 port of headphone amplifier.
- 4. Secondary Monitor
 - a. Plug in HDMI cable from HDMI splitter Output B to HDMI 1 port on back of secondary monitor.
 - b. Plug in power cable to secondary monitor.
 - c. Turn on secondary monitor and select HDMI 1 as source.
- 5. Primary Monitor
 - a. Plug in or DVI or HDMI cable to monitor input.
 - b. Plug in power cable for monitor.
 - c. Turn on monitor.
- 6. Sony HMZ-T1 HMD
 - a. Plug in HDMI cable from HDMI splitter Output A to Input port on rear of HMZ-T1 processor box.
 - b. Plug in connector cable from HMD itself to front of processor unit.
 - c. Plug in power adaptor for HMZ-T1 processor box.
 - d. Power on HMD using the power button on the underside of the HMD.
- 7. Sherwood Receiver, Vibrotactile Platform, and Headphone Amplifier

- a. Insert red (+) end of speaker wire from platform to Speaker B, right [R] red tab on rear of receiver.
- b. Insert black (-) end of speaker wire from platform to Speaker B, right [R] black tab on rear of receiver.
- c. Insert red (+) end of speaker wire from platform to Speaker B, left [L] red tab on rear of receiver.
- d. Insert black (-) end of speaker wire from platform to Speaker B, left [L] black tab on rear of receiver.
- e. Plug in the RCA cable red and white ends to CD Input connectors on rear of receiver.
- f. Plug in other side of RCA cable red and white ends to RCA side of 6.35mm stereo plug to RCA adapter.
- g. Plug in 6.35mm stereo plug end of adaptor to #3 port on headphone amplifier.
- h. Plug in power cable for receiver and power on the device.
- i. Press button to select Speaker B.
- j. Adjust volume knob to ~40.
- 8. Desktop
 - a. Plug in Logitech gamepad w/USB extension.
 - b. Plug in mini-gamepad w/USB extension.
 - c. Plug in InertiaCube or Hillcrest USB device.
 - d. Plug in HDMI cable from HDMI splitter Input #1.
 - e. Plug in DVI or HDMI cable from primary monitor.
 - f. Plug in pink (mic) end of headset to mic-in port.
 - g. Plug in keyboard & mouse USB devices.
 - h. Plug in power cable to desktop.
 - i. Power on desktop.
 - j. Ensure on the HDMI splitter that Output A, #1 and Output B, #1 green LEDs are active. Use the front buttons to change the Input, if necessary.
 - k. Carefully adjust volume level knobs on headphone amplifier for receiver and headset until desired sound levels achieved.

Laptop Connection Process – Sony HMZ-T1 HMD

Process is the same as Desktop, but omits steps related to Primary Monitor, as the built-in laptop screen acts as the Primary Monitor.

Desktop Connection Process w/Basic Audio – eMagin Z800 HMD

The below steps detail the process to connect the eMagin Z800 HMD and Desktop PC with all peripherals. This includes steps to connect the basic audio components. Diagrams for device and audio connections follow.

Please see the Recommended Setup under Audio Connections - eMagin Z800 for the optimal configuration providing advanced sound level control.

- 1. eMagin Z800 HMD Control Box
 - a. Plug in VGA cable to outside (right) VGA input of control box that will go to Desktop.
 - b. Plug in VGA cable to inside (left) VGA output of control box that will go to secondary monitor.
 - c. Plug in B end of USB cable to port on control box.
- 2. Secondary Monitor
 - a. Plug in VGA cable from Z800 control box to VGA port on back of secondary monitor.
 - b. Plug in power cable to secondary monitor.
 - c. Turn on secondary monitor and select VGA as source.
- 3. Primary Monitor
 - a. Plug in DVI cable to monitor input.
 - b. Plug in power cable for monitor.
 - c. Turn on monitor.
- 4. eMagin Z800 HMD
 - a. No further connection steps required.
- 5. Sherwood Receiver and Vibrotactile Platform
 - a. Insert red (+) end of speaker wire from platform to Speaker B, right [R] red tab on rear of receiver.
 - b. Insert black (-) end of speaker wire from platform to Speaker B, right [R] black tab on rear of receiver.
 - c. Insert red (+) end of speaker wire from platform to Speaker B, left [L] red tab on rear of receiver.
 - d. Insert black (-) end of speaker wire from platform to Speaker B, left [L] black tab on rear of receiver.
 - e. Plug in red and white ends of 3.5mm to RCA cable to corresponding CD Input connectors on rear of receiver.
 - f. Plug in power cable for receiver and power on the device.
 - g. Press button to select Speaker B.
 - h. Adjust volume knob to ~40.
- 6. Desktop
 - a. Plug in Logitech gamepad w/USB extension.
 - b. Plug in mini-gamepad w/USB extension.
 - c. Plug in USB cable from control box.
 - d. Plug in InertiaCube or Hillcrest USB device, if utilized.
 - e. Plug in VGA (or DVI to VGA) cable from control box.
 - f. Plug in DVI cable from primary monitor.
 - g. Plug in green (output) end of headset to one connector of 3.5mm audio cable splitter.
 - h. Plug in green (Line out) end of headphones to other connector of same 3.5mm audio cable splitter.
 - i. Plug 3.5mm cable splitter with connected headphone and headset into one connector of second 3.5mm audio cable splitter.
 - j. Plug 3.5mm end of 3.5mm to RCA cable to open connector of second 3.5mm audio cable splitter.
 - k. Plug the now linked 3.5 audio cable splitters into Line out (green) port.

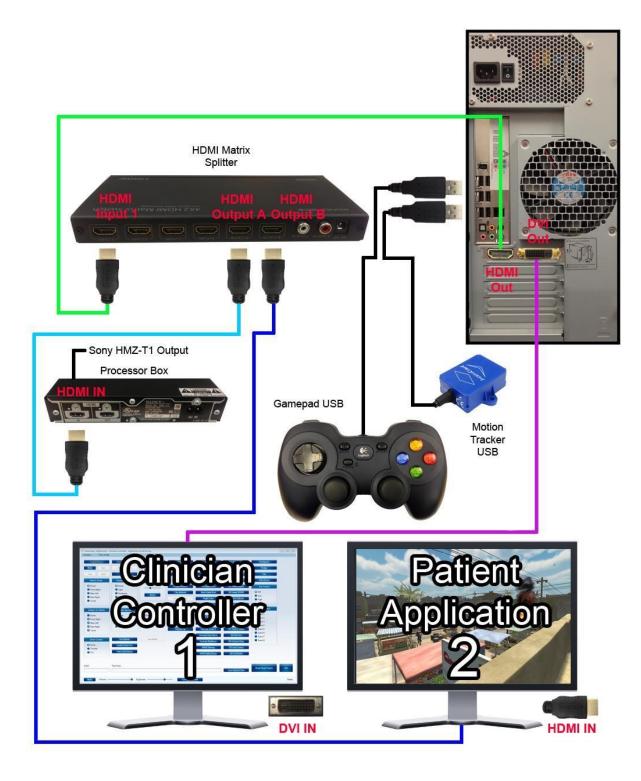
- 1. Plug in mic (pink) end of headset to mic-in port.
- m. Plug in keyboard & mouse USB devices.
- n. Plug in power cable to desktop.
- o. Power on desktop.

Laptop Connection Process w/Basic Audio – eMagin Z800 HMD

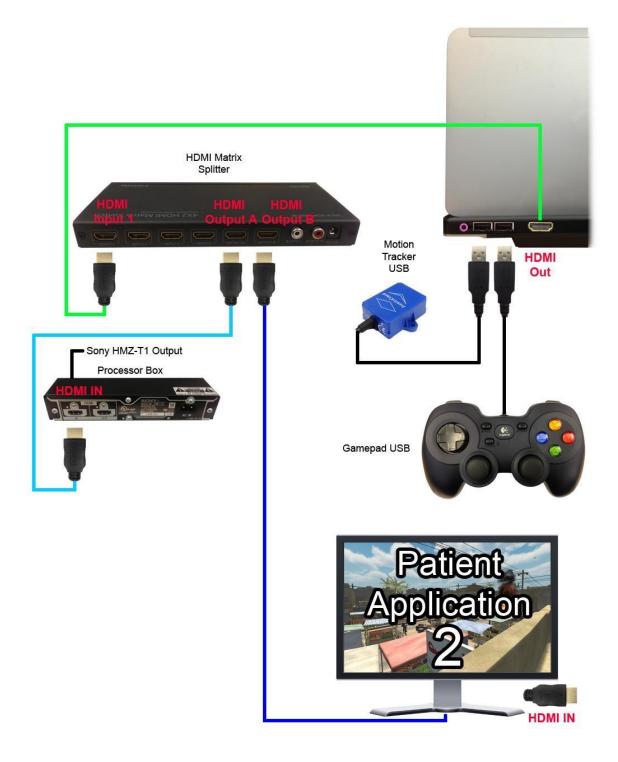
Process is the same as Desktop, but omits steps related to Primary Monitor, as the built-in laptop screen acts as the Primary Monitor.

Please see the Recommended Setup under Audio Connections - eMagin Z800 for the optimal configuration providing advanced sound level control.

Desktop Device Connection Diagram – Sony HMZ-T1 HMD

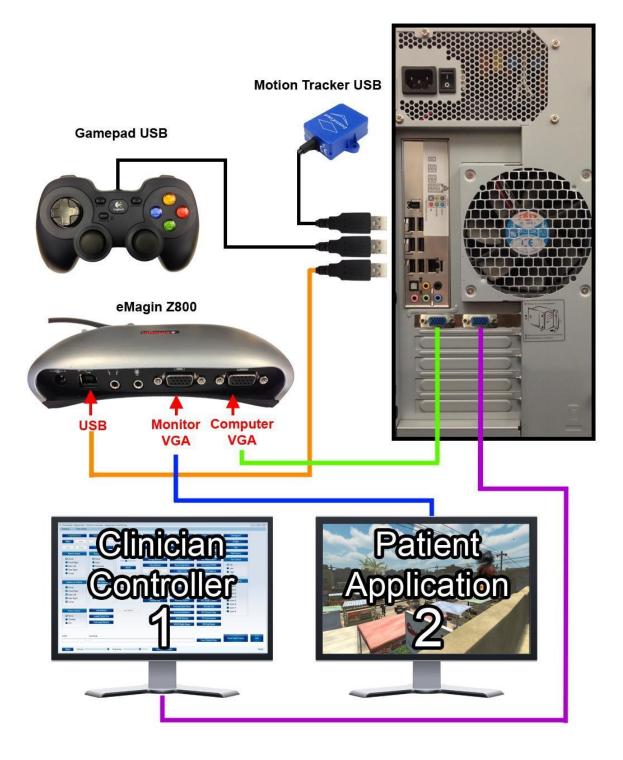


Laptop Device Connection Diagram – Sony HMZ-T1 HMD

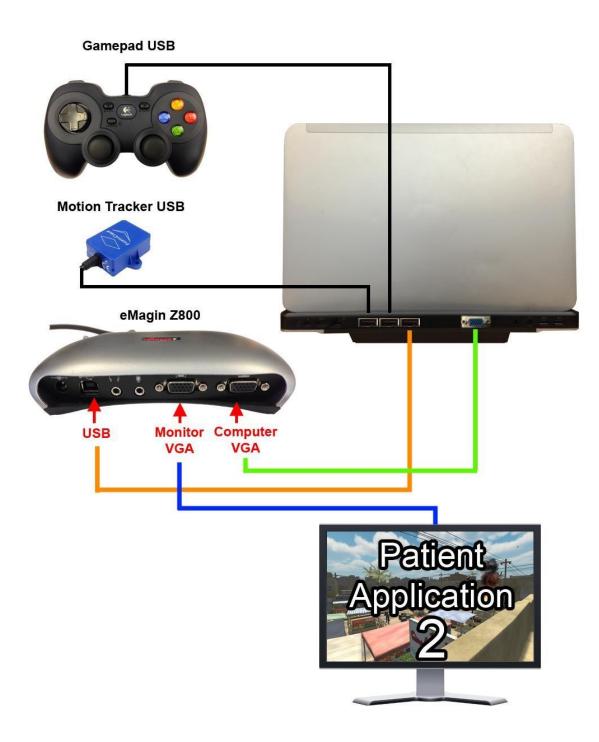


Note: The Clinician Controller will be displayed on the laptop screen.

Desktop Device Connection Diagram – eMagin Z800 HMD



Laptop Device Connection Diagram – eMagin Z800 HMD



Note: The Clinician Controller will be displayed on the laptop screen.

Audio Connections – Sony HMZ-T1 HMD

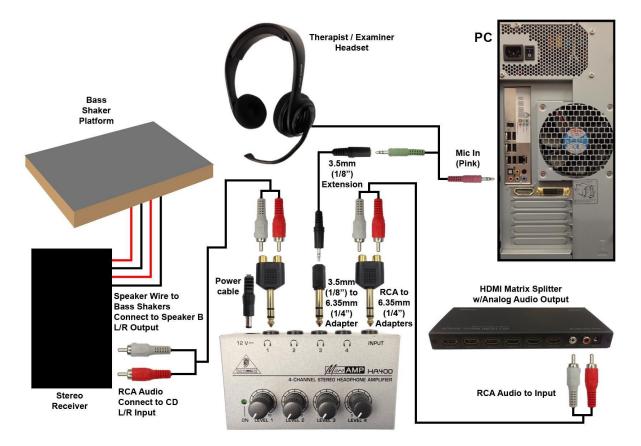
Recommended Setup

Audio components from the Sony HMZ-T1 HMD connection process in the previous section are illustrated in the diagram below. The Stereo Headphone Amplifier acts as a central hub to independently control volume levels for the Therapist Headset and Receiver/platform. This Amplifier receives its audio signal through the RCA connection to the HDMI Matrix Splitter. Combined, the Stereo Headphone Amplifier and HDMI Matrix Splitter simultaneously provide audio to all three components: Sony HMZ-T1 Patient Headphones, Therapist Headset, and Receiver/platform.

Use the "#1" volume knob to fine-tune the Receiver/platform; likely to be a value between 5-9.

Use the "#3" volume knob to fine-tune the Therapist Headset; likely to be a value between 3-6.

Note: The volume level for the Sony HMZ-T1 HMD must be adjusted using the in-visor controls.



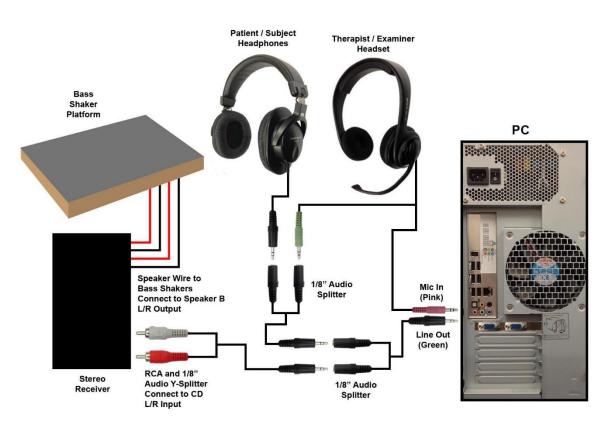
Refer to the Bass Shaker section for that specific equipment.

Audio Connections – eMagin Z800 HMD

Basic Setup

Audio components from the eMagin Z800 HMD connection process in the previous section are illustrated in the diagram below. The following setup can be used if the Desktop PC sound card output levels are satisfactory and the Headset and Headphones have independent (in-line) volume adjustment.

In this configuration, the dual 1/8in (3.5mm) Y-Splitters simultaneously provide audio to all three components: Patient Headphones, Therapist Headset, and Receiver/platform.



Refer to the **Bass Shaker** section for that specific equipment.

Recommended Setup

The below audio configuration for the eMagin Z800 HMD is strongly recommend over the basic configuration described above. Certain Desktop PC sound cards require external amplification to output a signal strong enough for all three audio components.

The Stereo Headphone Amplifier acts as a central hub to independently control volume levels for the Patient Headphones, Therapist Headset and Receiver/platform. This Amplifier simultaneously provides audio to all three components: Sony HMZ-T1 Patient Headphones, Therapist Headset and Receiver/platform.

Use the "#1" volume knob to fine-tune the Receiver/platform; likely to be a value between 5-9.

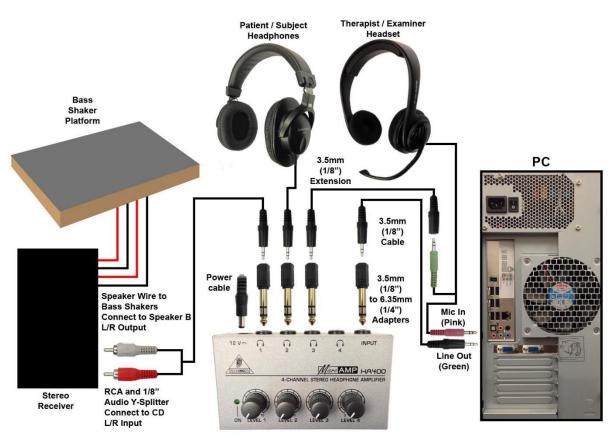
Use the "#2" volume knob to fine-tune the Patient Headphones; likely to be a value between 3-6.

Use the "#3" volume knob to fine-tune the Therapist Headset; likely to be a value between 3-6.

Equipment List:

- 1. Microphone Headset. Allows clinician to speak to patient and hear VR environment.
- 2. <u>Headphones</u>. For patient audio in virtual environment; high-quality and over-ear recommended.
- 3. 6 qty. <u>6.35mm (1/4") Stereo Plug to 3.5mm Stereo Jack Adapter</u>. For connecting 1/8in (3.5mm) plugs to 1/4in (6.35mm) input and outputs of Headphone Amplifier. 4 qty. used, extras on-hand for replacement.
- 4. <u>1/8" (3.5mm) stereo plug M to M cable, 6ft</u>. For Amplifier input connecting from Desktop PC.
- 5. <u>1/8" (3.5mm) F to M extension cable</u>, 6ft. For Headset output connecting from Amplifier.
- 6. <u>Behringer HA400 Headphone Amplifier</u>. Connects Desktop PC audio input to output devices.
- 7. <u>1/8" (3.5mm) stereo plug to RCA stereo Y-splitter cable</u>. Connects Amplifier to Receiver/platform.

Note: Tested Headset and Headphones brand is Sennheiser and model of Stereo Headphone Amplifier is the <u>Behringer HA400 MicroAmp</u>.



Steps to complete the audio configuration modeled in the diagram above:

- 1. Plug the 1/8" (mini) cable into Line Out (green) on the back of the PC.
- 2. Plug the other end of the 1/8" cable into a 1/8" to 1/4" adapter.

- 3. Plug this cable w/adapter into the "INPUT" of the Stereo Headphone Amplifier.
- 4. Ensure the Bass Shaker cables are connected to "Speaker B" on the Receiver.
- 5. Plug the Red and White ends of the RCA Y-Splitter cable into the CD In of the Receiver.
- 6. Plug the 1/8" end plug of the RCA Y-Splitter cable into a 1/8" to 1/4" adapter.
- 7. Plug this cable w/adapter into #1 of the Stereo Headphone Amplifier.
- 8. Plug the Patient/Subject Headphones 1/8" end into a 1/8" to 1/4" adapter.
 - a. Note: Certain models of headphones may not require a 1/8" to 1/4" adapter.
- 9. Plug this cable w/adapter into #2 of the Stereo Headphone Amplifier.
- 10. Plug the 1/8" Line Out end (green) of the Therapist/Examiner Headset into one end of the 1/8" extension cable.
- 11. Plug the other end of the 1/8" extension cable into a 1/8" to 1/4" adapter.
- 12. Plug this cable w/adapter into #3 of the Stereo Headphone Amplifier.
- 13. Plug the Line In (pink) end of the Therapist/Examiner Headset into the Mic In (pink) on the PC.
- 14. Plug the Stereo Headphone Amplifier power cable into the unit, the green light will turn on.

Refer to the **Bass Shaker** section for that specific equipment.

Signal Isolation – eMagin Z800 HMD and Sony HMZ-T1 HMD

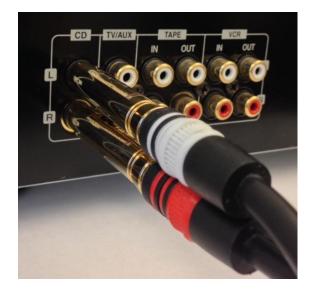
Minimize the "echo" effect caused by the high-frequency signals passed from the Sherwood Stereo Receiver to the bass shaker speakers in the vibrotactile platform by adding a simple signal isolator.

Harrison Labs FMOD Inline Crossover Pair 50 Hz Low Pass RCA

1. Plug each RCA isolator directly into the CD In of the Receiver.



2. Plug the Red and White ends of the RCA cable into the correct L and R RCA isolator.



Vibrotactile Platform

Use the following materials and construction diagrams as a guide for creating a basic vibrotactile platform, commonly called a "rumblefloor," that simulates the vibrations of vehicle engines, explosions, gunfire, etc. The patient will stand or be seated in a chair atop the platform.

Electronics:

- 1. One Amplifier (use the model listed below or an equivalent):
 - a. 100 Watts per Channel x 2 in Stereo Mode
 - b. Brand and Model: Sherwood, RX-4105
- 2. Four Bass Shakers (use the model listed below or an equivalent):
 - a. Brand and Model: <u>AURA, AST-2B-04, 4 Ω 50W</u>

Materials:

- 1. 3 ft. square piece of carpet
- 2. 3 ft. square plywood base, between .75 in. thick
 - a. One 2 ft. wide piece of plywood cut to 3 ft. in length
 - b. One 1 ft. wide piece of plywood cut to 3 ft. in length
- 3. 2x4 boards
 - a. Two 33 in. length 2x4s
 - b. Two 36 in. length 2x4s
- 4. 4 rubber footings to dampen vibration
- 5. Box of 3 in. screws
- 6. <u>30 ft. of speaker wire</u>

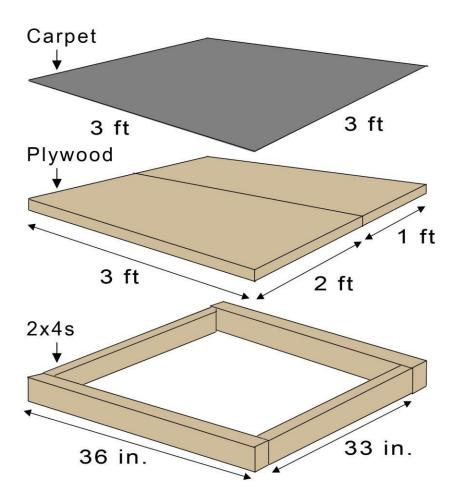
Construction Instructions and Diagrams:

Bass Shakers are basically speakers. The louder the bass coming from the amplifier, the more they shake. The approach we have taken is to screw 4 bass shakers to a platform directly underneath the 4 legs of a chair that would sit atop the platform. Then use speaker cord to connect the shakers to the speaker output of an amplifier.

