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under stress	re neurophysiological parameters (b nts on soldiers and assess correlations) prsian Guilt Monagers and assess correlations)	ons with military biological	neasure the im	pact of long (90 days or greater)	
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a recently developed physiologica	n a non-invasive technique to asses ipational specialty (MOS), will serve al measure of the brain's availability	as a comparison group for	the deployers.	P50 auditory sensory gating is	
Sensory gating will be transiently	course decisions. We hypothesize	, based on recent neurobio	logioal investi-	ates with the ability to maintain	
of brain wave changes with parts	impaired upon re-deployment when	compared to pre-deployment	of monourse	auditory	
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Validated self-report scale (SCL of	nes, neart rate, blood pressure and r	respiratory rate. We will ale	AC). Biologic	ai measures of stress will	
catecholamine metabolito measure	-R). We hypothesize that a subset	of soldiers, particularly the	o with stains	clated anxiety and stress on a	
that underlie sensory gating. A bit	es, will have impaired auditory sens rain function test may allow the Arm d in which soldiers these effects are	ory gating. Catecholamine	s are known to	block inhibitory brain functions	
medical personnel as well	ain function test may allow the Arm d in which soldiers these effects are	most pronounced. We will	ns diminish the	neurophysiological ability of	
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INTRODUCTION:

The purpose of the study is to: 1.Evaluate whether objective neurophysiological parameters can measure the impact of long and short deployments on soldiers and 2. Assess whether the stress of deployment results in impaired auditory sensory gating and secondary performance decrements in tests directly relevant to military performance. We will identify biological measures to assess central nervous system processing of information in soldiers during deployment and correlate these with other measures shown to be directly related to military performance. We will also determine the best subgroup of measures to measure how stress is affecting a soldier's ability to process information under stress, as well as whether putative deficits relate to psychological sequelae of deployment.

BODY:

We received funds to begin the study at Ft. Carson, described in the body of this proposal, in Sept. 2001, a week after the tragedy of 9/11. Because of restricted access to military bases, we were unable to brief the new command and start our data collection on schedule. It became clear that the command of the base no longer considered this study to be a priority. Ft. Carson command indicated that they would not be available as a research site in June 2002. We then obtained the approval of our case officer to transfer the study to Army Medical Reserve/Army National Guard units in the Denver area that may soon be deployed to the Middle East, Eastern Europe, or Iraq. We have also initiated contact with Naval Reserve medical units. Attached are letters of support from COL Robert House and COL Paula Walker as well as documents from Ft. Carson. (Appendix 1)

A summary of research tasks accomplished during the first year is:

1. We have refined and adapted the computerized neuropsychological screening software and the P50 software and hardware to enhance portability and to improve consistency with previous measures obtained on conventional desktop hardware.

2. We have trained research staff in administering and evaluating the biological and neuropsychological measures. Dr. Gary Kay has provided two two-day training sessions. We have also confirmed that the SCL-90-R computerized version will run on the same laptops.

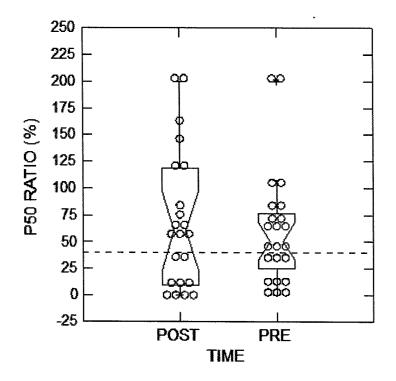
3. We have evaluated and trained research staff in the use of the new P50 hardware and software. We have completed validity testing of the new equipment compared to the version previously used by the research group. The manual for the P50 software is included in Appendix 2, and as a PDF file (Appendix 3).