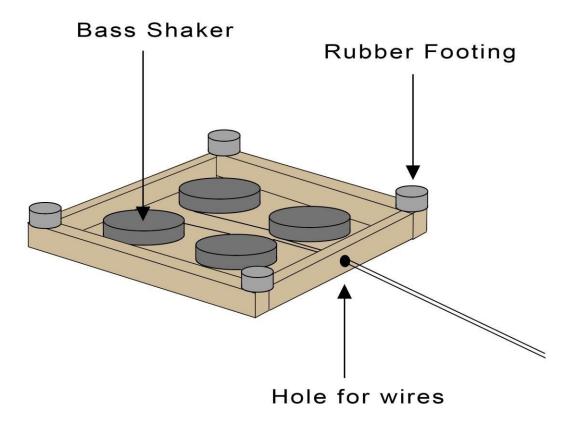
If constructing yourself and don't have a saw, you can have the 2x4s and plywood cut at the hardware store by a store assistant. A drill is handy for the screws and if you want to cut a hole in one of the 2x4s to thread the speaker wire. Handles can also be attached to the sides of the platform for easy transport.

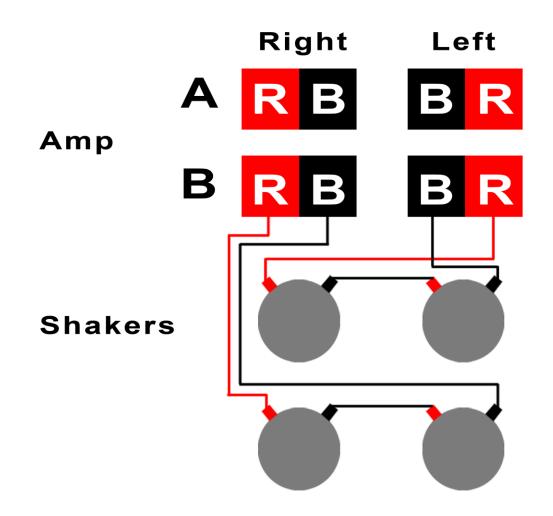
Note: Pre-built vibrotactile platforms available. Please contact us for vendor details.





Bottom View





IMPORTANT: The bass shakers are wired above in a "series" configuration to meet the minimum impedance for the Sherwood RX-4015 stereo receiver, which is 8 ohm per L or R speaker connection. The Aura bass shakers are 4 ohm each. Wired in a series, each pair of shakers creates a load of 8 ohm.

Scent Machine

The application currently supports the *EnviroScent Scent Palette* machine which plug & play connects to the computer over a USB device and uses up to 8 smell cartridges. For a two machine setup, connect the USB cord to the desktop or laptop computer. A small air compressor that is compatible with the machine is required to disperse the scents. Refer to the <u>Scent section</u> for critical information on how to operate the *ScentPalette*.

EnviroScent's Scent Palette



Note: Legacy model in larger black housing still supported.

Contact the manufacturer directly for ordering: HeadHunter 2000 Inc. <u>http://www.scentpalette.com/index.php</u> Scott Judge - <u>sjudgehh2k@aol.com</u> Phone: 708.533.3769

For an additional cost, a package is available with all hardware components:

- *Scent Palette*, w/USB and power cables
- Air hose w/attached fittings (quick-release), and tape roll
- *Paasche* D500SR compressor (or equivalent)

Note: Subject to change, verify selection upon ordering.

Various custom-made scents can be obtained directly from the manufacturer: Enviroscent Inc. <u>http://www.enviroscent.com</u> <u>customerservice@enviroscent.com</u> Phone: 866.435.1832

Sets of scents for the legacy Virtual Iraq / Afghanistan have included: Body Odor, Burning Rubber, Cordite, Diesel Fuel, Garbage, Mideast Spice, and Weapon Fire.

Note: Subject to change, verify selection upon ordering.

InterSense InertiaCube Mounting – Sony HMZ-T1 HMD

Detailed below is the method for mounting the InertiaCube to the Sony HMZ-T1 using Velcro tape. Alternative methods can be used depending on need or availability. One such example is a simple square of mounting tape on the underside of the InertiaCube, no Velcro necessary.

- 1. Cut both sides of the Velcro tape to the size of the InertiaCube base.
- 2. Stick the fabric side of the tape to the center front piece of the visor just above the logo.



3. Stick the gripper side of the Velcro tape to the base of the InertiaCube.



4. With the cable end of the InertiaCube facing out to the front of the HMZ-T1, press the InertiaCube onto the front piece.



5. Use tie-wraps, or a combination of small zip-ties or Velcro strips to fasten the cord along the left side of the frame.



InterSense InertiaCube Mounting – eMagin Z800 HMD

Detailed below is the method for mounting the InertiaCube to the eMagin Z800 using Velcro tape and tiewraps. Small zip-ties can be used instead of tie-wraps. Alternative methods can be used depending on need or availability. One such example is a simple square of mounting tape on the underside of the InertiaCube, no Velcro necessary.

- 1. Cut both sides of the Velcro tape to the size of the InertiaCube base.
- 2. Stick the fabric side of the tape to the center of the bridge piece on the Z800.



3. Stick the gripper side of the Velcro tape to the base of the InertiaCube.



4. With the cable end of the InertiaCube facing out to the front of the Z800, press the InertiaCube onto the bridge piece.



5. Thread one long tie-wrap through the mounting hole on one side of the cube, by first going over and under, out to the front of the Z800.



- 6. Take the other end and thread it between the bridge piece and the forehead pad of the Z800.
- 7. Loop the end around the bottom of the bridge piece, and then up between it and the hinged lens
- piece.8. Twist the ends together.
- 9. Repeat for the other side.



10. Use a shorter tie-wrap to keep the Z800 and InertiaCube cords together.



Hillcrest FSM-6 Enclosure Assembly

From the Required Components section, the following is required:

- 1. Micro-USB cable, 15ft. For connecting FSM-6 to PC.
- 2. <u>Mini Project Box</u>. Protects device and allows it to be mounted on HMD.

Note: The components linked to the vendors above are specific to this assembly.

For the below assembly method, the required tool is a needle or precision file. This can be obtained as part of a set from a hardware store.

Precision File Specs: Manufacturer: Grobet Vallorbe Shape: Equalling (flat on all sides) Length: 16cm Grooved width: 5mm Edge width: 1.5mm Groove/cut length: 8cm Cut: 0



The process is to create two notches on either side of the micro-USB plug casing that lock the plug in place between the aperture edges of the mini project box when the upper and lower pieces are firmly snapped together.

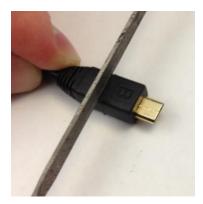
Note: Anti-static foam is recommended as an added measure to ensure the chip stays in place once housed inside the enclosure.

IMPORTANT: Work slowly, stopping frequently to check if the enclosure pieces will snap together with the plug inside. Stop immediately when pieces will snap together firmly.

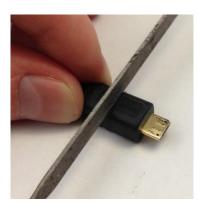
Note: Alternative methods for a secure enclosure are possible. Just be mindful of the orientation necessary when mounted, as detailed in the next section.

Ensure work space is clear, and small shavings from the plug can be easily gathered and removed.

1. Grasp the plug firmly or put it in a small vise so movement is minimal. Carefully begin to make a small notch in the center of the plug casing. Work slowly, checking notch depth.



2. Flip the plug over and secure it. Begin to make a second notch directly in line with the previous. Work slowly, checking notch depth.



3. Finished notch making should appear similar to below.



4. Connect the micro-USB cable to the chip's port.



5. Turn the chip over and place it inside the enclosure. Line up the plug casing notch with the aperture lip.



Note: If using anti-static foam, measure and cut the foam now before continuing. Ideally the foam is cut into two halves that as a whole consume all the negative space inside the enclosure.

6. Line up the bottom cover and press firmly to snap the two pieces together.



7. Once snapped together, the plug should be snug and not able to be easily slid or tilted inside the aperture.



8. FSM-6 ready for mounting.



Hillcrest FSM-6 Mounting – Sony HMZ-T1 HMD

Detailed below is the method for mounting the Hillcrest FSM-6 to the Sony HMZ-T1 using Velcro tape. Alternative methods can be used depending on need or availability. One such example is a simple square of mounting tape on the underside of the FSM-6, no Velcro necessary.

- 1. Cut both sides of the Velcro tape to the size of the FSM-6 base.
- 2. Stick the fabric side of the tape to the center front piece of the visor just above the logo.



3. Stick the gripper side of the Velcro tape to the base of the FSM-6.



4. With the cable end of the FSM-6 facing out to the front of the HMZ-T1, press the FSM-6 onto the front piece.



5. Use tie-wraps, or a combination of small zip-ties or Velcro strips to fasten the cord along the left side of the frame.



Hillcrest FSM-6 Mounting – eMagin Z800 HMD

Detailed below is the method for mounting the Hillcrest FSM-6 to the eMagin Z800 using Velcro tape. Alternative methods can be used depending on need or availability. One such example is a simple square of mounting tape on the underside of the FSM-6, no Velcro necessary.

- 1. Cut both sides of the Velcro tape to the size of the FSM-6 base.
- 2. Stick the fabric side of the tape to the center of the bridge piece on the Z800.



3. Stick the gripper side of the Velcro tape to the base of the FSM-6.



4. With the cable end of the FSM-6 facing out to the front of the Z800, press the FSM-6 onto the bridge piece.



5. Use a shorter tie-wrap to keep the Z800 and FSM-6 cords together.



Windows Configuration Settings

Display Settings

NVIDIA Control Panel

- 1. Right-click the desktop and choose NVIDIA Control Panel.
- Under "3D Settings > Adjust image settings with preview," set the performance slider to "Quality". If you notice the application running slowly, you can set this to "Balanced" to improve performance.



- 3. Under Display > Setup Multiple Monitors > 1. Choose the nView display mode to use: "Configured Independently from each other (Dual View)". Click Apply.
- 4. Click "Yes" to keep the display settings. Close the NVIDIA Control Panel.

Widows Screen Resolution

- 1. Make sure your HMD is connected according to the <u>correct configuration</u>.
- 2. Right-click the desktop and choose Screen Resolution. Or, open the Windows Control Panel > Display > Adjust resolution.

	ispl ▶ Screen ▼ 4 Search Con
Change the ap	opearance of your displays
	Detect Identify
Display:	1. DELL 2007WFP -
Resolution:	1680 × 1050 (recommended) ▼
Orientation:	Landscape 🔹
Multiple displays:	Extend these displays
	our main display. Advanced setting
This is currently yo	
Make text and othe	er items larger or smaller ngs should I choose?

3. Click the Identify button to identify which monitor is attached to the HMD. Click and drag the monitor with the same number that you identified, to the right of the primary, aligning the top edges. This monitor will now be known as the Client. The displays should match the diagram below:

eMagin Z800



Sony HMZ-T1



Note: The software will auto-set the Client monitor resolution to that of the Client application whenever it's launched. When the Client is closed, the original monitor resolution will be restored. Follow step #4 below if you wish to set the monitor resolution to always be that of the selected HMD.

- 4. Set the screen resolution of the Client to be the native resolution of the HMD you are using:
 - a. **eMagin Z800** = 800 x 600
 - b. **Sony HMZ-T1** = 1280×720

You should now be able to see the same image in the HMD as you see on the Client monitor.

Note: For eMagin Z800 HMD configurations - If the image fails to appear within the HMD, set the Client (secondary) monitor refresh rate to 72 or 75hz for the image to appear properly. See the <u>Troubleshooting</u> section for details.

- 5. Select the other monitor and check, "Make this my main display," if not already selected. This monitor should be set to a high resolution since the Controller application will be displayed on it. This monitor will now be known as the Controller.
- 6. Click Apply and OK to exit the Display Settings.

Audio Settings

With the audio configuration in place, ensure that system sound and microphone voice can be heard through the Patient Headphones, Therapist Headset, and Receiver/platform.

Headphone Amplifier Sound Levels – eMagin Z800 HMD and Sony HMZ-T1 HMD

With the recommended audio configurations of both devices, the Stereo Headphone Amplifier acts as a central hub to independently control the levels for the Patient Headphones (eMagin Z800 HMD only), Therapist Headset, and Receiver/platform.

Before continuing to the following Playback and Levels sections, turn each headphone amplifier volume knob between 3-5 to ensure audio can be heard from the corresponding component when enabled.

Afterward, use only the headphone amplifier volume knobs to fine-tune the sound levels of each connected component as needed from session to session.

Use the "#1" volume knob to fine-tune the Receiver/platform; likely to be a value between 5-9.

Use the "#2" volume knob to fine-tune the Patient Headphones (eMagin Z800 HMD only); likely to be a value between 3-6.

Use the "#3" volume knob to fine-tune the Therapist Headset; likely to be a value between 3-6.

Note: The volume level for the Sony HMZ-T1 HMD must be adjusted using the in-visor controls.

Headphone Playback – Sony HMZ-T1 HMD

When set correctly, Windows will detect the Sony HMZ-T1 as an HDMI audio device and output audio to the device through the HDMI Matrix Splitter. Use the below steps to configure/troubleshoot Windows audio settings.

- 1. Ensure HDMI Matrix Splitter and Sony HMZ-T1 are powered on.
- 2. Right click the Speaker icon in the Windows taskbar, choose Volume control options.



- 3. Ensure that Sony-HMD (or HDMI display) appears in the list, and is CHECKED. Click Apply/OK.
- 4. Right-click the speaker icon again, choose Playback devices > Playback tab.
 - a. Right-click Sony HMD-1 Output and choose "Enable as default device" and Apply.
 - b. Sound should now play in the HMZ-T1 headphones, Headset, and Receiver/platform.
- 5. Also, click the Speaker icon in the taskbar to check the level for the device is turned up to ~90.
- 6. On the Sony HMZ-T1, check the volume is at an acceptable level between 10-20 using the volume buttons on the underside of the visor.
- 7. If the above settings are correct, yet audio fails to play from both sources, leave all equipment and settings as is, and restart the machine. All settings should be retained after reboot.

Headphone Playback – eMagin Z800 HMD

- 1. The Realtek HD Audio Manager may prompt for what device was plugged in the back panel, either Headphone, or Front Speaker Out. Choose Headphone and click OK.
- 2. In the Manager, ensure in Stereo is selected from the channels dropdown. Then OK again to dismiss the Manager.
- 3. Ensure the Windows sound level is adequate, between 85-95% by clicking the speaker icon in the task bar and adjusting the slider.
- 4. If using the recommended audio configuration, fine-tune the "#2" volume knob as needed on the Stereo Headphone Amplifier.

Microphone Playback – eMagin Z800 HMD and Sony HMZ-T1 HMD

1. Right-click the speaker icon in the task bar



- 2. Choose Recording devices
- 3. Select Mic In at Front/Rear Panel (pink) and click the Properties button

4. Select the Listen tab

🔄 Microphone Properties
General Listen Levels Advanced
You can listen to a portable music player or other device through this Microphone jack. If you connect a microphone, you may hear feedback.
$\searrow \Rightarrow \bigcirc$
✓ Listen to this device
Playback through this device:
Default Playback Device 🔻
Power Management
Continue running when on battery power
Disable automatically to save power
Device Detection
Do not prompt when this device is plugged in
OK Cancel Apply

- 5. Check "Listen to this device" box
- 6. Ensure dropdown reads "Default Playback Device"
- 7. Click Apply, Ok, Ok, and test the microphone sound again by speaking into the Headset microphone and listening if voice is played back through the Therapist Headset and in the Patient Headphones.
- 8. With the recommended audio configurations, fine-tune the "#3" volume knob as needed on the Stereo Headphone Amplifier.

Note: Ensure the Headset's in-line mic controls, if equipped, are at a reasonable volume and unmuted.

Bass Shaker Sound Levels – eMagin Z800 HMD and Sony HMZ-T1 HMD

- 1. To provide the appropriate level of feedback and immersion through the Bass Shakers, ensure the Stereo Receiver volume dial is turned up between 45-55.
- 2. With the recommended audio configurations, fine-tune the "#1" volume knob as needed on the Stereo Headphone Amplifier.

Bass Shaker Tone Levels – eMagin Z800 HMD and Sony HMZ-T1 HMD

To best actuate the bass shaker platform, increase bass and decrease treble levels on the stereo receiver. Sounds in general from the platform will have noticeably more impact after this adjustment.

Note: Instructions will vary depending on model of stereo receiver in use. It may be necessary to consult the receiver's user manual. The below steps are for the Sherwood RX-4105.

- 1. On front of receiver, ensure the INPUT is set to what is normally used for Bravemind sessions, such as CD.
- 2. Press the TONE button to toggle between BASS and TRBL levels.

TONE BA		
	RECT	

- 3. With the bass level visible in the readout, press the UP ARROW button until the level reaches +8.
- 4. Next, press the TONE button so TRBLE is visible in the readout, press the DOWN ARROW button until the level reaches -10.
- 5. Open a Bravemind application session and stand on the platform to verify impact of sounds such as vehicle engine and explosions.

Game Controllers

The software accommodates multiple gamepads plugged into the computer and will support input from multiple gamepads simultaneously in an active scenario.

For example, in a Rural Driving scenario, the patient could hold and use the Logitech gamepad while steering the vehicle, then swap to the rifle-mounted mini-gamepad after the clinician clicks the Exit Vehicle command.

Logitech Gamepad Controls

The Logitech gamepad left analog stick can be used in the Rural Driving scenarios to increase/decrease the vehicle throttle and steer left/right.

In the Driving scenarios, once in the vehicle's Turret position, the gamepad's right trigger button (labeled 8 or RT) can be used to fire the mounted machine gun. From the same position, the right analog stick can rotate the mounted machine gun turret.

In dismounted scenarios, the gamepad left analog stick moves the patient avatar forward/back. The A button allows the avatar to jump over obstacles.

Note: Ensure the switch on the underside of the Logitech Rumble Gamepad F310/F510/F710 is set to "D" and not "X".



Note: Current Logitech gamepad models: F310 (pictured) and F710. The F510, Rumblepad2, and Precision are no longer manufactured.

Rifle Gamepad Controls and Wiring Diagram

The rifle-mounted mini-gamepad control scheme is rotated due to the orientation of the gamepad when mounted on the rifle.

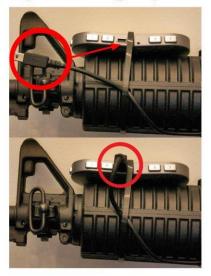
For added realism, use the Rifle Gamepad whenever the Patient avatar is dismounted within a scenario, such as for the various City scenarios or after exiting a vehicle within a Driving scenario.

Right and Left directional-pad buttons control forward and backward movement, respectively.

8 button increases walking speed and the 6 button allows the avatar to jump over obstacles.



Plug-in mini-USB end of cable to port on mini-gamepad





Note: Ion GoPad current model. Legacy model Genius MaxFre Pandora Pro supported. However, Increase Speed command now functions with pressure on small analog stick.

Application Installation Guide

General Pre-Installation Notes

1. Before installing the application, connect the Logitech Gamepad, Rifle Gamepad, eMagin HMD, and InterSense InertiaCube into the computer's USB ports. This is necessary to properly install the drivers for these devices.

Note: The USB port you connect the eMagin to during the driver installation is the ONLY port that will work with the simulation. It may be helpful to mark the port.

- 2. To help maintain stability and performance of the computer, minimize installations of additional software not included on within the executable
- 3. Windows Firewall may attempt to block the Controller or Client programs the first time they are run. Start each program and check to see if Windows has popped up a warning about blocking an application. Choose to "Unblock" the application. After this is done, both programs will load without being blocked any further.
- 4. It is recommended to update video card drivers to the most recent version: http://www.nvidia.com/Download/index.aspx?lang=en-us.

Software Installation

- 1. Save the Bravemind.#.#.####.zip file to the local machine.
- 2. Unzip this file using WinZip or a similar application.
- 3. Double-click the Bravemind.#.#.####.exe file to initialize the installer.
- 4. Click Next, then I Agree to proceed from the License Agreement screen.
- 5. Select from the menu the components to install. By default the installer will install:
 - a. Bravemind
 - b. Dependencies (drivers necessary to run the application)
 - c. Bravemind Uninstaller
- 6. Expand and uncheck any of these options to not install them. However, DO NOT uncheck any of the Dependencies unless it's certain that driver doesn't need to be re-installed (e.g. eMagin or InterSense drivers).

IMPORTANT: If using an InterSense InertiaCube 4, **uncheck** USB / Serial Drivers and InterSense IS900 driver entries. Instead, install the drivers included on disc with the device or latest available from the InterSense website.

Note: Download Logitech Gamepad software from the manufacturer <u>website</u> or install the drivers from the disc bundled with the gamepad package.

- 7. Click Next. The destination folder defaults to, C:\Bravemind. Click Install to begin the installation.
- 8. All files for the application will automatically be copied to the folder, and shortcuts will be placed in the Start Menu under "Bravemind" and on the Desktop.
- 9. Dependencies installers will then automatically initialize. Follow each set of instructions to complete installation.

Note: Multiple installers may begin simultaneously. Complete the installation of one driver before beginning the installation of anther. See the next section for complete install instructions.

IMPORTANT: Choose "Restart Later" or "No" in any "Restart Now" prompts given. Do not restart the computer until all installations have been completed.

- 10. Once all Dependencies are installed, click Finish to close the window.
- 11. If the checkbox for Show Readme was active, it will automatically open.
- 12. In the Windows Display Settings, adjust the secondary monitor position to be to the right of the primary, and aligned at the top edges. See the <u>Display Settings</u> for detailed instructions.
- 13. **IMPORTANT:** Restart the computer at this time.

Installing Dependencies

Use the steps below as a guide for completing dependency installation.

- 1. Microsoft .NET Framework 4.0 Runtime Setup:
 - a. Check the "I have read and accept the license terms" box.
 - b. Click Install.
 - c. Click Finish.
 - d. If prompted, choose Restart Later.
- 2. Microsoft Visual C++ 2008 Redistributable (x86) Setup:
 - a. Click Next.
 - b. Check the "I have read and accept the license terms" box.
 - c. Click Install.
 - d. Click Finish.
- 3. Java Runtime Setup:
 - a. Click Install.
 - b. Click Close at the completion screen.
- 4. ActiveMQ Server:
 - a. Click Next.
 - b. Choose a Destination Folder (default) then Next.
 - c. Click Install.
 - d. Choose Restart Later.
 - e. Click Close.
- 5. USB / Serial Drivers:
 - a. Completes automatically within its window.
- 6. InterSense Installation Wizard (IS900 Software):
 - a. Click Next.
 - b. Click Next.
 - c. In the IS900 Software window, click Next.
 - d. Choose "I Agree", and click Next.
 - e. Choose a Folder (default) and choose either Everyone or Just me. Click Next.
 - f. Click Next again to start the installation.
 - g. When complete, click Close.
 - h. Click "No" to prevent the IServer from loading automatically on boot.
 - i. Click Finish to close the Wizard window.
- 7. USC_ICT_Emagin_64-bit_Drivers:

Note: These drivers allow the internal motion tracker and displays to function and remain active with the software.

- a. Click Install.
- b. If two Windows Security prompts appear, choose "Install this driver software anyway" both times to proceed.
- c. If a prompt containing, "Your system is already using the best device driver" appears, click "Yes" to override the driver.
- d. Click "Close" when complete.

Note: USC_ICT_Emagin_64-bit_Drivers not available within installer at this time.