4. We have analyzed the data from the preliminary data obtained prior to receiving funding. We have recently completed our analysis of the P50 auditory sensory gating changes pre and post 6-month deployment in soldiers from Ft. Carson deployed to Bosnia. As discussed in the body of the proposal, the P50 ratio was used to assess auditory sensory gating. In this paradigm, normal controls who have not been under severe stress and subjects who have no family history of psychosis, have P50 ratios that are usually less than 40%. The P50 waveform of the averaged auditory evoked potential

is a positive waveform occurring 50 msec after an auditory stimulus. The waveform must be generated by averaging the electroencephalographic (EEG, brainwave) responses time-linked to the onset of a click stimulus. It cannot be seen in response to a single stimulus, because it is too small. By computer averaging 16-32 responses, the P50 waveform can be generated. The amplitude (size) of the average P50 waveform is five to ten microvolts. In normal subjects, the amplitude of the P50 waveform in response to the second of two closely paired click stimuli (0.5 secs apart) is greatly decremented. If we divide the amplitude of the P50 in response to the second stimulus by the amplitude of the response to the first stimulus, the ratio is usually well under 0.4, or 40%. Patients with an inherited deficit in auditory sensory gating, for example schizophrenic patients, usually have P50 ratios well over 60% (Adler et al, 1982; 1990). Increasing central nervous system (CNS) catecholamine release, whether through brief painful stress (such as the cold pressor test Johnson and Adler 1993)), or pharmacologically (for example, with yohimbine), causes an increase in P50 ratio which decreases to normal when the stressor is removed and the subject is calm again. PTSD and long-term abuse of stimulants, such as cocaine, is associated with a more permanent increase in P50 auditory gating (Adler et al. 2001).

In our preliminary data, we examined the P50 ratios of 23 soldiers prior to deployment, but in the acute stages of preparation for deployment. We also examined on their return, after six months of deployment in Bosnia.

The P50 ratios of the two groups are graphed in the box plot below. The y-axis is the P50 ratio, the x-axis shows the group pre and post deployment. Each circle represents one subject. The notch indicates the median. In order to reduce the effect of outliers and to make the data easier to graph, all P50 ratios over 200% were converted downward to 250 (%). The negative values of the y-axis does not indicate a negative P50 ratio, but simply an extension of the scale to permit the full range of values to be graphed.



Key points are as follows:

2. The dotted line is at 40%, considered the maximum normal ratio for most normal control subjects.

3.Most of the subjects, pre and post deployment, had P50 ratios greater than 60%, but there were subjects with P50 ratios of zero

- 4. The median P50 ratio pre deployment was 50.9%, mean = 61.7% +/- 11.2% std. error.
- 5. The median P50 ratio post deployment was 60.4%, mean = 69.0% + 13.7% std. error (SEM).
- 6. The differences are not significant by t-test, which is apparent from the overlap of the distributions.
- 7. These data suggest that P50 ratio increases above the normal range in both the immediate pre deployment preparation period and the return to CONUS. Interpretation of this data needs to be tempered by our not having been able to assess soldiers during a long period of stability prior to preparation for deployment, which we are attempting to control for in the funded study. Although we controlled for smoking status and caffeine, we were unable to control for sleep deprivation and level of stress.
- 8.We will be conducting more detailed analyses of effects of deployment on amplitudes of P50 pre and post deployment, relationship to catecholamines, and measures of individual stress, including neuropsychological measures, in the current study.

Recommended changes in the protocol:

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- 1. Given that we will be studying medical units, we will eliminate the tank identification test and switch to a test of medical performance. We will select measures recommended by the unit commanders.
- 2.We will study individuals mobilized separately from their units, as well as individual units pre and post deployment, because medical specialists are often deployed individually.
- 3. Given that the equipment is now completely portable, we propose training a medical officer medical administration officer in the use of the equipment so that it can be taken OCONUS for extended deployments. Although the P50 hardware box is not up to Milspec for desert conditions yet, it can be readily protected, as it is a self-contained unit.
- 4.We will also port the neuropsychological software screen, the P50 analysis software, and the SCL-90 to run on a Milspec laptop, for example, the Panasonic Toughbook series. Although it is unlikely that this would be immediately useful for a triage unit within a few miles of the actual combat, it could be useful for more detailed assessments in larger units, for example, units the size of a mobile hospital or Navy (Marine) Fleet Hospital. This kind of technology was unavailable during the Persian Gulf War when I was attached to Fleet Hospital 6. Because there are too few neuropsychologists or neuropsychology technicians to attach to forward echelon units or even larger Fleet Hospitals, this would enable the psych techs to screen soldiers or

sailors rapidly and have the output ready for the more senior clinician. Thus, this research will have a more immediate practical value. Results could then be e-mailed or faxed to neuropsychologists at larger hospitals in CONUS.

5.We will be modifying and testing additional short and long-term memory tests for the CogScreen-R. The presentation from Annual meeting of Biological Psychiatry, May 2001 is included in Appendix 4.

KEY RESEARCH ACCOMPLISHMENTS:

- •Completed analysis of previous pre and post deployment preliminary data (22 subjects).
- •Completed testing of modifications of P50 software and portable setup.
- •Completed PDF/MS Word manual for P50 software and equipment.
- •Modified P50 equipment/software to allow direct communication with USB port of any laptop or desktop.
- •Tested CogScreen-R with modifications for laptop and field.
- •Began transfer of study site to Army Reserve/Army National Guard Combat Stress Units.

REPORTABLE OUTCOMES:

Presented preliminary data at Annual Meeting of Biological Psychiatry, May 2001. Abstract attached as Appendix 4.

CONCLUSIONS:

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P50 ratios are increased both in the immediate pre deployment preparation period, and in the post-deployment period. These ratios are similar to those found in previous studies in subjects under behavioral or pharmacological stress. Causation cannot be inferred because of possible correlations with caffeine use, sleep deprivation, and factors, which were difficult to control. Obtaining data in subjects during the months prior to deployment, or comparing them to a group of nondeploying subjects is therefore important. That is a major focus of the present study, as will formal neuropsychological assessment, which was not studied previously.

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APPENDICES:

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1.Documentation of study site change.-letters of support.

2.P50 manual.

3.P50 manual in PDF format.

4. Presentation of preliminary data at Annual Meeting of Biological Psychiatry, May 2001.

APPENDIX I A – LETTERS OF COLLABORATION, CHANGE OF SITE



DEPARTMENT OF THE ARMY

5502D United States Army Hospital William T. Fitzsimons Army Reserve Center 13137 East 23rd Street Aurora, CO 80010-7417

AFRC-CUT-K-HC

3 October 2002

MEMORANDUM FOR: Lawrence E. Adler, MD, CAPT, MC, USNR (IRR), Professor of Psychiatry and Chief, Mental Health Service, Denver VA Medical Center, Denver, Colorado

SUBJECT: DAMD 17-01-1-0760: Impaired Auditory Sensory Gating and Military Performance: Effects of Deployment on Army Combat Readiness

- This letter is to express strong support by the command and soldier members of the 5502D USAH to participate in the following study: DAMD 17-01-1-0760: Impaired Auditory Sensory Gating and Military Performance Effects of Deployment on Army Combat Readiness.
- The 5502D USAH has a history of several Mobilizations including Desert Shield/Desert Storm, Operation Enduring Freedom, and Operation Noble Eagle. With so many recent mobilizations the command is very interested on the effects of deployment on the readiness of the soldier and the impact of deployments on their families. Recent deployments have ranged from 90 days to one year.
- 3. The 5502D USAH is a Tier IA unit giving it a high priority status with regard to future Mobilizations. In the past three months the unit has sent increments to Kuwait, Kosovo and Germany. This study is compatible with the command's interest in taking care of soldiers, pre and post mobilization, the impact of deployments on training, and the impact on unit/soldier readiness. The unit is very committed to this project as outlined in the study proposal. We are eager to work with you to ensure the study's success.
- 4. This study has been discussed with the 96th Regional Support Command Surgeon, Col William Pfeifer. He has strongly endorsed this study and is interested in the outcome as to interventions with other Reserve units within the command.
- 5. POC for the unit is CPT Debbie Giddens, Training Officer, 303-365-3055.