IMPORTANT: Restart the computer only after all installations have been completed.

Disabling Startup Applications

Java Auto Update Software

Once Java 6.27 installs, a Java Auto Update notification will appear regularly. To prevent this pop-up from disrupting sessions, and any accidental download of a new version, perform the following:

- 1. Press the Windows key and the R key to make the Run prompt appear, or go to the Start menu, and type "msconfig" in the "Search programs and files" field.
- 2. Type "msconfig" in the Run field, and click OK.
- 3. In the System Configuration window, select the Startup tab.
- 4. Uncheck the entry "Java Platform SE Auto Updater 20" or "SunJavaUpdateSched".
- 5. Click Apply, OK, and then Restart.

Manual Installation

eMagin Z800 HMD

Note: USC_ICT_Emagin_64-bit_Drivers not available within installer at this time.

Please verify the installation of the USC ICT Emagin 64-bit Drivers before initial session initialization.

Hardware Installation:

- 1. Ensure the eMagin HMD USB cable is plugged in and the USC_ICT_Emagin_64-bit_Drivers installation complete.
- 2. Right-click on My Computer from either the Desktop or Start Menu.
- 3. Choose Manage in the command menu.
- 4. In the Computer Management window, there will be a pane on the left. Inside the pane, select System Tools > Device Manager.
- 5. The pane on the right will become a hierarchy with the computer name at the topmost entry.
- 6. If already installed properly, under "libsub (WinUSB) devices" will be two entries, "EMAX" and "USB Input Device." Verification complete.
- 7. If either entry is not present, right-click the computer name and choose, "Scan for hardware changes."
- 8. Observe the "Other Devices" entry.

- 9. A child-entry marked with a yellow exclamation point will be present titled, "EMAX," or "Unknown device."
- 10. The easiest way to install these device drivers is to run the "Bravemind.#.#.#####.exe" installer directly once again.
- 11. Click "OK" in the prompt when asked to remove the previous version; this will open up the Uninstaller and the Installer.
- 12. Close the Uninstaller by clicking Cancel.
- 13. In the Installer, proceed forward by clicking "Next" and "I Agree" to reach the Choose Components screen.
- 14. Uncheck all items Bravemind, Dependencies, and Bravemind Uninstaller.
- 15. Expand Dependencies, and check only "USC_ICT_Emagin_64-bit_Drivers"
- 16. Click Install.
- 17. If two Windows Security prompts appear, choose "Install this driver software anyway" both times to proceed.
- 18. If a prompt containing, "Your system is already using the best device driver" appears, click "Yes" to override the driver.
- 19. Click "Close" when complete.
- 20. Two entries described in step #6 should now be present in the Device Manager. With the hardware installed, the manager can now be closed.
- 21. Lastly, ensure in the Control Panel Program entries that "USC ICT Emagin 64-bit Driver" is present.

Redistributable Installation:

Once a Bravemind scenario loads, the eMagin displays should turn on and the internal tracker should function. If wake/tracking doesn't work after having gone through the manual installation verification process, install the following:

- 1. Navigate to C:\Bravemind\drivers\HMD_Support\MS_VC_2010_C++_redists\
- 2. Run and install "vcredist_x86.exe"
- 3. Restart the machine, and then run Bravemind again.

InterSense InertiaCube

It is critical to verify the installation of the InterSense hardware drivers and that the InertiaCube be fully functional before session initialization.

Note: The steps below are only applicable to the InertiaCube 2+ motion tracker.

Hardware Installation:

- 1. Ensure the InertiaCube is plugged in and the driver installation complete (above).
- 2. Right-click on My Computer from either the Desktop or Start Menu.
- 3. Choose Manage in the command menu.
- 4. In the Computer Management window, there will be a pane on the left. Inside the pane, select System Tools > Device Manager.
- 5. The pane on the right will become a hierarchy with the computer name at the topmost entry.
- 6. Expand "Ports (Com & LPT)" and ensure an entry called "USB Serial Port" is present.
- 7. Expand "Universal Serial Bus controllers" and ensure an entry at the bottom called "USB Serial Port" is present.

- 8. If one or neither entry is present, right-click the computer name and choose, "Scan for hardware changes."
- 9. Observe the "Other Devices" entry.
- 10. A child-entry marked with a yellow exclamation point will be present titled, "USB to Serial Adapter," right-click the entry and choose "Update Driver."
- 11. Select the folder "C:\Bravemind\drivers\USB And Serial Drivers" and click OK. Windows will now install the driver. If this fails, manually run "CDM20814_Setup.exe" directly from the above location.
- 12. Both of the above entries described should now be present in the manager.
- 13. Close the manager.

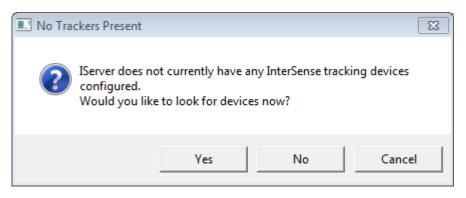
InertiaCube Detection Verification:

With the hardware drivers installed, run the InterSense IServer application.

1. Go to Start Menu > All Programs > InterSense IS-900 > IServer. It will then appear in the toolbar, as shown below.



2. Double-click the icon and in the resulting prompt, click Yes to detect trackers.



- If the above prompt doesn't appear, right-click the tool-bar icon and choose Detect Trackers.
- 3. In the resulting window, a green icon should appear and a corresponding working tracker status message with values updated as movement is detected. The Detection was successful if true.

IMPORTANT: Before running the Bravemind application, ensure the InterSense Server (IServer) application has been closed. Check the taskbar for its icon, as shown below.



Right-click the icon, and in the contextual menu ensure Launch at Startup is **unchecked**. This will disable the IServer from running upon reboot.

Open the context menu again and select Exit to quit the IServer application.

-	About	
	Exit	
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Sony HMZ-T1 Menu Settings

To better streamline and optimize use of the Sony HMZ-T1 for the application, it's recommended to make the following adjustments within the HMD's setup options.

Note: Refer to the System Settings section of the HMZ-T1 Reference Guide included with the device for detailed instructions.

- 1. Press the Menu button on the underside of the visor.
- 2. In the vertical line of main menu options that appear, navigate to Display.
 - a. Choose Wide Mode > Full
 - b. Choose Auto Display Area > On
- 3. Return to the vertical line of main menu options and navigate to Sound.
 - a. Choose Surround > Music
- 4. Return to the vertical line of main menu options and navigate to General Setup.
 - a. Choose Power off when unmounted > Off
 - b. Choose Prolong viewing warning > Off
 - c. Choose Startup viewer warning > Off
- 5. Return to the vertical line of main menu options and exit. Setup complete.

Administering a Scenario

Session Preparation

Before starting the application, ensure that all peripheral items (e.g gamepad, motion tracker, HMD, scent machine, etc.) are connected to the computer. All must be plugged in prior to launch for their input to be recognized by the application.

IMPORTANT: Before running the application, ensure the InertiaCube is positioned as level as possible. This minimizes the camera view off-set that may occur when the InertiaCube is positioned in extreme angles.

Once the scenario is running, one may not swap out such devices "on the fly" because they will not be redetected until the Patient Application is completely closed then reopened again.

Note: Sound is integral to the experience of immersion. It is advised that patients wear quality headphones during the session that will allow them to hear various sound effects while also being able to hear the therapist speaking through the headset.

Patient Comfort

In an effort to minimize discomfort that could break immersion, ensure the patient is situated comfortably in their chair or when standing on the platform. Take the extra time to fit the HMD properly to their head by following the manufacturer documentation, and adjusting all straps/bands as needed. The <u>comfort pads</u> for the Sony HMZ-T1 HMD will noticeably improve comfort of the device. Also, check for any cables that could be pulling tight against clothing or restricting movement.

Simulation Sickness

As the therapist, if you begin to feel simulation sickness from prolonged viewing of the Patient Application monitor, focus your eyes away from the monitor for brief periods to reduce the effect. Mitigating this issue is challenging from a development standpoint, as the Patient Application avatar camera and movement are meant to be solely manipulated by the patient. Investigation is ongoing.

HMD and Tracker Configuration

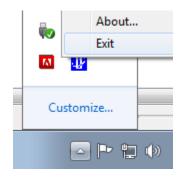
The software will automatically detect the active motion- tracker and utilize it during the selected scenarios.

If the InertiaCube fails to be recognized by the software/system, see the Manual Installation section.

IMPORTANT: Before running the application, ensure the InterSense Server (IServer) application has been closed. Check the taskbar for its icon, as shown below.



Right-click the icon, and in the context menu, choose Exit.



Sony HMZ-T1 Session Activation

- 1. Ensure the HMD is powered on.
- 2. Apply pressure to the forehead pad to view the image in the HMD. The HMD OLED displays will automatically sleep when the unit is not being worn, and will activate promptly when the unit is worn again by pressure on the forehead pad.
- **3**. A sequence of startup screens will appear, press the Menu button on the underside of the visor to skip through them.
- 4. The HMD is ready once the desktop mirrored in the secondary monitor is visible.
- 5. If needed, adjust the volume using the underside buttons as appropriate.
- 6. Use the IPD sliders to adjust as needed for the patient once worn.

eMagin Z800 Session Activation

No manual steps are required of the user to awaken the eMagin Z800 displays before a session. The USC eMagin 64-bit drivers will wake the Z800 displays once the Patient Application is launched, and allows them to remain awake for the duration of a session.

Note: The eMagin displays can be manually activated by pressing the center power button on the eMagin hub.

Session Initialization

To begin a session and ready the software for the patient, perform the following:

- 1. Select Clinician Controller from the Bravemind Start Menu folder, or double click the Desktop icon of the same name.
- 2. Select Patient Application from the Bravemind Start Menu folder, or double click the Desktop icon of the same name.
- 3. In the Configuration prompt Graphics tab choose the following:
 - a. Select the resolution from the dropdown.
 - i. **eMagin Z800** = 800×600
 - ii. **Sony HMZ-T1** = 1280 x 720
 - b. Check the box for Windowed.
 - c. Select a quality setting appropriate for the system.
 - i. "Fantastic" is adequate for most systems of the last 2 years.

Sony HMZ-T1

Bravemind Configuration
Source By
Graphics Input Screen resolution 1280 x 720 Graphics quality Fantastic
Play! Quit

eMagin Z800

Bravemind	Configuration			×
				,
Graphics	Input Screen resolution Graphics quality	800 x 600 · · · · · · · · · · · · · · · · · ·	V Windowed	
			Play! Qu	it

- 4. Click the "Play!" button to launch the Patient Application.
- 5. Once the Patient Application appears, it will automatically move to the second monitor so that it's centered and aligned within the view.

Note: The window appears with a blue background by default.

6. In the Controller, select a scenario from the main menu.

Note: Afghanistan Rural Driving, Afghanistan Rural Village, Iraq City Market Walking, Iraq Rural Driving, and USA Rural Driving scenarios are currently the most polished.

7. Within the Patient Application, wait approximately one minute to allow the scenario to fully load and for the tracker to initialize. Rotate the HMD/tracker in a 360 degree arc to pre-cache the

graphical elements of the scenario, thus ensuring a smooth performance of the virtual environment.

- 8. Once the patient is situated, click the Reset Head Tracker button inside the Controller to zero-out the vertical (pitch) and horizontal (yaw) field-of-view for the Patient Application.
- 9. The software is now ready for the session to begin.

Note: If head-tracking fails to work in X (yaw) properly after loading the first scenario, exit the scenario using the Exit button then re-select the scenario. Tracking should now work. If tracking fails altogether, completely exit the Controller and Patient Application then check the motion-tracker cable connections and verify the device driver installation as previously described.

Clinician Controller Interface

In order to deliver and control all of the features in the system, a "Wizard of Oz" type clinical interface, or "Controller" application, is employed. This Controller interface is a key element in the application, as it provides the clinician with a tool for selecting and placing the patient in VR scenario locations that resemble the contexts that are clinically relevant for a graduated exposure approach. The Controller interface also allows the clinician to further customize the therapy experience to the patient's individual needs via the systematic real-time delivery of stimuli in the environment. This is essential for fostering the anxiety modulation needed for therapeutic habituation.

Main Menu

Clinician Controller for Bravemind	
Afghanistan City Market Walking	
Afghanistan Rural Village Walking	
Afghanistan FOB Walking	
Afghanistan Bagram AB Walking	
Iraq City Market Walking	
Iraq City Checkpoint Walking	
Iraq City Palm Grove Walking	
Iraq City Poor Residential Walking	
Iraq City Residential Walking	
Iraq City Safe Zone Walking	
Iraq City Industrial Walking	
Afghanistan Rural Driving	
Iraq Rural Driving	
USA Rural Driving	
Exit	
Toggle Edition Sound Configuration Editor	Version 1.0.3

The main menu appears on startup and acts as a hub for launching scenarios. Simply click the button for the desired scenario and it will load in the Patient Application window. At the same time, the scenario specific user interface will appear inside the Clinician Controller.

Status Bar

Along the bottom edge of the main menu sits the status bar.

Toggle Edition Sound Configuration Editor

The Toggle Edition feature restricts scenarios and swaps assets pertaining to specific armed services.

Version 1.0.3

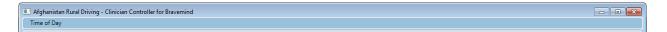
Note: Toggle Edition functionality work-in-progress.

The <u>Sound Configuration Editor</u> feature allows users to create and edit sound button panels for scenarios.

For reference, the version number of the software is located at the right edge of the status bar.

Version 1.0.3

Dropdown Menu



The dropdown menu along the top of the Controller is used to tailor a given scenario in a general sense.

1. **Time of Day:** Changes the lighting and surrounding sky environment. Set this value every time after changing scenarios.

	Time of Day	
	Dawn	
~	Morning	
	Noon	
	Afternoon	
	Sunset	
	Night	
	Cloudy	
	Night Vision	

Cloudy and Night Vision can be used with any time setting.

Scenario User Interface

The scenario user interface is where specific scripted events are triggered. An insurgent attack, IED explosion, or helicopter flyover are all examples of visual sequences that are at the clinician's fingertips in any scenario.

Events are scenes that play out, oftentimes with complex actions, at the clinician's command. As such, no event should ever be repeatedly clicked BEFORE it has run its course. Doing so may result in erratic behavior upon subsequent triggers. Click the Reset button for a particular event to return all of the set

pieces/actors to their initial state (If the clinician destroys a humvee, the clinician can later reset it as if nothing had happened). A general best practice is to reset the previous event before triggering the next event. Certain events, such as the A-10 and Black Hawk flyovers, have slightly different animations or paths for variety.

Detailed below are the functions of the Walking and Driving Scenario button layouts, including steps to use the Sound Button Configuration Editor, Data Collection (SUDS), and Fan and Scent Controls.

Walking Scenario Layout

e of Day	Inician Controller for Bravemine	i						
Ambient City Sounds	Police Siren	Directional IED	A-10 Flyover	Explosion 1	AK-47 Burst 1	Starting Lo	ation	
Wind	Call to Prayer		Black Hawk Flyover	Explosion 2	AK-47 Burst 2	Market E	ast	
Fog Sandstorm	Flying Insects		Black Hawk Orbit	Explosion with Debris 1	AK-47 Single Shot 1	Market V	/est	
Virtual Characters	Civilian Injuries		AK-47 Ambush	Explosion with Debris 2	AK-47 Single Shot 2	Alley No	rth	
Military	O None	Distance 35m	RPG Ambush	Mortar with Debris	M4 Single Shot	Alley So	Jth	
🔽 Civilian Men 🔽 Civilian Women	 Light Moderate 		VBIED	Mortar Firing	M16 Single Shot	Safe An	ea	
Children	Severe	Reset		RPG	.50 Caliber Bursts 1	Building Roof	top >>	
Animals				RPG with Debris	Bullets Hit Metal	Building Inter	ior >>	
				Rumble Noise 1	Bullet Hits Aluminum	5	cent Machine	
				Gun Battle Distant 1	Bullet Hits Metal 1	Scent 1	Scent 5	Fan
				Fire 1	Bullet Hits Metal 2	Scent 2	Scent 6	O Off
				Baby Crying	Bullet Fly By 1	Scent 4	Scent 8	High
				Crowd Reaction 2	US Small Arms			
				Radio 1	Iraqi Men Arguing 1			
				Radio 2	"American American"			
				IED SITREP	"Go back home!"			
S	Text Note							
					Save Entered Data	Reset Head	Fracker	Exit

Example Layout: Iraq City Market Walking

Related functions are grouped together by columns within the scenario user interface. Environment settings are found in the first two columns. Along with Time of Day, these should be set first when in the environment. The third and fourth columns consist of Directional IED, triggered events and ambushes. A two column sound button panel makes up the fourth and fifth columns. Teleport locations appear in the sixth column.

Environment Settings

- 1. Ambient City Sounds: Toggles a multi-layered, bustling market atmosphere.
- 2. Wind: Toggles Wind sound.
- 3. Fog: Toggles Fog visual effect.
- 4. Sandstorm: Toggles Sandstorm visual effect.
- 5. Virtual Characters: Toggles visibility of military, civilians, and animals.

- 6. **Floating Bodes:** Available only in Afghanistan Rural Village. Spawns body below central bridge and nearby shoreline.
- 7. **Mass Grave:** Available only in Afghanistan Rural Village. Spawns bodies inside grave on hill near Fields East teleport location.
- 8. Police Siren: Toggles looping siren sound.
- 9. Call to Prayer: Toggles looping prayer call over loudspeaker sound.
- 10. Flying Insects: Toggles looping noise of buzzing insects.
- 11. **Civilian Injuries:** Sets the severity of the trauma incurred by civilians near the VBIED car bomb. Set the value **before** detonating.

Directional IED, Triggered Events and Ambushes

- 1. **Directional IED**: Used to detonate IEDs in varying proximity from the patient avatar.
 - a. **Arrows:** Each arrow button detonates an IED from the corresponding direction surrounding the avatar. Think of the avatar as the center point. Down arrow button detonates in front, up arrow button detonates from behind, and so on.
 - b. Slider: Controls the distance an IED will detonate away from the avatar.
 - c. **Reset:** Resets the IED explosion effect. **Note:** NPC Civilians will not react to this event. Use Virtual Characters to hide NPCs as appropriate.
- 2. A-10 Flyover: Triggers an A-10 to fly over the avatar. Flight paths change slightly per trigger.
- 3. Blackhawk Flyover: Triggers a Black Hawk helicopter to fly over the avatar.
- 4. Blackhawk Orbit: Triggers a Black Hawk to orbit continuously around the environment.
- 5. **AK-47 Ambush:** Triggers an insurgent to run out from buildings or alleyways and shoot at the patient avatar with an AK-47 rifle. Spawn location relative to current avatar location.
- 6. **RPG Ambush:** Triggers an insurgent to fire a RPG from one of various building rooftops down to a point in street. Spawn location relative to current avatar location.
- 7. **VBIED:** Detonates a car bomb instanced in the scenario. The bomb will injure surrounding civilians, damage a nearby building, and cause Iraqi policemen to respond at the scene. Recommend waiting until the policemen are en route before resetting this event.
- 8. **Rolling VBIED:** Functional only in the Iraq City Checkpoint Walking scenario. Trigger causes parked car in the center lane to proceed forward outside the line of traffic to the front of the checkpoint barricade whereupon it explodes. Soldiers display mixed reaction animation.
- 9. **Mortar Attack:** Available only in Afghanistan FOB, Afghanistan Rural Village, and Iraq Industrial. When enabled, a series of mortar explosions will follow the avatar around the scenario.
- 10. **Foot Patrol:** Available only in Afghanistan Rural Village. Teleports the avatar behind soldiers that begin a patrol loop around the village.

Sound Button Panel

- 1. **Explosion 1:** Large explosion, quick falloff.
- 2. Explosion 2: Booming explosion, quick falloff.
- 3. **Explosion With Debris 1:** Explosion with falling debris and shrapnel.
- 4. **Explosion With Debris 2:** Explosion with falling debris and shrapnel.
- 5. Mortar with Debris: Single large mortar w/debris at impact.
- 6. Mortar Firing: Barrage of mortars firing w/impacts.
- 7. **RPG:** Single firing sound then impact explosion.
- 8. **RPG with Debris:** Single firing sound then impact explosion w/debris.
- 9. Rumble Noise 1: Low rumble sound to actuate bass shaker platform.
- 10. Gun Battle Distant 1: Long-range rifle fire w/US small arms.
- 11. Fire 1: Large-scale crackling fire.

- 12. Baby Crying: Upset baby crying.
- 13. Crowd Reaction 2: Crowd commotion, unrest, and coughing after an incident.
- 14. Radio 1: Non-specific radio communication w/o air traffic.
- 15. Radio 2: Non-specific radio communication w/air traffic.
- 16. IED SITREP: Vehicle crew over radio, "SITREP as follows..."
- 17. AK-47 Burst 1: Mid-range continuous AK-47 rifle firing.
- 18. AK-47 Burst 2: Close-range continuous AK-47 rifle firing.
- 19. AK-47 Single Shot 1: Distant shot from AK-47 rifle.
- 20. AK-47 Single Shot 2: Mid-range shot from AK-47 rifle.
- 21. M4 Single Shot: Close-range M4 single shot.
- 22. M16 Single Shot: Close-range M16 single shot.
- 23. .50 Caliber Bursts 1: .50 Cal M2 Machine Gun, 4 bursts w/casings.
- 24. Bullets Hit Metal: Bullets in bursts hitting metal mid-range.
- 25. Bullet Hits Aluminum: Bullet hitting aluminum close-range.
- 26. Bullet Hits Metal 1: Bullet hitting metal close-range.
- 27. Bullet Hits Metal 2: Bullet hitting metal close-range.
- 28. Bullet Fly By 1: Bullet snapping overhead, close-range.
- 29. US Small Arms: Close-range multiple M16 rife shots.
- 30. Iraqi Men Arguing 1: Local men arguing with heightened voices.
- 31. "American American": Local man says, "American American."
- 32. "Go back home": Locals shouting, "Go back home!"

Teleport Locations

- 1. Starting Location: Point at which the avatar first spawns within a scenario.
- 2. Market East: Teleports patient avatar to East end of market area.
- 3. Market West: Teleports patient avatar to West end of market area.
- 4. Alley North: Teleports patient avatar to area near alleyway.
- 5. Alley South: Teleports patient avatar to area near alleyway.
- 6. Safe Area: Teleports patient avatar to area near soldiers and convoy.
- 7. **Building Rooftop:** Teleports the avatar to a rooftop vantage point. With ">>" in the button label, on subsequent clicks, the avatar will teleport to a new vantage point in a rotating cycle. Available only in Afghanistan Rural Village, and Afghanistan/Iraq Market.
- 8. **Building Interior:** Teleports the avatar to a building interior with outside doorway access. With ">>" in the button label, on subsequent clicks, the avatar will teleport to a new interior in a rotating cycle. Available only in Afghanistan Rural Village, and Afghanistan/Iraq Market.

Note: Teleport locations vary by scenario.

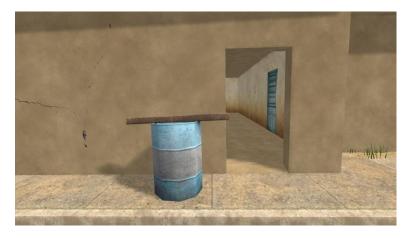
Techniques and Tips – Walking Scenarios

- 1. Afghanistan and Iraq City Scenarios
 - a. Crowd/NPCs fail to react to Directional IED trigger.
 - i. Tip Hide civilians first or trigger a separate ambush simultaneously.
 - b. RPG Insurgents may become stuck unable to fire from rooftops.
 - i. Tip Move the avatar to a different location and try the ambush again.
 - c. Ambush event lacks desired or impactful sound effect.
 - i. Tip Set one or more buttons in the sound button panel to supplement the event.
- 2. Afghanistan Rural Village
 - a. Fleeing civilians become stuck running in place.

- i. Tip Uncheck Civilians to hide them before AK-47 or RPG Ambush.
- b. Squad Foot Patrol soldiers stray or can become stuck against walls.
 - i. Tip Reset and toggle again.
- 3. Iraq City Checkpoint
 - a. Rolling VBIED fails to complete after multiple toggles.
 - i. Tip Toggle the event once to enable it until completion. Do NOT immediately toggle the event mid-sequence. Reload the scenario if necessary

POI Locators – Interiors and Stairways

Throughout both Market scenarios are blue barrels with a rod of scrap iron. These objects point the way to navigable spaces such as interiors and stairways. A horizontal rod directs to an interior, while a vertical rod indicates a stairway.



Example Locator: Interior

Example Locator: Stairway



Note: These types of navigable spaces are more simply represented by yellow doors and orange cones on guide map images.



Medevac Events – Afghanistan Bagram AB

A new development effort to expand content applicable for medevac service members, the Afghanistan Bagram AB scenario's central focus is the hospital receiving area. This scenario is designed as the last in a series of medevac events for the patient avatar that begin in <u>Afghanistan Rural Driving</u>.

- 1. **Medevac Reception:** Creates a periodic flow of medics with injured soldiers on wheeled gurneys. Each group spawns from the air field and proceeds to the hospital interior. Additionally, a stationary gurney with an injured soldier and two medics appear with this event.
- 2. **Note:** Content work-in-progress, use at your own risk. Please send any feedback on how this event could be improved for patient treatment.

Driving Scenario Layout

	Vehicle Headlights	Directional IED	A-10 Flyover	Explosion 1	AK-47 Burst 1	Starting Location
Wind	Civilian Vehicles		Black Hawk Flyover	Explosion 2	AK-47 Burst 2	City
Fog Sandstorm	Dirt Road		Black Hawk Orbit	Explosion with Debris 1	AK-47 Single Shot 1	Bridge
Distant Effects	Roadside Debris		Black Hawk Landing	Explosion with Debris 2	AK-47 Single Shot 2	Checkpoint
O Smoke	O None	Distance 35m	Road Ambush	Mortar with Debris	M4 Single Shot	Scent Machine
Fire and Smoke	 Light Moderate 		Grove Ambush	RPG	M16 Single Shot	Scent 1 Scent 5 Fan
Intensity 0	Severe		City Ambush	RPG with Debris	.50 Caliber Bursts 1	Scent 2 Scent 6 O Off
•	Burning	Reset				Scent 3 Scent 7 Low Scent 4 Scent 8 High
			Bridge Ambush	Rumble Noise 1	Gun Battle 1	
Patient Avatar	Soldiers In Vehicle	Soldier Injuries	Checkpoint IED	Fire 1	Gun Battle Distant 1	
Driver	🗹 Driver	O None	Child Crossing	Radio 1	Bullets Hit Metal	
Front Right	🔽 Front Right	Light				
Rear Left	Rear Left	Moderate	Vehicle Flip	Radio 2	Bullet Hits Aluminum	
Rear Right	🗹 Rear Right	Severe		"IED! Get Down!"	Bullet Hits Metal 1	
Turret	🔽 Turret					
Driver Control	Hide Lead Vehicle	Vehicle Damage		Truck One Hit by IED	Bullet Fly By 1	
Driver Control	Hide Lead vehicle	O None		Breaking Contact	Contact 2 o'Clock	
Off	Use MRAP	Light			Contact 9 o'Clock	
Throttle	Enable Turret Fire	Moderate		Moving Out	Contact 9 o Clock	
Full	Enable Turret Fire	Severe	Exit Vehicle	IED SITREP	"I Need Ammo!"	
	IED Audio Responses					

Example Layout: Iraq Rural Driving

Related functions are grouped together by columns within the scenario user interface. Environment settings are found in the first two columns. Along with Time of Day, these should be set first when in the environment. The third and fourth columns consist of Directional IED, triggered events and ambushes. A two column sound button panel makes up the fourth and fifth columns. Teleport locations appear in the sixth column with the Scent Machine controls.

Environment Settings

- 1. Engine Sound: Toggles the looping vehicle engine noise.
- 2. Wind: Toggles Wind sound.
- 3. Fog: Toggles Fog visual effect.
- 4. Sandstorm: Toggles Sandstorm visual effect.
- 5. **Distant Effects:** Used to emit continuous smoke and fire effects 50 meters ahead of the avatar vehicle.
 - a. Smoke: Black smoke only; appears grey at greater distances.
 - b. Fire and Smoke: Black smoke with intense fire, simulating a burning oil field.
 - c. **Slider:** Controls the intensity of the effects emitting from sides of the roadway. A value of 1 will emit effects from a single location; greater values will emit from multiple. Slide back to 0 in order to make all effects disappear.
 - d. **Note:** Emitter locations are static once triggered; the avatar vehicle can drive past them. Manually adjust the slider an integer in either direction to emit effects from new locations as the vehicle progresses forward.
- 6. **Patient Avatar:** Changes the patient avatar point of view within the vehicle (e.g. from the driver to passenger to gunner).
- 7. **Driver Control:** The option "Throttle" is selected by default and allows the patient to increase/decrease speed of the vehicle using the gamepad. Control of the vehicle is done automatically by the computer when using "None." Using the "Full" option allows complete steering freedom using the gamepad.
- 8. Vehicle Headlights: Toggles the vehicle's headlights during the "Night" Time of Day setting.
- 9. Civilian Vehicles: Toggles visibility of civilian vehicles in Iraq Driving.
- 10. **Dirt/Paved Road:** Sets the road in the scenario to be either dirt or paved.
- 11. **Roadside Debris**: Adjusts frequency and severity of debris at edges of roadway. Toggle the Burning option to emit fire from random debris elements.
- 12. Soldiers in Vehicle: Toggles visibility of the soldiers within the vehicle.
- 13. Hide Lead Vehicle: Toggles visibility of the front vehicle at any time.
- 14. Use MRAP/Humvee: Dynamic, instant toggle of vehicle models. Recommend setting this once, and only at the start of the scenario. Certain triggered events my not track the switched vehicle.
- 15. **Enable Turret Fire:** Toggles firing of the vehicle's mounted machine gun using the gamepad right trigger (8 or RT button) when the avatar is in the Turret position.
- 16. IED Audio Responses: Toggles on/off vehicle crew reaction sound clip to IEDs.
- 17. **Soldier Injuries**: Controls how much the Front Right (passenger) soldier will be wounded when the IED is triggered or when insurgents shoot at the vehicle. By default the trauma is set to none, and the soldier will not be wounded at all. The Reset button under Humvee IED or resetting any ambush will restore the soldier to a non-wounded state.
- 18. Vehicle Damage: Creates bullet holes in the windshield and sides of the vehicle, as well as visible body damage depending on severity selected. Moderate or Severe settings will cause the vehicle to slow to a stop until Reset under Directional IED is clicked.
- 19. **Exit Vehicle:** Allows the patient avatar to exit and re-enter the vehicle from any position, at any point in time.

Directional IED, Triggered Events and Ambushes

- 1. **Directional IED**: Used to detonate IEDs in varying proximity of the patient avatar vehicle.
 - a. **Arrows:** Each arrow button detonates an IED from the corresponding direction surrounding the vehicle. Think of the vehicle itself as the center point. Down arrow button detonates in front of it, up arrow button detonates in back, and so on.

- b. Slider: Controls the distance an IED will detonate away from the vehicle.
- c. **Reset:** Resets the road damage, turns off the reaction sound, and resets the passenger soldier's trauma wounds and damage to the vehicle itself. Allows the vehicle to resume movement under Moderate or Severe Vehicle Damage conditions.
- d. Note: Reference will become avatar-centric after exit of the vehicle.
- 2. A-10 Flyover: Triggers an A-10 jet pass above the roadway.
- 3. Blackhawk Flyover: Triggers a Black Hawk helicopter pass above the roadway.
- 4. **Blackhawk Orbit:** Triggers a Black Hawk to orbit continuously around the area occupied by the vehicle when first triggered. Will not follow the vehicle.
- 5. **Blackhawk Landing/Take off:** Located in the left area just beyond the bridge location. Triggers a Black Hawk to land, then take off if triggered again. Recommend not triggering until vehicle is at the Bridge or Checkpoint locations.
- 6. **Road Ambush:** Triggers insurgents alongside the road to fire AK-47s at the vehicle windshield. Insurgents appear behind instances of debris near roadside.
- 7. Grove Ambush: Triggers insurgents to run out of the palm grove and fire AK-47s at the vehicle.
- 8. **City Ambush:** Triggers an insurgent ambush in the small city area where an RPG is fired from a rooftop and multiple ground insurgents appear, firing AK-47s at the vehicle
- 9. **Bridge Ambush:** Triggers an insurgent AK-47 attack from a bridge overpass and the US Soldiers parked nearby to return gunfire and kill the insurgents.
- 10. Checkpoint IED: Detonates a car bomb (VBIED) inside the Checkpoint location line of cars.
- 11. Child Crossing: Triggers a child that will cross in front of the patient avatar vehicle.
- 12. Vehicle Flip: Triggers an IED that rolls the front convey vehicle, starting an engine fire.
- 13. **Helicopter Ride:** Teleports patient avatar to a helicopter that circles the convoy. Recommend allowing sufficient time for the helicopter to disappear before re-triggering.

Sound Button Panel

- 1. **Explosion 1:** Large explosion, quick falloff.
- 2. Explosion 2: Booming explosion, quick falloff.
- 3. **Explosion With Debris 1:** Explosion with falling debris and shrapnel.
- 4. **Explosion With Debris 2:** Explosion with falling debris and shrapnel.
- 5. Mortar with Debris: Single large mortar w/debris at impact.
- 6. **RPG:** Single firing sound then impact explosion.
- 7. **RPG with Debris:** Single firing sound then impact explosion w/debris.
- 8. **Rumble Noise 1:** Low rumble sound to actuate bass shaker platform.
- 9. **Fire 1:** Large-scale crackling fire.
- 10. Radio 1: Non-specific radio communication w/o air traffic.
- 11. Radio 2: Non-specific radio communication w/air traffic.
- 12. IED! Get Down!": Vehicle crew callouts, "IED! Get Down! Gunner's down!"
- 13. Truck One Hit By IED: Vehicle crew callouts, "Truck one was just hit, left side. Push! Push!"
- 14. Breaking Contact: Vehicle crew over radio, "Breaking contact with them, moving out..."
- 15. Moving Out: Vehicle crew callouts, "Moving Out! Push it up!"
- 16. **IED SITREP:** Vehicle crew over radio, "SITREP as follows..."
- 17. AK-47 Burst 1: Mid-range continuous AK-47 rifle firing.
- 18. AK-47 Burst 2: Close-range continuous AK-47 rifle firing.
- 19. AK-47 Single Shot 1: Distant shot from AK-47 rifle.
- 20. AK-47 Single Shot 2: Mid-range shot from AK-47 rifle.
- 21. **M4 Single Shot:** Close-range M4 single shot.
- 22. M16 Single Shot: Close-range M16 single shot.
- 23. .50 Caliber Bursts 1: .50 Cal M2 Machine Gun, 4 bursts w/casings.
- 24. Gun Battle 1: Mid-range rifle fire w/US small arms.

- 25. Gun Battle Distant 1: Long-range rifle fire w/US small arms.
- 26. Bullets Hit Metal: Bullets in bursts hitting metal mid-range.
- 27. Bullet Hits Aluminum: Bullet hitting aluminum close-range.
- 28. Bullet Hits Metal 1: Bullet hitting metal close-range.
- 29. Bullet Fly By 1: Bullet snapping overhead, close-range.
- 30. Contact 2 o'Clock: Vehicle crew callouts, "Contact 2 o'clock!..."
- 31. Contact 9 o'Clock: Vehicle crew callouts, "Contact 9 o'clock!..."
- 32. "I Need Ammo!": Vehicle crew callouts, "I need ammo!"

Teleport Locations

- 1. Starting Location: Point at which the avatar convoy first spawns within a scenario.
- 2. **City:** Teleports patient avatar vehicle to urban area.
- 3. Farm: Available only in Afghan Driving. Teleports patient avatar vehicle to farm area.
- 4. Bridge: Teleports patient avatar vehicle to area before overpass.
- 5. Checkpoint: Teleports patient avatar vehicle to roadside Army checkpoint.

Note: Certain locations and ambush events not available in Afghanistan or USA Rural Driving scenarios.

Medevac Events – Afghanistan Rural Driving

A new development effort to expand content applicable for medevac service members, the Afghanistan Rural Driving scenario now contains a new farm location central to a series of medevac events. The last of these events takes place at the hospital receiving area in <u>Afghanistan Bagram AB</u>.

- 1. **Medevac Insertion:** Teleports the patient avatar to a medevac helicopter outbound to an IED incident. Two crew medics appear relaxed onboard. Patient avatar must be inside the vehicle before activating the event.
- 2. **Medevac Pickup:** Creates a post-event situation where crew medics prepare an injured soldier for medevac while surrounded by the local population. A smoldering IED crater and destroyed Humvee block the roadway. Recommend that upon teleport to the farm location, the patient vehicle convoy slowly approaches the scene.
- 3. **Medevac Extraction:** Teleports the patient avatar to a medevac helicopter inbound to an airbase hospital. The injured soldier appears on the stretcher between two attending crew medics. Patient avatar must be inside the vehicle before activating the event.
- 4. **Note:** Content work-in-progress, use at your own risk. Please send any feedback on how these events could be improved for patient treatment.

Techniques and Tips – Driving Scenarios

- 1. Rural Driving, global
 - a. Simulate large plumes of distant grey smoke.
 - i. Tip Upon loading a scenario, teleport to the Checkpoint location (or any point after the city) then use the Distant Effects slider to create a smoke effect. After teleport back to the Starting Location, the avatar vehicle will appear to progress toward large plumes of grey smoke.
 - b. Same soldier reaction audio plays for IED events.
 - i. Tip Toggle off the vehicle crew reaction audio by clicking IED Audio Response button. On the next IED event trigger, supplement the event with a vehicle crew callout from a sound button in the sound button panel.

- c. Few instances of Roadside Debris in proximity to avatar vehicle.
 - i. Tip Toggle between Moderate and Severe to make debris appear closer.
- d. Directional IED avatar-centric orientation after Exit Vehicle.
 - i. Tip The Directional IED orientation will switch to reference that of the avatar after exiting the vehicle, which is similar to all walking scenarios. When reentering the vehicle, reference will switch back to that of the vehicle.
- e. Front vehicle will slow down and brake at City intersection.
 - i. Tip Slow avatar vehicle using gamepad to avoid ramming the front vehicle.
- f. Terrain fails to loop under Driver Control Full.
 - i. Tip Teleport the avatar vehicle manually after the Checkpoint location.
- g. Front vehicle may swerve or become stuck after terrain loops to starting point or after Vehicle Flip reset.
 - i. Click the Palm Grove location or another location to correct.
- h. Directional IED Vehicle Damage level selection.
 - i. Recommended that clinicians first review each level of Vehicle Damage that appears on the vehicle exterior caused by trigger of the Directional IED. Set the damage level, trigger the IED, then click Exit Vehicle to observe the result.
 - ii. The below graphic shows the damages states from a front IED hit.

Humvee Vehicle Damage Levels: None, Light, Moderate, and Severe



Reset Head Tracker

Click this button to zero-out the vertical (pitch) and horizontal (yaw) orientation for the Patient avatar. Ensure the Patient's head is positioned comfortably looking forward before clicking.



Exit

Click this button to exit the scenario and return to the main menu.



Mute/Volume/Brightness

Mute: Turns off sound for the entire scenario.

Volume: Adjusts the global volume level for the simulation.

Brightness: Fine tunes the overall lighting to be brighter or darker.

Mute	Volume	Brightness	
------	--------	------------	--

Data Collection (SUDS)

This feature can be used to log short notes into a log file during a session. The text entered into the SUDS and Text Note fields will be written out when the therapist clicks the Save Entered Data button. The log file is named, "ClinicianNotes.txt" and is located in the C:\Bravemind directory.

SUDS	Text Note	
		Save Entered Data

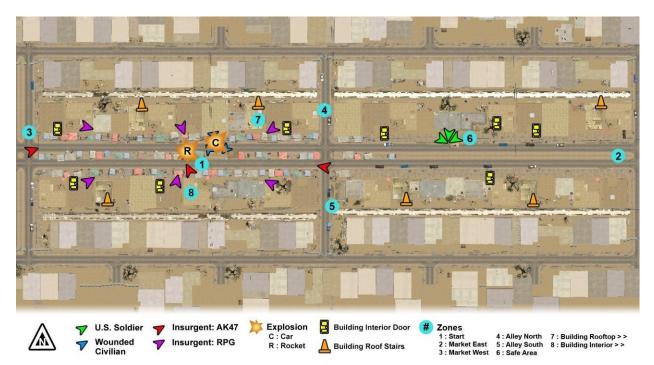
IMPORTANT: All saved entries accumulate in this text file. Existing entries in this file will be appended with new entries from future sessions. Copy out any entries that must remain by themselves into a separate file with a user-defined naming convention.

Map Peek

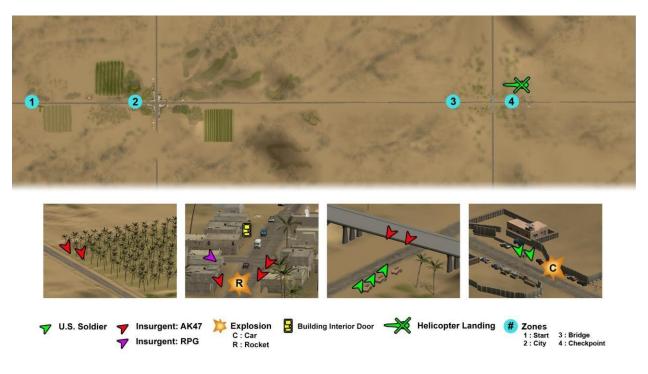
Hover the mouse cursor over the "Map Peek" text in the lower right corner to make a top-down view of the current scenario appear over the layout. The images display all the same icons for locations, explosions, insurgents, soldiers, wounded, entryways and stairways found in images of the <u>Guide Maps</u> section of this manual. Simply move the cursor away to dismiss the image.

Map Peek

Example Map: Iraq City Market Walking



Example Map: Iraq Rural Driving



Sound Button Configuration Editor

The Sound Button Configuration Editor allows clinicians to create and edit sound button panels. Each panel consists of 32 sound button slots divided into two columns.

A sound button panel is presented within the Clinician Controller scenario interface between triggered event buttons and location teleport buttons. Clicking a sound button plays the sound assigned to that slot.

Clinicians can layer sounds on top of one another by quickly clicking from one sound button to another within the scenario's sound button panel. This can create sequences of sounds such as a chaotic firefight or explosion in a crowded environment.

Clinicians can create and save any number of custom sound panels.

See the section <u>Sound Button Catalog</u> for a list of available sounds.

Using the Sound Button Configuration Editor

From the Clinician Controller main menu, click the Sound Configuration Editor button to open the editor window.

Sound Configuration Editor

The Editor window is divided into three sections: 1) Load and Save options 2) Sound button panel work space 3) Sound button editing tools.

The Editor automatically opens to a blank sound button panel of inactive panel buttons and disabled editing tools. A temporary file name is given to the panel, visible in the window title bar.

Note: Whenever a panel change is made within the Editor, an asterisk (*) appears next to the panel name in the title bar. Be sure to save any changes using the Save option before clicking the OK button to close the window.

Load	Click to Enable	Click to Enable	Sound to Play:
Save	Click to Enable	Click to Enable	Button Label:
	Click to Enable	Click to Enable	
	Click to Enable	Click to Enable	Apply
	Click to Enable	Click to Enable	Clear
	Click to Enable	Click to Enable	Move Up
	Click to Enable	Click to Enable	Move Dowr
	Click to Enable	Click to Enable	Move Over
	Click to Enable	Click to Enable	
	Click to Enable	Click to Enable	
	Click to Enable	Click to Enable	
	Click to Enable	Click to Enable	
	Click to Enable	Click to Enable	
	Click to Enable	Click to Enable	
	Click to Enable	Click to Enable	
	Click to Enable	Click to Enable	ОК

Click any inactive panel button to enable the editing tools. The selected button will highlight in orange text.



Next, click the arrow within the Sound to Play dropdown for a scrollable list of selectable sounds. Related sounds are grouped together.

Load	Click to Enable	Click to Enable	Sound to Play:
Save	Click to Enable	Click to Enable	
	Click to Enable	Click to Enable	Environment
	Click to Enable	Click to Enable	Air Raid Siren Baby Crying
	Click to Enable	Click to Enable	Barking Dog
			Barking Dogs
	Click to Enable	Click to Enable	Call to Prayer
	Click to Enable	Click to Enable	Crowd Reaction 1
	Click to Enable	CIICK to Enable	Crowd Reaction 2
	Click to Enable	Click to Enable	Fire 1
			Fire 2
	Click to Enable	Click to Enable	Flying Insects 1
	Click to Enable	Click to Enable	Flying Insects 2
			Incoming Alert Iragi Market
	Click to Enable	Click to Enable	Motor Pool 1
			Motor Pool 2
	Click to Enable	Click to Enable	Radio 1
	Click to Enable	Click to Enable	Radio 2
			Rumble Noise 1
	Click to Enable	Click to Enable	Rumble Noise 2
	Click to Enable	Click to Enable	Explosions
	Click to Enable	Click to Enable	Explosion 1
	Click to Enable	Click to Enable	Explosion 2
			Explosion with Debris
	Click to Enable	Click to Enable	Explosion with Debris

Select a sound from the list and it will appear within the Sound to Play and Button Label fields.

SoundButtonConfigu	ation.btn - Sound Button Config	uration Editor	
Load	Click to Enable	Click to Enable	Sound to Play:
Save	Click to Enable	Click to Enable	.50 Caliber Bursts 1
Jave	Click to Enable	Click to Enable	Button Label:
	Click to Enable	Click to Enable	.50 Caliber Bursts 1
	Click to Enable	Click to Enable	Apply
	Click to Enable	Click to Enable	Clear

Click the Apply button to set that sound to the active sound button slot in the panel.

NewSoundButtonConfigura	ition.btn* - Sound Button Config	uration Editor	×
Load	.50 Caliber Bursts 1	Click to Enable	Sound to Play:
Save	Click to Enable	Click to Enable	.50 Caliber Bursts 1
			Button Label:
	Click to Enable	Click to Enable	.50 Caliber Bursts 1
	Click to Enable	Click to Enable	Apply
	Click to Enable	Click to Enable	Clear

Clinicians also have the option to edit the sound label. Enter the desired name in the Button Label field then click Apply. The new label appears on the active button slot.