Robert-M. House COL MC USAR Commanding

+7208576500



DEPARTMENT OF THE ARMY 1835th Medical Detachment (Combat Stress Control) J.P. Martinez United States Army Reserve Center 12211 East 56th Avenue Denver, CO 80239-5301

REPLY TO ATTENTION OF:

AFRC-CUT- ACO-MF (220-1)

S:

10/3/02

MEMORANDUM FOR Lawrence E. Adler, M.D., Professor of Psychiatry and Chief, Mental Health Service, Denver VA Medical Center, Mental Health Administration-116 (8C-109E), 1055 Clermont St., Denver, CO 80220

SUBJECT: Impaired Auditory Sensory Gating and Military Performance: Effects of Deployment on Army Combat Readiness

1. Per our discussion earlier this summer, the 1835th Medical Detachment is able to accept the change of the DAMD17-01-0760 study to our unit.

2. Please be aware that although the study examines impairments in the ability to process auditory stimuli that occur with the stress of deployment, we have no soldiers that have deployed in support of Operation Enduring Freedom. However, do have soldiers with histories of being deployed to support other missions. We would be happy to request volunteers from our unit for the study.

3. Thank you for research that furthers our understanding of military psychiatry. I will await the revised protocol and look forward to our continued collaboration.

4. Point of contact for this memorandum is CPT Bradley McClure (303) 903-0551 or bradley.mcclure@us.army.mil

Jal M. Weller

PAULA M. WALKER COL, AN, USAR Commanding

APPENDIX I B – CORRESPONDENCE WITH FORT CARSON

From: Lawrence E. Adler, M.D;CAPT, MC, USNR(IRR)

To: Shari Wilmott mailto:(Shari.Wilmott@AMEDD.Army.Mil)

SUBJ: (DAMD17-01-1-0760: Impaired Auditory Sensory Gating and Military Performance: Effects of Deployment on Army Combat Readiness

P.I.: Lawrence E. Adler, M.D.

Ms.Wilmott,

Thank you for your email. I did get a note from Dr. Pincus. This response is delayed because I just took over as Chief of Mental Health Services at

the Denver VAMC on Feb. 11th, and jumped straight into the worst budget crisis the VA has had in the last twenty years. I did not have a working computer with email until last week and my university email took time to reach me.

The study referenced above has been funded as of Sept. 1,2001. On Sept. 11, we suffered the worst terrorist attack on the U.S. When I contacted COL Conaway,

he was concerned that should there be extensive deployments to Afghanistan via Ft. Carson, our study might interfere with the emergency deployments. Since I was very familiar with these problems, having deployed to the Persian Gulf in a Fleet Hospital in 1991, I told him that we would wait until the situation resolved. However, we are in a bit of a bind. Here are the issues:

- 1. We have no wish to adversely effect deployment status or morale at Ft. Carson.
- 2. In our preliminary study, we were able to complete the study on 27 subjects without interfering with training.
- 3. This study is more directly related to performance measures.
- 4. Although our new study has been approved, funded, and reviewed by the DOD, we still need to send our updated protocol through the Great Plains IRB. To do this, we still need one signature from your institution.
- 5. If your senior staff believes that this study would adversely affect performance, then I would simply request a letter stating that directly and I will apply to change the site to Reserve and Guard units in the Denver area. However, I believe that we can do this with a minimum of inconvenience.
- 6. We have an Army colonel, board certified in psychiatry and child psychiatry, who will be joining us July 2003 to participate in this study (funded from 9/1/2001-8/30/2005).
- 7. Should any of your medical staff be interested in helping us organize this (we would do the actual research work), we would be happy to include them.
- 8. I am quite willing to brief senior staff on the project, including objectives and details.
- 9. If a copy of the proposal cannot be found, we will photocopy it and send it to you.

At this point, given the logistical considerations and the recent inclement weather, it would be unlikely that we could schedule the study until late spring or early summer. That would give us more than enough time to review the study with any staff and line officers whose soldiers might chose to participate.

Again, I appreciate your efforts, those of COL Conaway and COL Bradshaw, and the assistance MAJ Goemere gave me by phone. I would appreciate it if you would forward this to them and to anyone else who is interested.