SoundButtonConfigu	ration.btn* - Sound Button Confi	guration Editor	
Load	Machine Gun	Click to Enable	Sound to Play:
			.50 Caliber Bursts 1
Save	Click to Enable	Click to Enable	Button Label:
	Click to Enable	Click to Enable	Machine Gun
	Click to Enable	Click to Enable	Apply
			0
	Click to Enable	Click to Enable	Clear

Save the sound button panel by first clicking the Save button. A standard dialog box appears that allows clinicians to choose a unique name for the panel. Enter a unique name and click the Save button to save the panel file to disk. Saved panel files are appended with the file extension *.btn and are written by default to the directory C:\Bravemind\ClinicianController\SoundButtonConfigurations.

Note: A confirmation prompt appears if attempting to overwrite an existing *.btn file.

IMPORTANT: All *.btn files must be saved to the C:\Bravemind\ClinicianController \SoundButtonConfigurations directory for automatic scenario load by the Clinician Controller.

Save As	×
🔾 🖓 🖉 bin 🕨 Release 🔺 SoundButtonConfigurations 🕨 🔹 🛃 Search SoundButtonConfigura	P
Organize ▼ New folder BEE ▼	0
Name	*
🗋 AfghanistanBagramABWalking.btn	
AfghanistanCityMarketWalking.btn	
AfghanistanFOBWalking.btn	
AfghanistanRuralDriving.btn	
AfghanistanRuralVillage.btn	
IraqCityCheckpointWalking.btn	
IraqCityIndustrialWalking.btn	=
IraqCityMarketWalking.btn	
IraqCityPalmGroveWalking.btn	
IraqCityPoorResidentialWalking.btn	
IraqCityResidentialWalking.btn	
IraqCitySafeZoneWalking.btn	-
III.	•
File name: Patient_001_Configuration.btn	•
Save as type: Button Configuration Files (*.btn)	•
Hide Folders Save Cancel	

The unique name now appears in the title bar of the Editor window.

Patient_001_Configuration.b	tn - Sound Button Configuration	on Editor	X
Load	Machine Gun	Click to Enable	Sound to Play:
Save	Click to Enable	Click to Enable	.50 Caliber Bursts 1
	Click to Enable	Click to Enable	Machine Gun
	Click to Enable	Click to Enable	Apply
	Click to Enable	Click to Enable	Clear

Additional editing tools allow existing sound buttons to be shifted to any button slot.

Use the Move Down button to shift the active sound button down a row.

Machine Gun	Click to Enable	Move Up
Click to Enable	Radio 1	Move Down
Click to Enable	Click to Enable	Move Left

Use the Move Up button to shift the active sound button up a row.

Machine Gun	Radio 1	Move Up
Click to Enable	Click to Enable	Move Down
Click to Enable	Click to Enable	Move Left

Use the Move Left/Right button to shift the active sound button from one column to the other.

Radio 1	Machine Gun	Move Up
Click to Enable	Click to Enable	Move Down
Click to Enable	Click to Enable	Move Right

Existing sound button slot assignments can be returned to an unasssigned state by first selecting the slot, then clicking the Clear button. The Sound to Play and Button Label fields will empty.

Patient_001_Configuration.b	otn - Sound Button Configuration	n Editor	
Load	Machine Gun	Click to Enable	Sound to Play:
Save	Click to Enable	Click to Enable	Button Label:
	Click to Enable	Click to Enable	
	Click to Enable	Click to Enable	Apply
	Click to Enable	Click to Enable	Clear

Next, click the Apply button to set the unassigned state.

Patient_001_Configuration.	btn* - Sound Button Configuration	on Editor	
Load	Click to Enable	Click to Enable	Sound to Play:
Save	Click to Enable	Click to Enable	Button Label:
	Click to Enable	Click to Enable	
	Click to Enable	Click to Enable	Apply
	Click to Enable	Click to Enable	Clear

Every scenario by default has its own preset sound button panel that can be left as-is, or edited to the clinician's own preference.

Open an existing scenario sound button panel by clicking the Load button. Then choose the desired file from the *.btn list and click Open.

Open	X			
COOVER Release > SoundButtonConfigurations > + 47	Search SoundButtonConfigura 🔎			
Organize 🔻 New folder	·····			
Name	*			
AfghanistanBagramABWalking.btn				
AfghanistanCityMarketWalking.btn				
AfghanistanFOBWalking.btn				
AfghanistanRuralDriving.btn				
AfghanistanRuralVillage.btn				
IraqCityCheckpointWalking.btn				
IraqCityIndustrialWalking.btn				
IraqCityMarketWalking.btn				
IraqCityPalmGroveWalking.btn	=			
IraqCityPoorResidentialWalking.btn				
IraqCityResidentialWalking.btn				
IraqCitySafeZoneWalking.btn				
IraqRuralDriving.btn				
USARuralDriving.btn	-			
٠	Þ.			
File name: IraqRuralDriving.btn	Button Configuration Files (*.b 🔻			
	Open Cancel			

The existing scenario sound button panel appears in the sound button panel work space. Click any existing sound button slot to begin making changes.



Note: Clinicians wishing to restore a preset sound button panel to its default sound button assignments can perform the following:

- 1. Click Load.
- 2. In the Open *.btn file list dialog, double-click the Default sub-folder.
- 3. Select the desired scenario *.btn file in the list and click Open.

- 4. The sound button panel will appear in the Editor. Click the Save button.
- 5. In the Save *.btn file list, ensure the location is C:\Bravemind\ClinicianController\SoundButtonConfigurations
- 6. Select the desired *.btn file. Its name will appear in the File name field.
- 7. Click Save and confirm to overwrite the file.

Using the Customize Scenario Option

One or more saved sound button panels can be loaded during the time a scenario is active within the application. For example, in a Rural Driving scenario, once the patient avatar exits the vehicle, the sound button panel could be switched to a saved dismounted-centric sound button panel.

IMPORTANT: The active sound button panel will be saved for the next time that specific scenario is loaded from the main menu of the Clinician Controller. This setting will also persist after closing completely out of the application and reopening it.

After loading a scenario from the main menu, click the Customize button at the bottom of the interface to open the Customize Scenario window.



The current sound button panel name appears in the Sound Button Configuration field.

Customize Scenario		×
Sound Button Configuration:		
IraqRuralDriving.btn		Browse
	ОК	Cancel

Click the Browse button then in the Open dialog select the desired *.btn file and click Open.

Open	×				
Search SoundButtonConfigurations > • • • • • • • • • • • • • • • • • •	9				
Organize New folder	2				
Name	*				
AfghanistanCityMarketWalking.btn					
AfghanistanFOBWalking.btn					
AfghanistanRuralDriving.btn					
AfghanistanRuralVillage.btn					
IraqCityCheckpointWalking.btn					
IraqCityIndustrialWalking.btn					
IraqCityMarketWalking.btn					
IraqCityPalmGroveWalking.btn					
IraqCityPoorResidentialWalking.btn					
IraqCityResidentialWalking.btn					
IraqCitySafeZoneWalking.btn					
IraqRuralDriving.btn					
Patient_001_Configuration.btn					
USARuralDriving.btn	-				
۲ III	Þ.				
File name: Patient_001_Configuration.btn	-				
Open Cancel					

IMPORTANT: All *.btn files must be saved to the C:\Bravemind\ClinicianController \SoundButtonConfigurations directory for automatic scenario load by the Clinician Controller.

The selected sound button panel name appears in the Sound Button Configuration field.

Customize Scenario		×
Sound Button Configuration:		
Patient_001_Configuration.btn		Browse
	ОК	Cancel

Click OK. The custom sound button panel now appears within the Clinician Controller scenario interface.

Engine Sound	Vehicle Headlights	Directional IED	A-10 Flyover	Machine Gun	1	Starting Loc	ation	
Wind	Civilian Vehicles		Black Hawk Flyover			City		
Fog Sandstorm	Dirt Road		Black Hawk Orbit			Bridge		
	Untribut							
Distant Effects	Roadside Debris		Black Hawk Landing			Checkpo	int	
Smoke	O None		Road Ambush			S	cent Machine	()
Fire and Smoke	Light	Distance 35m	Grove Ambush			Scent 1	Scent 5	Fan
Intensity 0	Moderate		Grove Ambush			Scent 2	Scent 6	O Off
· · · · · · · · · · · · · · · · · · ·	 Severe Burning 	Reset	City Ambush			Scent 3	Scent 7	Low
	Burning		Bridge Ambush			Scent 4	Scent 8	🔵 High
Patient Avatar	Soldiers In Vehicle	Soldier Injuries	Checkpoint IED					
Driver	💟 Driver	O None	Child Crossing					
Front Right	🔽 Front Right	Light	Child Crossing					
Rear Left	🔽 Rear Left	Moderate	Vehicle Flip					
Rear Right	🔽 Rear Right	Severe						
Turret	🗹 Turret							
	Hide Lead Vehicle	Vehicle Damage						
Driver Control	Hide Lead Vehicle	O None						
Off	Use MRAP	Light						
O Throttle	Enable Turret Fire	Moderate						
Full	Lindble Fuffet file	Severe	Exit Vehicle					
	IED Audio Responses							
							_	
s	Text Note				Save Entered Data	Reset Head 1	racker	Exit

Note: The preset sound button panel *.btn file names match that of its scenario name.

 AfghanistanBagramABWalking.btn

 AfghanistanCityMarketWalking.btn

 AfghanistanFOBWalking.btn

 AfghanistanRuralDriving.btn

 IraqCityCheckpointWalking.btn

 IraqCityMarketWalking.btn

 IraqCityMarketWalking.btn

 IraqCityMarketWalking.btn

 IraqCityPalmGroveWalking.btn

 IraqCityPoorResidentialWalking.btn

 IraqCityResidentialWalking.btn

 IraqCityPoorResidentialWalking.btn

 IraqCitySafeZoneWalking.btn

 IraqCitySafeZoneWalking.btn

 USARuralDriving.btn

IMPORTANT: Do NOT delete or move *.btn files manually until absolutely certain the *.btn file is no longer being automatically loaded by the Clinician Controller for any scenario.

Scent Machine Controls

The Scent Machine controls exist to deliver olfactory stimuli. Scents may be employed as direct stimuli (e.g., scent of burning rubber) or as cues to help immerse users in the world (e.g., ethnic food cooking). The scents selected for this application include burning rubber, cordite, garbage, body odor, smoke, diesel fuel, Iraqi food spices, and gunpowder.

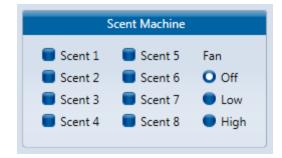
The capacities for smell and emotion are both rooted in brain's limbic system. The olfactory center also interacts directly with the hippocampus, a brain area involved in the formation of new memories. Smells can therefore be used to trigger vivid recollections of memories and emotions in patients.

The scents consist of resin beads that are packaged inside small jars. When the clinician is preparing for a session they should unscrew a jar and place it inside one of the 8 independent airtight chambers of the *ScentPalette* machine. The front panel of the machine unscrews and folds down. After the jars are placed, the clinician should note on paper which scents are in which chamber and then screw the front panel tightly back into place to seal the scents and keep the pressurized air from leaking out.

Connect the machine with the USB cord to the computer and plug in the power. A small air compressor is needed to pressurize the chambers prior to the session. Connect the compressor with a compatible tube to the back of the *ScentPalette* and turn the compressor on and monitor the pressure gauge until the PSI (Pounds Per Square Inch) reaches the correct pressure (The *ScentPalette* operates at 50-80 PSI and should not exceed 100 PSI).

When the clinician clicks a "Scent" checkbox, a valve for the corresponding numbered chamber is opened and the pressurized air escapes. Next, clicking the "Low" or "High fan setting allows the accumulated scent to disperse into the flow of air towards the patient. To clear the scent from the air, turn off the scent and turn the fan on Low or High to clean out the smell.

The pressure will eventually fall and the compressor will turn back on to re-pressurize the chambers. This sound may be distracting to the patient. Refer to the manual for your compressor to see if it can be powered off after the PSI has been set and still maintain the pressure.



Scent Controls:

1. **Scent 1-8**: Check a box and a valve for the corresponding numbered chamber is opened and the pressurized air escapes, allowing the scent to accumulate inside the upper chamber. Turn on the fans to "Low" or "High" to then disperse the scent towards the patient. Uncheck the box again to close the valve.

Fan Controls:

- 1. **Off**: Turns off all fans.
- 2. Low: Turns on two fans.
- 3. **High**: Turns on all four fans.

Session Close

Use the Exit button in the scenario layout first to return to the main menu, and then click the Exit button to close the Patient Application and Controller.

Sony HMZ-T1 Session De-Activation

The HMD displays will automatically sleep within 5-minutes of closing the session. If the equipment will not be used for 24 hours or more, it's recommended to turn off the HMD completely by pressing and holding the power button on the underside. The light on the processor box will turn from green to red.

Exit

eMagin Z800 Session De-Activation

No additional steps are required with the HMD after completion of a session. The HMD displays will automatically sleep within 5-minutes of closing the session.

Application Uninstallation Guide

Software Uninstallation

Uninstall Bravemind

Follow the steps below to remove the main application.

- 1. To uninstall the software, go to the Start Menu > Bravemind > Uninstall. The uninstaller can also be launched directly from the main C:\Bravemind folder.
- 2. Click "Uninstall" to begin.
- 3. Click "Close" once finished.

Uninstall Dependencies

To remove all dependencies required of the main application, go to the Start menu > Control Panel > Programs and Features > Uninstall a program. Select and choose to Uninstall the below entries.

- 1. Microsoft .NET Framework 4 Extended:
 - a. Choose Remove.
 - b. Click Next.
 - c. Click Continue.
 - d. Click Finish.
 - e. Choose Restart Later.
- 2. Microsoft .NET Framework 4 Client Profile:
 - a. Choose Remove.
 - b. Click Continue.
 - c. Click Finish.
 - d. Choose Restart Later.
- 3. Microsoft Visual C++ 2008 Redistributable (x86):
 - a. Click Yes.
- 4. Java [™] 6 Update 27:
 - a. Click Yes.
 - b. Click No to restart later. The entry will be removed after system reboot.
- 5. ActiveMQ:
 - a. Click Uninstall.
 - b. Click Close.
- 6. Logitech Gaming Software 5.10:
 - a. Click Yes.
- 7. IS900 Software:
 - a. Check the toolbar to ensure the IServer is closed.
 - b. Click Yes.
- 8. USC ICT Emagin 64-bit Drivers:
 - a. No listed dependencies.
- 9. After all uninstalls are complete, restart the machine.

Sound Button Catalog

The table below lists each sound available from the Sound to Play dropdown within the <u>Sound Button</u> <u>Configuration Editor</u>. Use the table to aid in selecting sounds that best fit a patient's account.

Name	Description	Length
Environment		
Air Raid Siren	Repeating sound of defense siren when under attack	:39
Baby Crying	Upset baby crying	:06
Barking Dog	Repeating dog barks	:03
Barking Dogs	Repeating barks w/growling, 2-3 dogs	:09
Call to Prayer	Loudspeaker prayer call	:25
Crowd Reaction 1	Sustained, heightened crowd activity post-incident	:40
Crowd Reaction 2	Crowd commotion, unrest, and coughing post-incident	:15
Fire 1	Large-scale crackling fire	:26
Fire 2	Intense crackling fire	:07
Flying Insects 1	Multiple buzzing flies	:20
Flying Insects 2	Swarm of buzzing flies	:05
Incoming Alert	Approximates repeating base incoming alert system	0:27
Iraqi Market	Busy city market w/vocals, traffic	01:26
Motor Pool 1	Frequent power tool and metal shop sounds	01:29
Motor Pool 2	Sporadic power tool and metal shop sounds	:56
Radio 1	Non-specific radio communication w/o air traffic	01:13
Radio 2	Non-specific radio communication w/air traffic	01:13
Rumble Noise 1	Low rumble sound to actuate bass shaker platform	:16
Rumble Noise 2	Low rumble sound to actuate bass shaker platform	:16
Explosions		
Explosion 1	Large explosion, quick falloff	:02
Explosion 2	Booming explosion, quick falloff	:02
Explosion with Debris 1	Explosion with falling debris and shrapnel	:08
Explosion with Debris 2	Explosion with falling debris and shrapnel	:03
Mortar 1	Incoming "whistling" noise from repeating shots	:15
	w/impacts	
Mortar 2	Distant firing of shots w/impacts at close range	:13
Mortar Firing	Barrage of mortars firing w/impacts	:06
Mortar with Debris	Single large mortar w/debris at impact	:12
Phalanx Firing	Phalanx defense system firing sequence	:21
RPG	Single firing sound then impact explosion	:03
RPG with Debris	Single firing sound then impact explosion w/debris	:05
		1
Firearms		
AK-47 Burst 1	Mid-range continuous AK-47 rifle firing	:02
AK-47 Burst 2	Close-range continuous AK-47 rifle firing	:02
AK-47 Single Shot 1	Distant shot from AK-47 rifle	:01
AK-47 Single Shot 2	Mid-range shot from AK-47 rifle	:01
AK-47 Single Shot 3	Mid-range shot from AK-47 rifle	:01

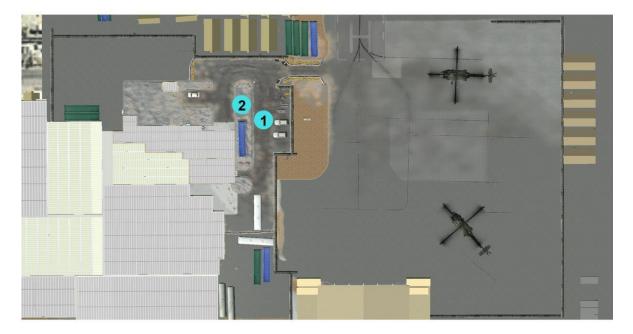
Bullet Fly By 1	Bullet snapping overhead, close-range	:01
Bullet Fly By 2	Bullet passing overhead, close-range	:01
Bullet Hits Aluminum	Bullet hitting aluminum close-range	:01
Bullet Hits Metal 1	Bullet hitting metal close-range	:01
Bullet Hits Metal 2	Bullet hitting metal close-range	:01
Bullet Hits Metal 3	Bullet hitting metal close-range	:01
Bullets Hit Aluminum	Bullets in sustained burst hit aluminum close-range	:02
Bullets Hit Metal	Bullets in bursts hitting metal mid-range	:02
Gun Battle 1	Mid-range rifle fire w/US small arms	:13
Gun Battle 2	Mid-range rifle fire w/US small arms	:08
Gun Battle Distant 1	Long-range rifle fire w/US small arms	:06
Gun Battle Distant 2	Long-range rifle bursts w/US small arms	:07
.50 Caliber Bursts 1	.50 Cal M2 Machine Gun, 4 bursts w/casings	:07
.50 Caliber Bursts 2	.50 Cal M2 Machine Gun, 4 bursts w/o casings	:10
M4 Long Burst	Close-range M4 firing entire clip	:03
M4 Single Shot	Close-range M4 single shot	:01
M16 Short Burst 1	Close-range M16 rifle burst fire	:01
M16 Short Burst 2	Mid-range M16 rifle burst fire	:01
M16 Single Shot	Close-range M16 single shot	:01
Shooting Range 1	Close-range M4 rifle shots at target	:17
Shooting Range 2	Mid-range M4 rifle shots at target	:14
Shooting Range 3	Long-range rifle shots at target	:32
Shooting Range 4	Long-range rifle shots at target	:14
Shooting Range 5	Long-range rifle shots at target	:20
Shooting Range 6	Long-range rifle shots at target	:20
US Small Arms	Close-range multiple M16 rife shots	:06
		.00
Vocal Arabic		
Iraqi Men Arguing 1	Local men arguing with heightened voices	:18
Iraqi Men Arguing 2	Local men arguing with heightened voices	:22
Iraqi Men Arguing 3	Local men arguing with heightened voices	:26
Vocal Taunts		- 00
"American American"	Local man says, "American American"	:02
"American dollar"	Vender proclamation, "American dollar"	:15
"Go back home!"	Locals shouting, "Go back home!"	:03
"When you go home?"	Local angrily asks, "When you gonna go home?"	:14
"Where you goin?"	Locals inquire, "Where you goin' American?"	:08
Vocal Vehicle Crew		
"Await One for SITREP"	Vehicle crew over radio, "Await One for SITREP"	:03
Breaking Contact	Vehicle crew over radio, Breaking contact with them, moving out"	:20
Contact 2 o'Clock	Vehicle crew callouts, "Contact 2 o'clock!"	:06
Contact 9 o'Clock	Vehicle crew callouts, "Contact 9 o'clock!"	:19
Gunner Scanning	Turret scanning w/crew callouts	:18
Guns Status Green	Vehicle crew over radio, "Gun1: Green green green"	:12
"IED! Get Down!"	Vehicle crew callouts, "IED! Get Down! Gunner's down!"	:05

IED SITREP	Vehicle crew over radio, "SITREP as follows"	:35
"I Need Ammo!"	Vehicle crew callouts, "I need ammo!"	:09
Moving Out	Vehicle crew callouts, "Moving Out! Push it up!"	:17
Moving to Checkpoint	Vehicle crew over radio, "Moving to checkpoint"	:05
Radio Out	Vehicle crew over radio, "Roger, on our way to a checkpoint"	:12
Radio Status Green	Vehicle crew over radio, "Situation is amber green green, over."	:31
Received Contact	Vehicle crew over radio, "We have just received contact Small arms fire!"	:08
Truck One Hit By IED	Vehicle crew callouts, "Truck one was just hit, left side. Push! Push!"	:23
Truck One Status	Vehicle crew SITREP, "We got one casualty KIA. One possible amputee. We gotta get him to the cache ASAP"	:22

Guide Maps

Afghanistan Bagram AB Walking Map

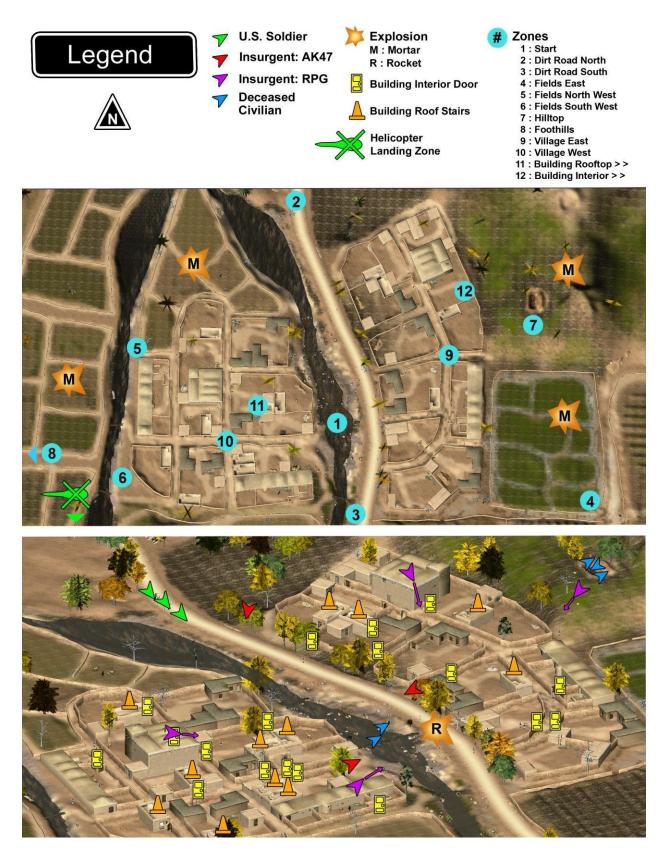






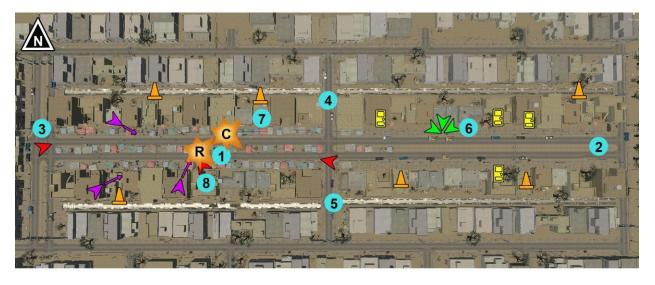
Afghanistan FOB Walking Map U.S. Soldier Explosion M : Mortar Zones 1 : Start 2 : Main Gate 3 : Motor Pool Legend 1 Building Interior Door 4 : Tower 5 : Mountain Trail Start 6 : Mountain Trail Midpoint 7 : Mountain Outpost Μ Μ 6 1 Μ 3 Μ 2 M

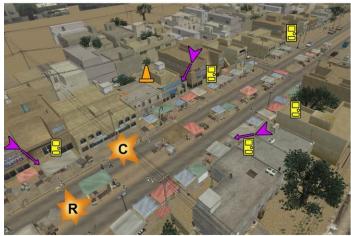
Afghanistan Rural Village Walking Map



Afghanistan Market Walking Map



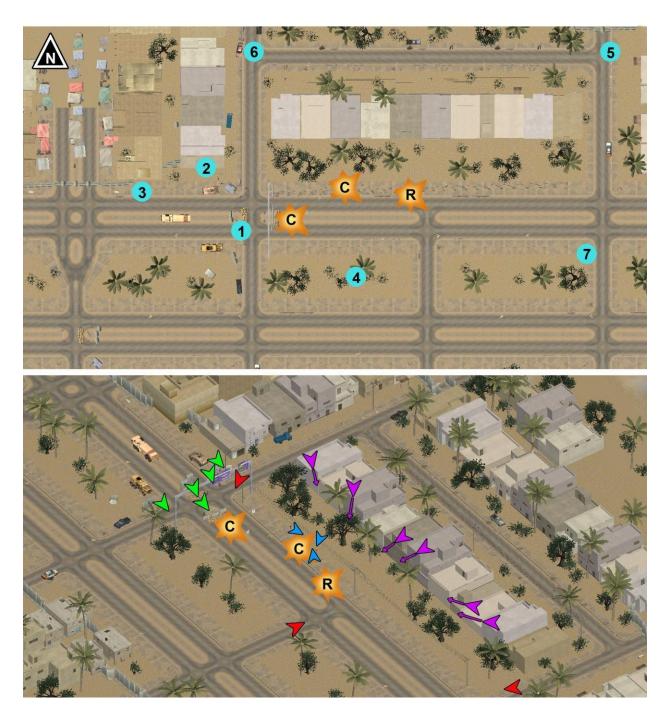






Iraq City Checkpoint Walking Map





Iraq City Industrial Walking Map



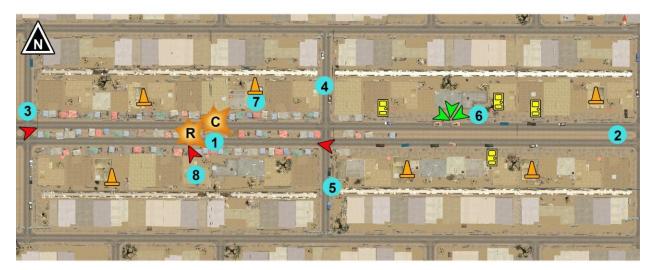


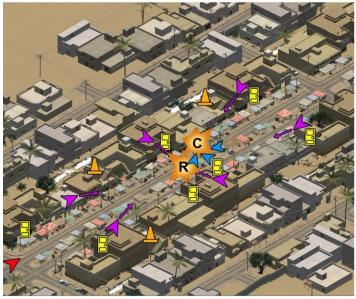


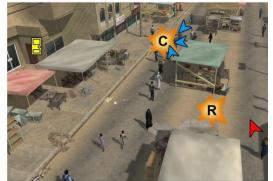


Iraq City Market Walking Map

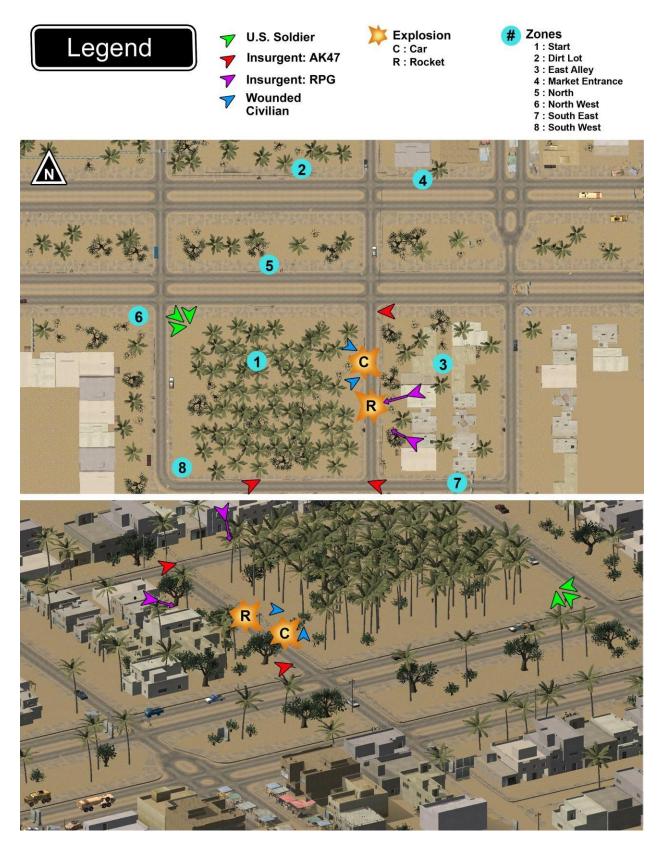


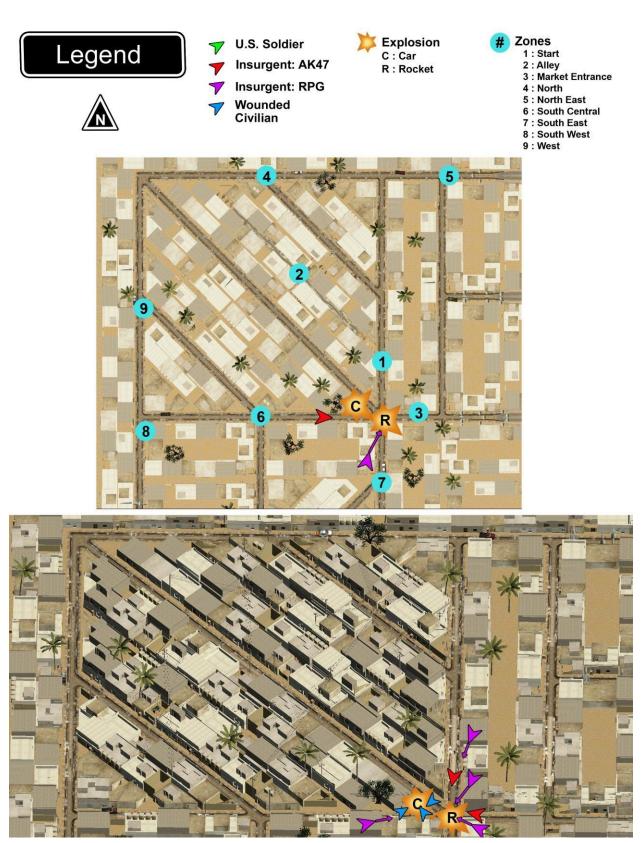




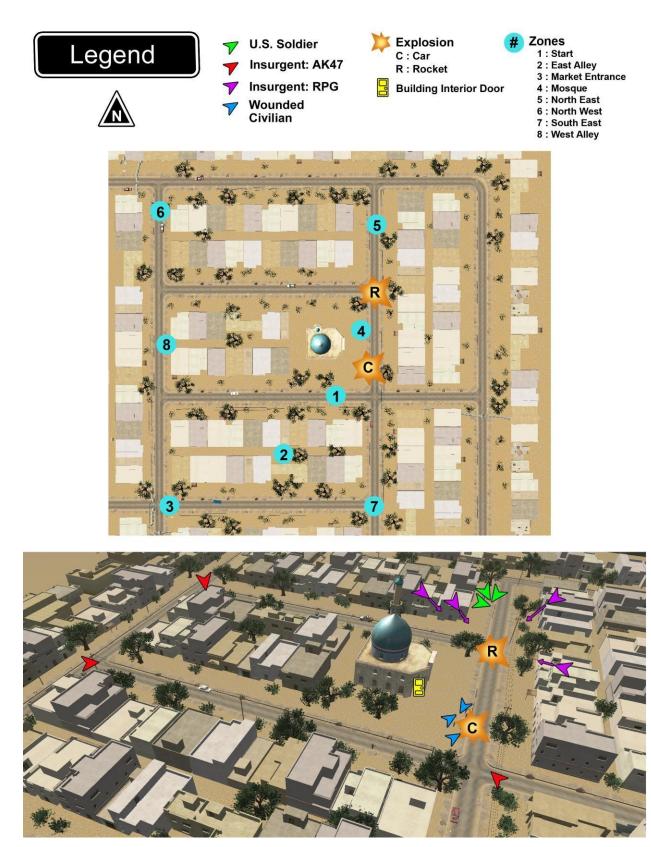


Iraq City Palm Grove Walking Map

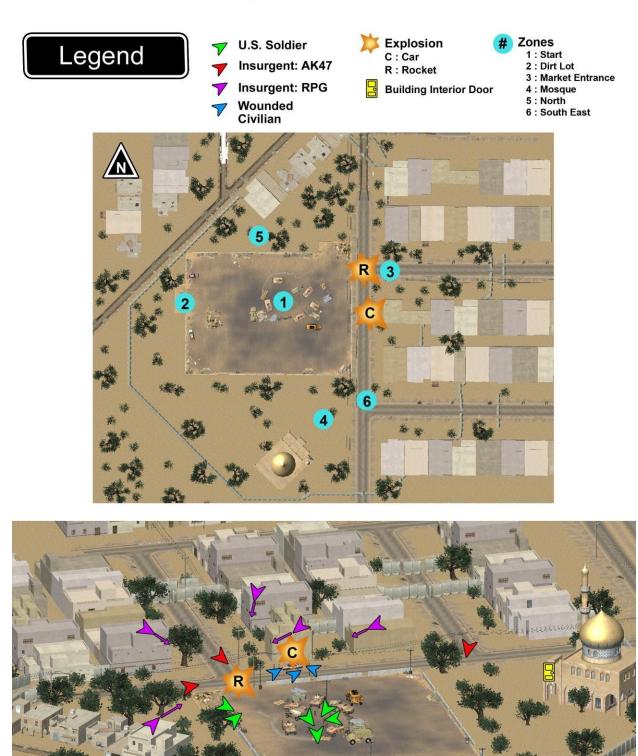




Iraq City Poor Residential Walking Map

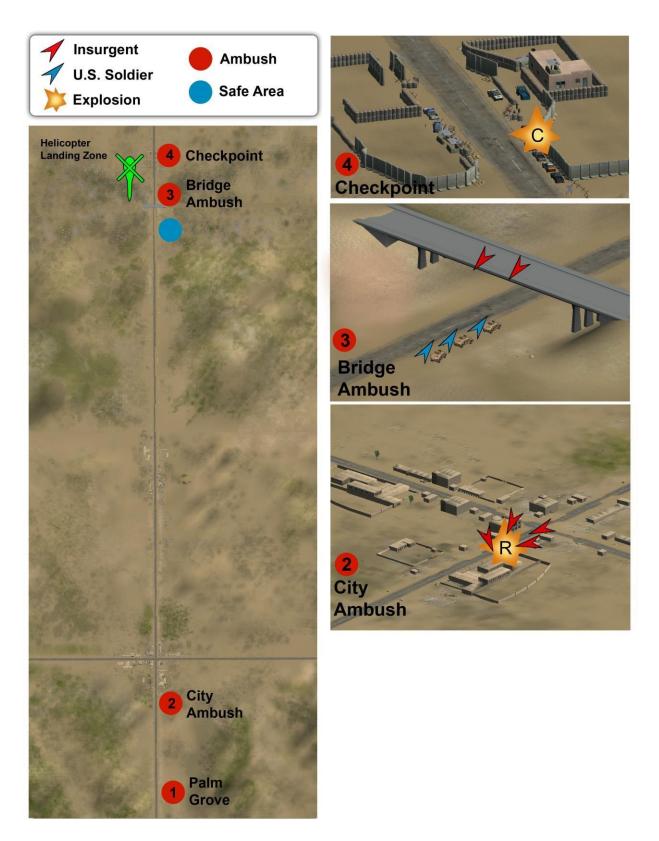


Iraq City Residential Walking Map

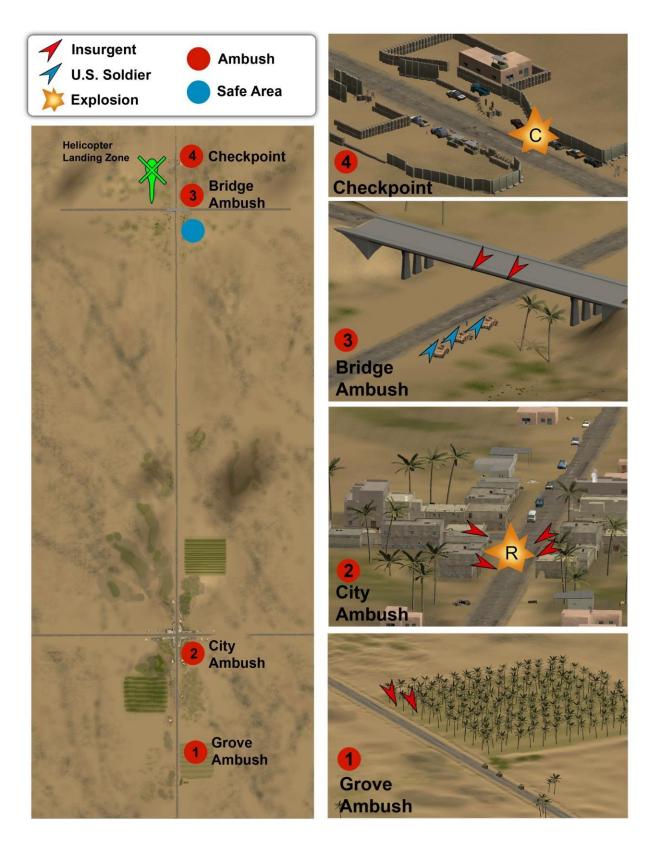


Iraq City Safe Zone Walking Map

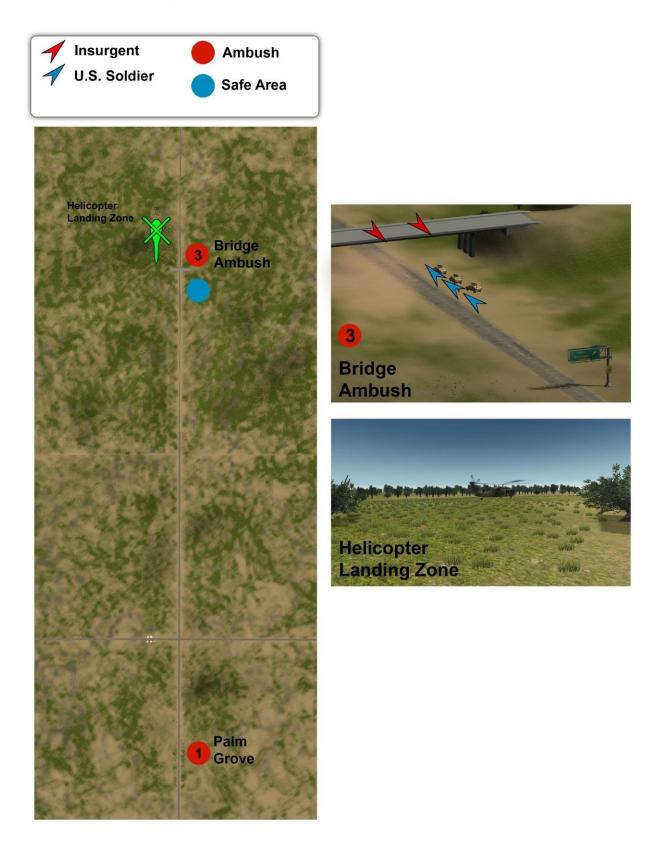
Afghanistan Rural Driving Map



Iraq Rural Driving Map



USA Rural Driving Map



Troubleshooting

Control and Gamepad Issues

- Game view spins continuously
 - If you are using the Logitech Rumble Gamepad F510 you need to make sure the switch on the back is set to "D" and not "X".
- Avatar moves forward constantly when using Rumblepad 2 gamepad
 - Completely close the application then unplug the gamepad from the PC USB port. Ensure the gamepad analog sticks in neutral position before plugging back in gamepad.
- Right trigger run command and/or left analogue stick walk command not functional with Logitech Rumble Gamepad F210/F510/F710
 - Ensure the gamepad is in the Direct-Input mode:
 - On the bottom of the controller, slide the switch to the "D" side.
 - Ensure the gamepad Mode light is off:
 - Press the Mode button to toggle the feature to off (no light).
- Getting stuck while walking
 - If the patient becomes stuck in a wall or in a place where movement is restricted:
 - Move backward using the gamepad or try moving in a different direction.
 - Select a new Location to teleport out of the stuck position.

General Scenario Event Issues

- Scenario triggered events or AI behavior becomes unstable
 - A progression of actions to take when something goes awry: Reset the ambush > Change locations > Exit to main menu, then reselect the scenario > Close/Reopen Clinician Controller & Patient Application.
- Patient Application freezes or hangs
 - Close/Reopen the Patient Application.
 - Open/Change scenarios through the main menu, not the Scenario Dropdown.

HMD, InertiaCube, and Monitor Issues

- eMagin Z800 internal tracking jitters on load of scenario.
 - This is a known issue with code to stabilize the device's internal tracking on initial scenario load. The jitter should go away within 30 seconds and not occur again unless the application is closed and reopened.
- InterSense InertiaCube only controls Pitch or Yaw movement, but not both at once.
 Occurs with initial scenario only. Reload the scenario to correct.
 - The graphics look strange / objects are textured incorrectly
 - This may be a bug related to your video card driver. Try updating your video card drivers to see if it fixed the problem.
- Monitor does not receive input
 - Check that all the appropriate cables are plugged in, according to the diagram under the Machine Configuration section of this manual.
 - Go to the Windows Display Settings through Display in the Control Panel or by rightclicking on the Desktop and choosing Properties in the context menu.
 - Ensure the secondary monitor appears in the configuration view.

- Check the box "Extend my Windows desktop onto this monitor".
- Screen is black/static and/or secondary monitor does not display view of eMagin HMD
 - Check that the light on the eMagin HMD controller is amber during a scenario.
 - If it is flashing green during a scenario, press the Power button in the middle of the controller to awaken it from standby mode. This will activate if no movement is detected by the tracker for 10 minutes.
 - Go to the Windows Display Settings through Display in the Control Panel or by rightclicking on the Desktop and choosing Properties in the context menu.
 - Ensure the resolution of the secondary monitor is set to 800 x 600 to match the HMD.
 - If using Windows XP, ensure the secondary monitor refresh rate is set to 60Hz by clicking the Advanced button, then selecting the value in the Monitor tab.
 - If using Windows 7, see the first listing under "Windows 7 Related Issues" for instructions. 60Hz may also work for installations of this type.
- InterSense InertiaCube not detected by software; IServer fails/freezes
 - Ensure the device drivers are properly installed as described in the <u>Manual Installation</u> section.
 - Close/Exit out of Bravemind and the IServer utility. Unplug the InertiaCube USB cable from the back of the PC, then plug it back in. Windows will re-detect the device.

Launch Failure Issues

- Controller crashes on load and/or Patient Application is unresponsive on launch
 - Ensure the ActiveMQ service is running.
 - Right-click on My Computer from either the Desktop or Start Menu.
 - Choose Manage in the command menu.
 - In the Computer Management window, there will be a pane on the left. Inside the pane, select Services and Applications > Services.
 - Select the ActiveMQ entry and click Start the service.
 - Once the service is running, retry the Controller/Patient Application
 - Close the Manager window.

Windows 7 Related Issues

- Client view is stretched in secondary monitor and off-center in eMagin HMD view
 - Adjust the refresh rate of the secondary monitor to 75 Hertz:
 - Right-click the desktop and choose "Screen resolution" in the context menu.
 - In the new window, select the secondary monitor and choose "Advanced Settings" below.
 - In the properties window, click the "Monitor" tab and choose 75 Hz from the "Screen refresh rate" dropdown.
 - Click Apply, Yes, and OK.
 - Here you may also need to adjust the color from 32-bit, to 16-bit.
 - If the image is still stretched, using the built-in adjustment menu of the monitor, ensure the aspect ratio is set to 4:3.

• Examiner speech into headset mic not heard in other headphones

- Ensure mic is plugged in and playback of microphone audio is enabled:
 - Right-click the speaker icon in the task bar.
 - Choose Recording Devices.

- Select Microphone and click Properties button. Select Listen tab. •
- •
- Check "Listen to this device" box. •
- Ensure dropdown reads "Default Playback Device".
 Click Apply, Ok, Ok, and test sound again.

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MICHAEL VALDOVINOS, PsyD, ABPP Licensed Clinical Psychologist

EDUCATION

- 2009 PsyD California School of Professional Psychology at Alliant International University Los Angeles, California Major: Clinical Psychology (APA accredited) Graduated Cum Laude
- 2006 MA California School of Professional Psychology at Alliant International University Los Angeles, California Major: Clinical Psychology
- 2002 BA University of California, Davis Davis, California Major: Psychology
- 1999 AS Associate of Science Santa Rosa Junior College Santa Rosa, California

BOARD CERTIFICATION/LICENSURE

- 2012 American Board of Professional Psychology (ABPP) Specialty: Cognitive and Behavioral Status: Current
- 2011 Licensed Psychologist (License No. 1965) Behavioral Sciences Board, Kansas Status: Current

PROFESSIONAL CAREER HISTORY

Oct 2015- PresentPalo Alto Veterans Affairs Health SystemPalo Alto, CaliforniaClinical Psychologist, Telemental Health and Evidence-Based Psychotherapy Program

- Conduct bio-psychosocial evaluations and diagnose mental disorders, conduct psychological and neuropsychological assessments, treat mental disorders through a variety of modalities and provide adjunctive rehabilitation-oriented interventions for the treatment of medical disorders and disabilities. Modalities include but are not limited to individual, couples, group, and family psychotherapies for a largely Veteran population.
- Conduct evidence-based psychotherapy services, primarily via telemental health, to the VA Palo Alto Heath Care System Mental Health Clinics. Therapies provided include but are not limited to Cognitive

Valdovinos, updated 1 Nov 2015

Behavior Therapy for Depression, Acceptance and Commitment Therapy, Prolonged Exposure Therapy, and Cognitive Processing Therapy.

 Research and participate in the development and implementation of novel mental health assessment and treatment interventions utilizing existing and emerging technologies.

Nov 2012- Oct 2015 Landstuhl Regional Medical Center-US Army Europe Landstuhl, Germany Chief, Outpatient Behavioral Health Services

- Lead the DoD largest overseas outpatient mental health team composed of 35 mental health providers (Military, General Service, Contractors) and 22 mental health paraprofessionals, interns, and European local nationals across 5 product lines.
- Translated management goals and objectives into well-coordinated and controlled work operations by developing productivity standards for mental health outpatient services and successfully executing a \$3.9M annual operations budget while managing and directing the largest DoD multidisciplinary adult outpatient mental health clinic in Europe (30K annual appointments, 2.7M annual RVUs) to accomplish US Army Europe enterprise goals and objectives.
- Provided, oversaw and coordinated quality improvement initiatives and guidelines to assure safe competent, evidence-based clinical practices in accordance with DoD/VA clinical practice guidelines, The Joint Commission, and local and national medical standards. Managed overall outpatient treatment services (including neuropsychological and psychological assessment) to active duty service members, family members, retirees, and medically evacuated military and civilian personnel from Europe, Southeast Asia, Africa, and the Middle East.
- Developed, monitored and executed both short and long range outpatient behavioral health planning efforts and goals:
 - Short term: Identified deficiencies thru employee productivity analysis; developed templates to increase RVU production by ~19% for multiple mental health product lines; built business plans to support hospital construction of expanded clinic space, acquired outside funding for \$62K Virtual Reality equipment to compliment evidence-based practice in the treatment of PTSD; acquired Polycom equipment and provided training for all outpatient behavioral health service staff to expand telemedicine capabilities to meet growing demand from enrolled European patient population, Southeast Asia, Africa, and the Middle East.
 - Long term: Through analysis of workflow processes, identified deficiencies and created new mental health documentation standards resulting in optimized provider availability and increased access to care by 30% for all beneficiaries; served as the primary liaison among 8 robust mental health multidisciplinary departments, addressing interdepartmental conflicts and establishing a collaborative working environment.
- Reviewed long and short range plans and resource projections while planning, setting priorities and meeting multiple deadlines by supervising and managing sole European DoD mental health care service line for rapid stabilization of evacuated personnel from Africa, Southeast Asia, Middle East and Europe (patient flow: CY2012 – 923 personnel; CY2013 – 611 personnel, CY2014 – 474 personnel).
- Developed and implemented intensive outpatient PTSD/military sexual assault program and embedded behavioral health program to provide expanded care for the enrolled population as well as the greater European footprint including remote areas in Romania, Poland, the Middle East and Africa.
- Selected and served as the lead operational psychologist for special operations joint service, 40
 member, 7 agency reintegration response team that psychologically reintegrated the last American
 Prisoner of War since Vietnam. Subsequently, selected by Royal Netherlands Air Force to lead
 development of multinational plan for Dutch mental health reintegration program of isolated personal
 and POWs.
- Lead consultant to Landstuhl Regional Medical Center for integration of technology and mental health.

Aug 2009- Oct 2012 David Grant Medical Center, Travis Air Force Base Fairfield. CA Licensed Clinical Psychologist (75%)

Executive Officer to the Hospital CEO/Commander (25%)

- Applied evidence-based mental health assessment, treatment, prevention, and outreach services for large active duty military (approximately 7.260), dependent and retiree population (approximately 3,770) at the largest US Air Force's hospital on the West Coast. Formulated treatment and disposition plans, utilized mood scales, symptom checklists, and personality inventories for differential diagnosis. Documented patient progress towards individualized, collaborative treatment goals. Primary therapeutic orientation is cognitive- behavioral.
- Selected as the US Air Force's highest utilizer of Virtual Reality (VR) exposure therapy for the treatment of PTSD. Appointed lead consultant for VR and Exposure-Based treatments to both David Grant Medical Center while providing VR consultation to San Francisco VA Medical Center. First psychologist at Travis Air Force Base to be appointed Executive Officer by David Grant Medical Center Chief Executive Officer and senior hospital leadership.
- Served as liaison between David Grant Medical Center Chief Executive Officer and 7 hospital department chiefs and executive leadership. Executed executive management tasks while overseeing all hospital departments and programs to meet business plan objectives and health inspection compliance. Additional duties entailed review of enlisted and officer performance reports, promotion recommendation reports, and general correspondence staffed to hospital leadership, Travis Air Force base leadership and Air Force Headquarters.
- Led Traumatic Stress Response Team to include suicide prevention and outreach services.
- Directly supported David Grant Medical Commander with the creation of the DoD/VA Joint Inpatient Mental Health Unit.
- Completed 7 Month operational psychology deployment to Afghanistan in support of Operation Enduring Freedom. Devised ways to adapt work operations to new and changing mental health programs, staffing, and environmental challenges to meet high-visibility organizational unit needs while in austere environments with individual and groups presenting widely divergent backgrounds, interests and points of view.

August 2008-August 2009 Wilford Hall Medical Center, US Air Force Pre-doctoral (APA-accredited) Psychology Internship Training Program

- Named "Outstanding Training Program" by the Association for Behavioral and Cognitive therapies.
- Trained in: Clinical Health Psychology (800 hr. rotation); Outpatient Mental Health (600 hr. rotation); • Primary Care Behavioral Health Consultation (104 hr. rotation). Operational Psychology (delivering clinical interventions in diverse environments) and additional electives in Alcohol Drug and Prevention.
- Applied evidence-based psychological principles and techniques from a cognitive-behavioral orientation to large military, civilian and retiree outpatient mental health clinic, clinical health psychology, and primary care and dual diagnosis clinics. Formulated treatment and disposition plans, utilized mood scales, symptom checklists, and personality inventories for differential diagnosis. Documented patient progress towards individualized, collaborative treatment goals.
- Conducted specialized comprehensive psychological screening and evaluations for selection of special duty military assignments.

2007-2008 Glendale Adventist Medical Center Pre-doctoral Health Psychology/Primary Care Practicum

- Conducted evidence-based individual, group and family cognitive-behavioral psychotherapy to adolescent and adult patients of varied ethnic backgrounds in a primary care optimization model.
- Participated in behavioral health consultation and training of family practice residents in areas of cognitive-behavioral therapy interventions and health psychology, psychosocial assessment, psychosocial issues, mental health diagnosis and referral.
- Developed behavioral health initiatives for medical providers to resolve patient noncompliance. Valdovinos, updated 1 Nov 2015

Glendale, CA

San Antonio, TX

• Developed and co-facilitated first ever Spanish-speaking cancer support group at Glendale Adventist Hospital.

2006-2007 Children's Hospital Los Angeles Pre-doctoral Health Psychology Practicum

- Conducted individual, group family psychotherapy and crisis intervention, both in English and Spanish, for at-risk teenagers through the Children's Hospital-Division of Adolescent Medicine at Los Angeles High School.
- Performed case consultation within a treatment team approach consisting of Children's Hospital physicians, educators, probation officers, academic counselors, and hospital mental health professionals.
- Developed mental health workshops and instructed medical staff in cognitive-behavioral interventions via adolescent medicine grand rounds and didactic training seminars at Children's Hospital.

2005-2006

Santa Anita Family Service

Monrovia, CA

Hollywood, CA

Pre-doctoral Psychology Practicum

- Implemented empirically based individual psychotherapy to multiethnic adults and children in English and Spanish.
- Co-facilitated court ordered domestic violence and outpatient drug therapy process groups in Spanish.

RESEARCH EXPERIENCE

2009 California School of Professional Psychology at AIU, Los Angeles

PsyD Doctoral Project- unpublished

• Depression risk and transmission to children in a sample of clinically depressed Latina mothers.

2001-2002 California Primate Research Center, University of California Davis

Research Assistant

- Research assistant to Katalin M. Gothard, MD, PhD, Department of Psychiatry, University of California, Davis.
- Assisted in all aspects of research including: experimental design, data collection, data analyses and interpretation, and communication of findings.
- Laboratory research activities included non-human primate experiments that addressed neural basis
 of behavior involving eliciting emotions in rhesus monkeys through (1) multiple reference frames
 while (2) recording neural activity from several brain areas in conjunction with (3) cardiovascular
 and other autonomic measurements.

HONORS/AWARDS

- Air Force Meritorious Service Medal 2012
- Air Force Commendation Medal 2012
- Psi Alpha Omega Honor Society for the Psychological Study of Ethic Minority Issues 2011
- United States Air Force Outstanding Psychology Resident of the Year 2009
- United States Air Force Health Professions Scholarship Recipient 2006 2008
- Enrique and Lucy Garcia Family Foundation Scholarship Recipient 2004 2007

PROFESSIONALTRAINING & ADDITIONAL QUALIFICATIONS

- Fellow, American Board of Cognitive and Behavioral Psychology 2012-Current
- Registrant, National Register of Health Service Provides in Psychology (#53149) 2011- current
- Cognitive Processing Therapy- Uniformed Services University January 2010
- Prolonged Exposure and Virtual Reality for PTSD -Emory University June 2010
- Basic Crisis/Hostage Negotiation Federal Bureau of Investigation Travis Air Force Base July 2010
- Behavioral Health Consultant in Primary Care- Wilford Hall Medical Center-June 2009
- Survival, Evasion, Resistance and Escape (SERE) Trained -Oct 2009
- National Provider Identifier (NPI #1952559015) 2009 current
- Basic Life Support Certified, 2008 current
- Air Force Allied Health Provider, Centralized Credentials Verification Office Evaluator (Peer Reviewer)
- Cognitive Behavioral Couples Therapy for Combat Stress and Intimate Relationship Problems-Wilford Hall Medical Center- September 2008
- Behavioral Healthcare Optimization Program (BHOP) Provider
- Spanish: Fluent-Bilingual Proficiency

ASSESSMENT EXPERIENCE

Intellectual

- Wechsler Abbreviated Scales of Intelligence (WASI)
- Wechsler Adult Intelligence Scale (WAIS)
- Wechsler Intelligence Scale for Children (WISC)
- Woodcock-Johnson Tests of Cognitive Abilities (WJ-III COG)
- Shipley Institute of Living Scale -2

Achievement

- Wide Range Achievement Test (WRAT-III)
- Woodcock-Johnson Tests of Achievement (WJ-III ACH)

Attention/Concentration

- Conners' Continuous Performance Test (CPT)
- ADHD Behavior Rating Scales
- Test of Attentional and Interpersonal Style (TAIS)

Personality

- Personality Assessment Inventory (PAI)
- Minnesota Multiphasic Personality Inventory (MMPI-2)
- Million Clinical Multiaxial Inventory III (MCMI-III)
- Neo Personality Inventory-R

Neuropsychological

- RBANS (Repeatable Battery for the Assessment of Neuropsychological Status)
- The Mini Mental Status Exam (MMSE)
- Trail-making Test (Forms A & B)
- Cancellation Test
- Word Fluency Test (FAS, categories)

Behavioral

- The Clinician-Administered PTSD Scale (CAPS)
- The Structured Clinical Interview for DSM disorders (SCID)
- Alcohol Use Disorder Identification Test (AUDIT)
- Posttraumatic Stress Disorder Checklist (PCL)

- The Short-Form (36) Health Survey (SF-36)
- Beck Depression Inventory (BDI)
- Patient Health Questionnaire 9 (PHQ-9)
- Outcome Questionnaire 45 (OQ-45)

PROFESSIONAL PRESENTATIONS

 Over the past 7 years I have provided or participated in approximately 100 professional presentations on topics covering theory, practice, and research. Presentations have spanned a broad range of topics, including suicide prevention, repatriation, clinical practice guidelines, evidence-based treatments, integration of mental health and technology, multicultural mental health, and military psychology.

REFRENCES

- Daphne Brown, PhD, ABPP Chief, Division of Behavioral Health Landstuhl Regional Medical Center, Germany
- Scott Bodine, PhD Clinical Psychologist Landstuhl Regional Medical Center, Germany
- Brian Hayes, MD, MPH
 Associate Chief of Staff
 Ambulatory Care Durham VA Medical Center
 Associate Professor, Duke University School Of Medicine, NC
- William A. Satterfield, PhD, ABPP Senior Policy Analyst, United States Public Health Service Deployment Psychological Health Condition-Based Specialty Care, Clinical Support Division Defense Health Agency Defense Health Headquarters (DHHQ), Falls Church, VA

APA Accredited Pre-Doctoral Internship

 Ann Hryshko-Mullen, PhD, ABPP-CHP, CBSM Director, Clinical Psychology Training Joint Base San Antonio-Lackland, TX

Paula L. Domenici, Ph.D.

EDUCATION, LICENSURE AND AWARDS

UNIVERSITY OF MARYLAND. College Park, MD.

- Doctorate of Philosophy, Counseling Psychology, 2002
- GPA: 3.98

TEACHERS COLLEGE, COLUMBIA UNIVERSITY. New York, NY.

- Master of Arts, Developmental Psychology, 1995
- GPA: 4.0

BROWN UNIVERSITY, Providence, RI.

- Bachelor of Arts, English and American Literature, 1989
- Magna Cum Laude

LICENSURE & AWARDS

- Licensed in Maryland: 2007 to present (active) and California: 2003 to present (inactive).
- 2006 Silver Award, ForeWord Magazine's Self-Help Book of the Year, *Courage After Fire: Coping Strategies for Troops Returning from Iraq and Afghanistan and Their Families.*
- Special Appreciation Award, Development of Clinical Program to Assist Returning OIF/OEF Veterans, Department of Veterans Affairs Medical Center, San Francisco, CA, June 2005.
- Graduate Fellowship, International Christian University of Japan, September 2000 to June 2001.
- Student Diversity Award, Division of Psychotherapy, APA, College Park, MD August 2000.

TEACHING, TRAINING, AND CLINICAL EXPERIENCE

UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES, Bethesda, MD. *Adjunct Professor*, Department of Medical and Clinical Psychology, January 2011 to present.

CENTER FOR DEPLOYMENT PSYCHOLOGY. Headquarters, Rockville, MD.

Director, Civilian Training Programs, November 2011 to present.

Deliver trainings to mental health providers on evidence-based psychotherapies and deployment topics and supervise CDP personnel in developing, promoting and delivering presentations.

- Oversee and manage all CDP civilian programs including 1-week courses and university trainings.
- Supervise staff and faculty in creating, presenting, and evaluating training programs.
- Provide trainings and webinars on the deployment cycle, student veterans, ethics, TBI, PTSD,
- moral injury, sleep problems, Prolonged Exposure Therapy and other topics.
- Serve as member of the Executive Team in advancing CDP's growth and vision.

CENTER FOR DEPLOYMENT PSYCHOLOGY, Headquarter, Rockville, MD.

Head, Division of Training Programs, September 2009 to October 2011.

- Instruct clinicians and trainees on Prolonged Exposure Therapy at 2-day workshops offered across the country and at different military installations.
- Direct and lecture at 1-day, 1-week and 2-week programs covering the deployment cycle, suicide, depression, TBI, PTSD, military culture, insomnia and other topics.

• Design, teach and disseminate new research-based curriculum with other subject matter experts on the emotional impact of combat on service members and their families.

CENTER FOR DEPLOYMENT PSYCHOLOGY. Uniformed Services University, Bethesda, MD. *Deployment Behavioral Health Psychologist*, October 2007 to September 2009.

Planned and delivered deployment-related curriculum and executed multi-day workshops with CDP faculty for military and civilian mental health providers, and handled continuing education procedures.

- Coordinated and directed 1 week and 2-week trainings addressing topics in deployment psychology and the behavioral health of service members and their families.
- Collaborated with CDP faculty to improve continuing education programming and accreditation processes and develop new modules and products based on research findings.
- Designed and led workshops on prevention, assessment and treatment of mental health problems at Navy Deployment Health Clinics across the country.

CENTER FOR DEPLOYMENT PSYCHOLOGY. National Naval Medical Center, Bethesda, MD. *Deployment Behavioral Health Psychologist*, September 2006 to September 2007.

Provided treatment to Marines and Navy personnel with behavioral health problems, assisted in training Navy psychology interns, and led classes on pre- and post-deployment emotional concerns.

- Provided short- and long-term clinical services to military outpatients with PTSD, depression, anxiety or TBI, and coordinated their care with other providers.
- Administered mental health assessments and delivered individual therapy to physically injured service members in the Casualty Care Unit soon after sustaining blasts or gunshot wounds in theater.
- Spearheaded new therapy group for family members of severely injured Marines.
- Delivered lectures on post-deployment adjustment problems and clinical interventions.

DEPARTMENT OF VETERANS AFFAIRS MEDICAL CENTER. San Francisco, CA. *Staff Psychologist, PTSD Clinic.* January 2004 to August 2005.

Served on the PTSD Clinical Team providing comprehensive mental health services to veterans as well as education and training to psychology interns and externs.

- Supervised students in therapy, assessment, and writing case reports, and co-led seminars.
- Managed the triage process for referrals and conducted clinical interviews and individual therapy.
- Coordinated all group therapies and developed several new groups for veterans with PTSD.
- Led the mental health program for veterans returning from Iraq and Afghanistan resulting in increased outreach, funding, and staffing and improved levels of care.

DEPARTMENT OF VETERANS AFFAIRS MEDICAL CENTER. San Francisco, CA. *Postdoctoral Fellow, Major Rotation: Trauma; Minor Rotations: Substance Abuse and Neuropsychology.* September 2002 to August 2003.

One of two postdoctoral fellows selected for 1-year APA-accredited fellowship in PTSD and substance abuse rotations focusing on therapy, assessment, teaching, and leadership skills.

- Performed PTSD, substance abuse, and neuropsychological evaluations and wrote reports.
- Provided individual, couples, and group therapy and drafted treatment plans and case notes.
- Led multidisciplinary meetings and coordinated training for psychology students and residents.
- Created and launched group therapy program for spouses of PTSD patients. Program was recognized as one of the PTSD Clinic's core clinical components.

DEPARTMENT OF VETERANS AFFAIRS MEDICAL CENTER. Baltimore, MD. *Predoctoral Intern, Major Rotations: Trauma, Inpatient, and Primary Care.* July 2001 to June 2002.

- Conducted individual therapy with inpatients and outpatients.
- Facilitated inpatient and outpatient therapy groups and directed psychoeducational workshops.
- Administered structured interviews and test batteries and wrote reports.
- Developed treatment plans and presented case formulations at team meetings.

DEPARTMENT OF VETERANS AFFAIRS MEDICAL CENTER. Baltimore, MD. *Extern, Addictions Day Treatment Program.* September 1999 to May 2000.

- Performed individual therapy with substance abuse outpatients.
- Led therapy groups and community milieu meetings.

THE UNIVERSITY OF MARYLAND COUNSELING CENTER. College Park, MD.

Therapist (Practica and Pre-Practicum). Sept. 1997 to Dec. 1998 and Sept. 1999 to Jan. 2000.

- Provided individual therapy to college students with emotional concerns.
- Conducted career counseling and assessments with college students.

THE UNIVERSITY OF MARYLAND ASIAN DIVISION. Yokosuka Navy Base, Japan. *Instructor (Introduction to Counseling Psychology).* January to March 2001.

• Designed and taught an undergraduate course to Navy personnel and spouses living at Japan base.

THE UNIVERSITY OF MARYLAND COUNSELING/PERSONNEL SVCS. College Park, MD. *Supervisor for Pre-Practicum Clinical Course.* March 1999 to May 2000.

- Provided clinical supervision to graduate students for their counseling sessions.
- Lab Instructor for the Helping Relationship Skills Course. January to May 1998.
- Coached and trained undergraduate students in learning therapy skills.

THE GEORGE WASHINGTON UNIVERSITY DEPT. OF COUNSELING. Washington, DC. *Lab Section Leader for the Counseling and Interview Skills Course.* January to May 1997.

- Taught counseling skills to graduate students and facilitated group practice of new techniques *Teacher's Assistant for the Career Counseling Course.* January to May 1997.
- Conducted review sessions, organized readings, and assisted graduate students in writing reports.

THE JAPANESE EXCHANGE TEACHING PROGRAM. Ashikaga, Japan.

- English Teacher of Japanese Elem. and Junior High School Students. August 1990 to April 1991.
- Taught English to Japanese students at various schools and promoted cultural exchange.

POLICY AND CONSULTING EXPERIENCE

AMERICAN PSYCHOLOGICAL ASSOCIATION (APA). Washington, DC.

Congressional Fellow, Office of Senator Hillary Rodham Clinton. September 2005 to August 2006. One of four psychologists selected by APA for a congressional fellowship to promote better-informed policy decisions by applying psychology and bridging the gap between science and policy.

- Designed and recommended policy strategies concerning mental health, aging, and veterans' issues for the Senator's health team.
- Drafted statements for committee hearings, coordinated briefings, and met with constituents.
- Developed the *Heroes at Home Act* to help OIF/OEF veterans with PTSD, TBI, and reintegration.

THE UNIVERSITY OF MARYLAND CAMPUS COMPLIANCE OFFICE. College Park, MD. *Consultant (Consultation Practicum).* January to May 1999.

- Consulted with Campus Compliance Officer (CCO) weekly to increase outreach efforts.
- Garnered data and formulated plan and interventions to enhance CCO's visibility to students.

THE OFFICE OF HUMAN RELATIONS PROGRAMS. College Park, MD.

Coordinator of the Sexual Harassment Prevention Program. September 1998 to May 1999.

- Spearheaded delivery of sexual harassment prevention workshops to faculty, staff, and students.
- Developed training seminars and manuals, recruited volunteers, and drafted quarterly newsletters.

RESEARCH EXPERIENCE

THE UNIVERSITY OF MARYLAND COUNSELING/PERSONNEL SVCS. College Park, MD. *Primary Investigator for Dissertation Study.* February 2000 to October 2001.

- Investigated biopsychosocial predictors of well-being and depression in Westerners in Tokyo. *Primary Investigator for Thesis Study.* February 1998 to November 1999.
- Researched the help-seeking attitudes of Asian-American college students.

THE GEORGE WASHINGTON UNIVERSITY. Washington, DC.

Research Assistant in Department of Counseling. September 1996 to June 1997.

• Performed literature reviews on sexual abuse and conducted intakes with victims of incest.

THE NATIONAL INST. OF CHILD HEALTH & HUMAN DEVELOPMENT. Bethesda, MD. *Research Assistant in Laboratory of Social and Emotional Development.* Oct. 1995 to Sept. 1996.

• Managed 150 cases of children's sexual abuse testimony and coded forensic interviews.

THE NEW YORK STATE PSYCHIATRIC INSTITUTE. New York, NY.

Research Assistant in Department of Clinical and Genetic Epidemiology. Oct. 1994 to Aug. 1995.

• Abstracted data from multiple sources on children of drug-addicted parents for comparative study.

PUBLICATIONS, PRESENTATIONS, AND WORKSHOPS

Chrestman, K. & Domenici, P. (October, 2016). <u>Prolonged Exposure Therapy.</u> Workshop presented in *Second Life* on behalf of the Center for Deployment Psychology.

Riggs, D. & Domenici, P. (September, 2016). <u>Prolonged Exposure Therapy</u>. Workshop presented at Uniformed Services University of the Health Sciences in Bethesda, MD on behalf of the Center for Deployment Psychology.

Holloway, K. & Domenici, P. (September, 2016). <u>Prolonged Exposure Therapy</u>. Workshop presented in *Second Life* on behalf of the Center for Deployment Psychology.

Chrestman, K. & Domenici, P. (August, 2016). <u>Prolonged Exposure Therapy Refresher.</u> Workshop presented in *Second Life* on behalf of the Center for Deployment Psychology.

Brim, W. & Domenici, P. (June, 2016). <u>Prolonged Exposure Therapy.</u> Workshop presented at Andrews Air Force Base on behalf of the Center for Deployment Psychology.

Domenici, P. (June, 2016). <u>Military PTSD.</u> Training presented at the Summer Institute at Uniformed Services University of the Health Sciences on behalf of the Center for Deployment Psychology.

Domenici, P. (May, 2016). <u>Insomnia, Ethics and Substance Abuse.</u> Trainings presented in New Paltz, NY for the Star Behavioral Health Providers Program on behalf of the Center for Deployment Psychology.

Domenici, P. (May, 2016). <u>Insomnia, Ethics and Substance Abuse.</u> Trainings presented in New York City, NY for the Star Behavioral Health Providers Program on behalf of the Center for Deployment Psychology.

Domenici, P (April, 2016). <u>PTSD, Insomnia, Ethics and Substance Abuse</u>. Trainings presented in Des Moines, IA for the course, *Addressing the Psychological Needs of Service Members and Their Families*, on behalf of the Center for Deployment Psychology.

Chrestman, K., Riggs, D. & Domenici, P (April, 2016). <u>Prolonged Exposure Therapy.</u> Workshop presented in *Second Life* on behalf of the Center for Deployment Psychology.

Domenici, P. (December, 2016). <u>University Counseling Center Core Competency Program.</u> Workshop presented at Albany State University, Albany, GA on behalf of the Center for Deployment Psychology.

Domenici, P. (November, 2016). <u>Prolonged Exposure Therapy</u>. Workshop presented at Portsmouth Naval Medical Center, VA on behalf of the Center for Deployment Psychology.

McCormick, A. & Domenici, P. (November, 2016). <u>University Counseling Center Core</u> <u>Competency Program.</u> Workshop presented at Fresno City College, Fresno, CA on behalf of the Center for Deployment Psychology.

Domenici, P. (October, 2016). <u>Prolonged Exposure Therapy.</u> Workshop presented at the Massachusetts General Home Base Program, Boston, MA on behalf of the Center for Deployment Psychology.

Domenici, P. (October, 2016). <u>Assessment and Treatment of Anger and Moral Injury in</u> <u>Veterans.</u> Trainings presented at Maryland's Commitment to Veterans Conference, Linthicum Heights, MD on behalf of the Center for Deployment Psychology.

Domenici, P. (August, 2015). <u>Prolonged Exposure Therapy.</u> Workshop presented at Aviano AFB, Italy on behalf of the Center for Deployment Psychology.

Domenici, P. (July, 2015). <u>Prolonged Exposure Therapy.</u> Workshop presented in Indianapolis, IN for the Star Behavioral Health Providers Program on behalf of the Center for Deployment Psychology.

Domenici, P. (June, 2015). <u>Military PTSD.</u> Workshop presented at the Summer Institute at the Uniformed Services University of the Health Sciences, Bethesda, MD on behalf of the Center for Deployment Psychology.

Domenici, P. (June, 2015). <u>University Counseling Center Core Competency Program.</u> Workshop presented at Brown University, Providence, RI on behalf of the Center for Deployment Psychology.

Domenici, P. (May, 2015). <u>Assessment and Treatment of PTSD, Moral Injury in Veterans and</u> <u>Parents of Service Members: An Underserved Population.</u> Trainings presented at the Serving Together Conference, John Hopkins University, Montgomery County Campus, Rockville, MD on behalf of the Center for Deployment Psychology.

Domenici P. (April, 2015). <u>Insomnia, Ethics and Substance Abuse.</u> Trainings presented in Atlanta, GA for the Star Behavioral Health Providers Program on behalf of the Center for Deployment Psychology.

Domenici, P. (March, 2015). <u>Prolonged Exposure Therapy</u>. Workshop presented at Fort Stewart, GA on behalf of the Center for Deployment Psychology.

Domenici, P. (February, 2015). <u>Prolonged Exposure Therapy</u>. Workshop presented at the Uniformed Services University of the Health Sciences, Bethesda, MD on behalf of the Center for Deployment Psychology.

Domenici, P. (January, 2015). <u>Prolonged Exposure Therapy.</u> Workshop presented at the University of Texas at Tyler, TX on behalf of the Center for Deployment Psychology.

Domenici, P. (January, 2015). <u>Moral Injury in Veterans.</u> Webinar presented at the Headquarters Office of the Center for Deployment Psychology, Rockville, MD.

Domenici, P. (December, 2014). <u>Prolonged Exposure Therapy.</u> Workshop presented in Miami, FL on behalf of the Center for Deployment Psychology.

Domenici, P. (November, 2014). <u>Parents of Service Members: An Underserved Population.</u> Webinar presented at the Headquarters Office of the Center for Deployment Psychology, Rockville, MD for the Association of American Medical Colleges and White House Joining Forces Initiative.

Domenici, P. (October, 2014). <u>University Counseling Center Core Competency Program.</u> Workshop presented at the American College Counseling Association in San Antonio, TX on behalf of the Center for Deployment Psychology.

Domenici, P. (October, 2014). <u>Moral Injury in Veterans.</u> Keynote address presented at the American College Counseling Association in San Antonio, TX on behalf of the Center for Deployment Psychology.

Domenici, P. (August, 2014). <u>Parents of Service Members: An Underserved Population</u>. Webinar presented at the Headquarters Office of the Center for Deployment Psychology for the Star Behavioral Health Providers Program.

Domenici, P. (July, 2014). <u>Prolonged Exposure Therapy.</u> Workshop presented at Langley AFB, VA on behalf of the Center for Deployment Psychology.

Domenici, P. (June, 2014). <u>Prolonged Exposure Therapy.</u> Workshop presented in Kalamazoo, MI for the Star Behavioral Health Providers Program on behalf of the Center for Deployment Psychology.

Domenici P. (June, 2014). <u>Insomnia, Ethics and Substance Abuse.</u> Trainings presented in San Diego, CA for the Star Behavioral Health Providers Program on behalf of the Center for Deployment Psychology.

Domenici, P. (April, 2014). <u>Prolonged Exposure Therapy</u>. Workshop presented in Washington, DC on behalf of the Center for Deployment Psychology.

Domenici P. (April, 2014). <u>Insomnia, Military Sexual Assault, TBI and Military Families.</u> Trainings presented in Perdue, IN for the Star Behavioral Health Providers Program on behalf of the Center for Deployment Psychology.

Domenici, P. (March, 2014). <u>University Counseling Center Core Competency Program.</u> Workshop presented at Clemson University, GA on behalf of the Center for Deployment Psychology.

Domenici, P. (March, 2014). <u>University Counseling Center Core Competency Program</u>. Workshop presented at University of GA, Athens, GA on behalf of the Center for Deployment Psychology.

Domenici, P. (November, 2013). <u>Parents of Service Members: An Underserved Population.</u> Webinar presented in Rockville, MD for the Association of American Medical Colleges and White House Joining Forces Initiative on behalf of the Center for Deployment.

Domenici, P. (October, 2013). <u>University Counseling Center Core Competency Program.</u> Workshop presented at Michigan State University, MI on behalf of the Center for Deployment Psychology.

Domenici, P. (September, 2013). <u>Student Veterans and Suicide</u>. Workshop presented for the Education Directorate of the American Psychological Association in Washington, DC on behalf of the Center for Deployment Psychology.

Domenici, P. (August, 2013). <u>University Counseling Center Core Competency Program.</u> Workshop presented at University of Wisconsin, Madison, WI on behalf of the Center for Deployment Psychology.

Domenici, P. (August, 2013). <u>University Counseling Center Core Competency Program.</u> Workshop presented at University of Delaware, Wilmington, DE on behalf of the Center for Deployment Psychology.

Domenici, P., Best, S., & Armstrong, K. (July, 2013). <u>Courage after Fire for Parents of Service</u> <u>Members: Strategies for Coping When Your Son or Daughter Returns from Deployment.</u> Oakland, CA: New Harbinger.

Domenici, P. (July, 2013). <u>Prolonged Exposure Therapy.</u> Workshop presented at Colorado State University, CO on behalf of the Center for Deployment Psychology.

Domenici, P. (July, 2013). <u>Prolonged Exposure Therapy.</u> Workshop presented at Widener University, Chester, PA on behalf of the Center for Deployment Psychology.

Holloway, K. & Domenici, P. (June, 2013). <u>Prolonged Exposure Therapy</u>. Workshop presented at the Institute for Disaster Mental Health, New Paltz, NY on behalf of the Center for Deployment Psychology.

Domenici, P. (May, 2013). <u>Prolonged Exposure Therapy.</u> Workshop presented to the Los Angeles Police Department, Los Angeles, CA on behalf of the Center for Deployment Psychology.

Domenici, P. (April, 2013). <u>Prolonged Exposure Therapy</u>. Workshop presented in Phoenix, AZ on behalf of the Center for Deployment Psychology.

Domenici, P. (April, 2013). <u>Assessment and Treatment of Sleep Disturbance Associated with</u> <u>Deployment.</u> Workshop presented in Phoenix, AZ on behalf of the Center for Deployment Psychology.

Domenici, P. (April, 2013). <u>Prolonged Exposure Therapy.</u> Workshop presented in Indianapolis, IN for the Star Behavioral Health Providers Program on behalf of the Center for Deployment Psychology.

Domenici, P. (February, 2013). <u>Prolonged Exposure Therapy.</u> Workshop presented at Fort Gordon, GA on behalf of the Center for Deployment Psychology.

Furman, K. & Domenici, P. (February, 2013). <u>Managing Crisis Situations with Veterans.</u> Workshop presented to law enforcement personnel in Winchester, VA on behalf of the Center for Deployment Psychology.

Nofziger, D. & Domenici, P. (February, 2013). <u>Managing Crisis Situations with Veterans.</u> Workshops presented for the Los Angeles Police and Sheriff Departments, Los Angeles, CA on behalf of the Center for Deployment Psychology.

Domenici, P. (February, 2013). <u>Prolonged Exposure Therapy.</u> Workshop presented for the Los Angeles Police Department, Los Angeles, CA on behalf of the Center for Deployment Psychology.

Bonar, T. & Domenici, P. (January, 2013). <u>Prolonged Exposure Therapy.</u> Workshop presented at San Diego State University, CA on behalf of the Center for Deployment Psychology.

Domenici, P. (December, 2012). <u>Assessment of PTSD and Substance Abuse</u>. Trainings presented in Blacksburg, WV on behalf of the Center for Deployment Psychology.

Domenici, P. (December, 2012). <u>Military Culture, the Deployment Cycle and Sleep</u> <u>Disturbances in Service Members.</u> Trainings presented for the New York Social Work Conference, Lake Placid, NY on behalf of the Center for Deployment Psychology.

Domenici, P. (November, 2012). <u>Prolonged Exposure Therapy.</u> Workshop presented at Tripler Army Medical Center, HI on behalf of the Center for Deployment Psychology.

Holloway, K. & Domenici, P. (October, 2012). <u>Prolonged Exposure Therapy.</u> Workshop presented at Fort Belvoir, MD on behalf of the Center for Deployment Psychology.

Domenici, P. (July, 2012). <u>Prolonged Exposure Therapy.</u> Workshop presented at Wright-Patterson, OH on behalf of the Center for Deployment Psychology.

Bonar, T. & Domenici, P. (June, 2012). <u>University Counseling Center Core Competency</u> <u>Program.</u> Workshop presented at West Virginia University, WV on behalf of the Center for Deployment Psychology.

Domenici, P. (May, 2012). <u>University Counseling Center Core Competency Program.</u> Workshop presented in Cincinnati, OH on behalf of the Center for Deployment Psychology.

Parins, Elizabeth & Domenici, P. (May, 2012). <u>University Counseling Center Core</u> <u>Competency Program.</u> Workshop presented in Akron, OH on behalf of the Center for Deployment Psychology.

Sermanian, D. & Domenici, P. (April, 2012). <u>University Counseling Center Core Competency</u> <u>Program.</u> Workshop presented at Montgomery College in Rockville, MD on behalf of the Center for Deployment Psychology.

Domenici, P. (March, 2012). <u>Prolonged Exposure Therapy.</u> Workshop presented in Sacramento, CA on behalf of the Center for Deployment Psychology.

Domenici, P. (March, 2012). <u>Assessment and Treatment of Sleep Disturbance Associated with</u> <u>Deployment.</u> Workshop presented in Sacramento, CA on behalf of the Center for Deployment Psychology.

Domenici, P. & Pelton, D. (February, 2012). <u>Prolonged Exposure Therapy.</u> Workshop presented at Walter Reed National Military Medical Center, Rockville, MD on behalf of the Center for Deployment Psychology.

Domenici, P. (February, 2012). <u>Prolonged Exposure Therapy.</u> Workshop presented at Fort Campbell, KY on behalf of the Center for Deployment Psychology.

Domenici, P. (February, 2012). <u>Prolonged Exposure Therapy</u>. Workshop presented in Tampa, FL on behalf of the Center for Deployment Psychology

Domenici, P. (January, 2012). <u>University Counseling Center Core Competency Program.</u> Workshop presented at Colorado State University, CO on behalf of the Center for Deployment Psychology.

Bonar, T.C. & Domenici, P.L. (2011). Counseling and connecting with the military undergraduate: The intersection of military service and university life. Journal of College Student Psychotherapy, 25: 204-219.

Domenici, P. (September, 2011). <u>Cognitive-Behavioral Therapy for Insomnia and Traumatic</u> <u>Brain Injury.</u> Workshop presented at Ft. Richardson/Elmendorf AFB, AK on behalf of the Center for Deployment Psychology. Domenici, P. (August, 2011). <u>Prolonged Exposure Therapy.</u> Workshop presented at Edelweiss, Germany on behalf of the Center for Deployment Psychology.

Domenici, P. (July, 2011). <u>Prolonged Exposure Therapy.</u> Workshop presented at Dover AFB, DE on behalf of the Center for Deployment Psychology.

Brim, W. & Domenici, P. (June, 2011). <u>Prolonged Exposure Therapy.</u> Workshop presented at Portsmouth Naval Medical Center, VA on behalf of the Center for Deployment Psychology.

Domenici, P. (May, 2011). <u>Assessment and Treatment of Sleep Disturbance Associated with</u> <u>Deployment.</u> Workshop presented in Colorado Springs, CO on behalf of the Center for Deployment Psychology.

Riggs, D. & Domenici, P. (May, 2011). <u>Prolonged Exposure Therapy.</u> Workshop presented in Colorado Springs, CO on behalf of the Center for Deployment Psychology

Domenici, P. (May, 2011). <u>Prolonged Exposure Therapy.</u> Workshop presented at Travis AFB, CA on behalf of the Center for Deployment Psychology.

Domenici P. (April, 2011). <u>Etiology, Assessment and Treatment of Depression.</u> Workshop presented at Turf Valley, MD on behalf of the Center for Deployment Psychology.

Domenici, P. (March, 2011). <u>Identification, Prevention and Treatment of Suicidal Behavior.</u> Workshop presented at Widener University, Chester, PA on the behalf of the Center for Deployment Psychology.

Domenici, P. (March, 2011). <u>Prolonged Exposure Therapy.</u> Workshop presented at Moody AFB, GA on behalf of the Center for Deployment Psychology.

Domenici P. (February, 2011). <u>Assessment of PTSD and Assessment and Treatment of Sleep</u> <u>Disturbance Associated with Deployment.</u> Trainings presented in Honolulu, HI on behalf of the Center for Deployment Psychology.

Domenici, P. & Bowers, J. (January, 2011). <u>Addressing the Psychological Health of Troops.</u> Workshop presented at Howard University, Washington, DC on behalf of the Center for Deployment Psychology.

Domenici, P. (November, 2010). <u>Epidemiology, Assessment and Treatment of PTSD.</u> Workshop presented in Virginia Beach, VA for the Wounded Warrior Program on behalf of the Center for Deployment Psychology.

Riggs, D. & P. Domenici (June, 2010). <u>Prolonged Exposure Therapy</u>. Workshop presented at Camp Lejeune, NC on behalf of the Center for Deployment Psychology.

Riggs, D. & P. Domenici (May, 2010). <u>Prolonged Exposure Therapy.</u> Workshop presented at Portsmouth Navy Medical Center, VA on behalf of the Center for Deployment Psychology.

Domenici, P. (April, 2010). <u>Assessment of PTSD.</u> Workshop presented in Austin, TX on behalf of the Center for Deployment Psychology.

Brim, W. & Domenici, P. (February 2010). <u>Prolonged Exposure Therapy.</u> Workshop presented in Okinawa, Japan on behalf of the Center for Deployment Psychology.

Domenici, P. (November, 2009). <u>Etiology of PTSD and Identification, Prevention and</u> <u>Treatment of Suicidal Behavior</u>. Trainings presented in Pensacola, FL on behalf of the Center for Deployment Psychology.

Domenici, P. (September, 2008). <u>Etiology, Assessment and Treatment of Depression.</u> Workshop presented in Bethesda, MD on behalf of the Center for Deployment Psychology.

Riggs, D. & P. Domenici (September, 2008). <u>Prolonged Exposure Therapy</u>. Workshop presented at Camp Lejeune, NC on behalf of the Center for Deployment Psychology.

Brim, W., & Domenici, P. (September, 2008). <u>Prolonged Exposure Therapy.</u> Workshop presented in Bethesda, MD on behalf of the Center for Deployment Psychology.

Domenici, P. (2006, December). <u>It Takes Courage after Fire: Clinical Strategies to Help</u> <u>Returning Troops and Their Families.</u> Grand rounds presentation at the Brooklyn, VAMC, Brooklyn, NY.

Batten, S., Wright, T., Chard, K., Domenici, P., Kimerling, R., & Zeiss, A. (2006, November). <u>Applying and Adapting Empirically Supported Treatments for Veterans Returning from Operation</u> <u>Iraqi and Enduring Freedom</u>. Clinical roundtable at the 40th Annual Convention of the Association for Behavioral and Cognitive Therapies, Chicago, IL.

Domenici, P. (2006, August). <u>Courage after Fire: Helping Our Troops and Their Families</u> <u>Readjust to Civilian Life.</u> Workshop presented at the 21st Annual Uniformed Services Social Work and Seamless Transition Conference: Innovations in Practice – Ensuring a Coordinated Community Response, Arlington, VA.

Domenici, P., Gilberg, B., Hoffman, E., & Walton, G. (2006, August). <u>Applying Psychological</u> <u>Knowledge to Federal Policymaking – The Experiences of APA Congressional Fellows.</u> Symposium provided at the American Psychological Association Annual Convention, New Orleans, LA.

Domenici, P. (2006, May). <u>Courage after Fire: Tips to Assist First Responders and Law</u> <u>Enforcement Agents in Helping Our Troops.</u> Workshop presented at the 12th Annual Meeting of the Minds Mental Health Conference and Resource Fair: Recovery and Transformation through Collaboration, Anaheim, CA.

Armstrong, K., & Domenici, P. (2006, April). <u>Courage after Fire.</u> Workshop presented at the Veterans Expo at the Mattawan High School, Kalamazoo, MI.

Domenici, P., & Armstrong, K. (2006, March). <u>Self-Assessment and Self-Help for Returning</u> <u>Veterans and Their Families</u>. Workshop presented at the National Behavioral Health Conference on Returning Veterans and Their Families: Restoring Hope and Building Resiliency, Washington, DC.

Armstrong, K., Best, S., & Domenici, P. (January, 2006). <u>Courage after Fire: Coping Strategies</u> for Returning Troops and Their Families. Berkeley, CA: Ulysses Press. Domenici, P., & Armstrong, K. (2005, April). <u>Clinical Update on Soldiers Returning from Iraq</u> <u>and Afghanistan.</u> Workshop presented at the 20th Annual Uniformed Services Social Work and Seamless Transition Conference: Fostering Resiliency through Partnership, Arlington, VA.

Domenici, P. (2005, March). <u>Suggestions for First Responders about PTSD and Helping</u> <u>Returning Veterans.</u> Workshop presented at the Stepping in Conference: Understanding the Impact of Violence & the Trauma of War, Los Angeles, CA.

Rhodes, G., Tichenor, V., Domenici, P., & Lin, D. (2004, November). <u>Issues of Presentation</u> <u>and Treatment in Male Military Sexual Trauma.</u> Workshop presented at the International Society for Traumatic Stress Studies 20th Annual Meeting, New Orleans, LA.

Domenici-Lake, P. L. (2002). Eating disorders in young Asian women: A critical review of 11 studies that used the EAT-26. <u>Educational Studies</u>, 44, 111-125.

Domenici-Lake, P. L., & Hoffman, M.A., (2001, August). <u>Biopsychosocial Influences on</u> <u>Female Accompanying Expatriate Spouses' Psychological Well-Being in Tokyo, Japan.</u> Poster presented at the American Psychological Association Annual Convention, San Francisco, CA.

Domenici-Lake, P. L., & Hoffman, M. A. (2000, August). <u>Attitudes toward Seeking</u> <u>Psychological Help of Students of Asian Descent.</u> Poster presented at the American Psychological Association Annual Convention, Washington, DC.

Domenici-Lake, P. L., & Hoffman, M. A. (1999, November). <u>The Relationship between</u> <u>Attitudes toward Seeking Professional Psychological Help, Acculturation Level, and Use of Coping</u> <u>Strategies among Undergraduate Students of Asian Descent.</u> Poster presented at the Society for Psychological Research, College Park, MD.

Marotta, S. A., Domenici-Lake, P., & Byrne, D. L. (1998, March). <u>Educating Counselors for a</u> <u>Violent Society</u>. Poster presented at the American Counseling Association's World Conference, Indianapolis, IN.

Roberts, K. P., Lamb, M. E., Sternberg, K. J., Beresford, J., Domenici-Lake, P. L., & Heiges, K. (1997, April). <u>The Effects of a Delay on the Incorporation of Post-Event Information into</u> <u>Children's Eyewitness Memory.</u> Poster presented at the Annual Meeting of the Society for Research in Child Development, Washington, DC.

Friedman, R. J., Zahn-Waxler, C., Mizuta, I., Cole, P. M., Hiruma, N., & Domenici-Lake, P. (1994, June). <u>Symbolic Play, Narratives, and Emotions in Japanese and American Preschoolers.</u> Poster presented at the XIIIth Biennial Meetings of the International Society for the Study of Behavioral Development, Amsterdam.