My new contact numbers and address are:

Lawrence E. Adler, M.D. Professor of Psychiatry and Chief, Mental Health Service, Denver VA Medical Center

Denver VA Medical Center Mental Health Service, Administration-116 (8C-109F) 1055 Clermont St. Denver, CO 80220

Phone: (303) 393-2832; Fax: (303) 393-4683; pager: 1-888-444-9053 Email: Lawrence.Adler@med.va.gov

-----Original Message-----From: Pincus, Simon H LTC TAMC [mailto:Simon.Pincus@haw.tamc.amedd.army.mil]

Sent: Tuesday, February 19, 2002 2:24 PM To: 'lawrence.adler@uchsc.edu' Subject: Re: Deployment Study

Ms. Wilmott,

Thank you for your e-mail.

I spoke with Dr. Adler today. The grant was finally approved in September 01. As stated, there have been many personnel changes since the original submission. I will forward him this e-mail to update him on the current status.

Simon Pincus SIMON H. PINCUS LTC, MC Chief, Outpatient Psychiatry Tripler Army Medical Center Work: (808) 433-2739 Pager: (808) 577-7674 Fax: (808) 433-3339

-----Original Message-----From: Wilmott, Shari E Ms EACH Sent: Tuesday, February 19, 2002 6:25 AM To: Pincus, Simon H LTC TAMC Subject: FW: VA Study?

Dr. Pincus

I thought I would pass this information on to you. Don't know if you want to contact Dr. Adler or not? No one here seems to recall much and I'm trying to get information back to MAJ Goemere, SGS at HQs Ft. Carson so he can call Dr. Adler back.

Shari Wilmott DSN 691-7500

-----Original Message-----From: Polo, James A LTC EACH Sent: Thursday, February 14, 2002 4:25 PM To: Conaway, Cass COL EACH; Wilmott, Shari E Ms EACH; McGaha, James F COL EACH; Wilber, Jennifer T COL EACH; Chowen, Steven LTC EACH Cc: Pittman, James O COL ERMC; Pincus, Simon H LTC TAMC Subject: RE: VA Study?

Sir,

This study proposal was designed by Dr. Adler and Dr. Simon Pincus. COL Pittman had supported this project. I have not seen the proposal. Dr. Pincus is currently assigned to Tripler.

v/r, Jim

-----Original Message-----From: Conaway, Cass COL EACH Sent: Thursday, February 14, 2002 2:55 PM To: Wilmott, Shari E Ms EACH; McGaha, James F COL EACH; Wilber, Jennifer T COL EACH; Chowen, Steven LTC EACH; Polo, James A LTC EACH

Subject: RE: VA Study?

I've already given my input. thanks, Cass

-----Original Message-----From: Wilmott, Shari E Ms EACH Sent: Thursday, February 14, 2002 1:43 PM To: McGaha, James F COL EACH; Conaway, Cass COL EACH; Wilber, Jennifer T COL EACH; Chowen, Steven LTC EACH; Polo, James A LTC EACH Subject: FW: VA Study?

Please see COL Bradshaw's note below.

Shari

-----Original Message-----From: Bradshaw, Donald M, COL Fort Carson [mailto:Donald.Bradshaw@Tricare.carson.army.mil] Sent: Thursday, February 14, 2002 10:37 AM To: Wilmott, Shari E Ms EACH; Bradshaw, Donald M, COL Fort Carson Subject: RE: VA Study?

Shari - he was working this with the military psychiatrist that left Carson MEDDAC and went to training (I forgot this name). We had briefed MG Soriano, COL Scott (CofS), and prior G3 (again I forget his name) and MG S had given a tentative OK.

I would support but since all players have changed what do we need to do to get it going?

Donald M. Bradshaw COL, MC, U.S. Army Director, Clinical Operations TRICARE Central Region Specker Ave. Bld. 1011 Ft. Carson, CO 80913 719-524-2613 FAX 719-524-2655 DSN: 883-

-----Original Message-----From: Wilmott, Shari E Ms EACH [mailto:Shari.Wilmott@AMEDD.Army.Mil] Sent: Thursday, February 14, 2002 8:39 AM To: 'COL BRADSHAW' Subject: FW: VA Study?

Please see message below. Does any of this ring any bells with you?

Shari

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-----Original Message-----From: Goemaere, Russell D, MAJ Fort Carson [mailto:Russell.Goemaere@us.army.mil <mailto:Russell.Goemaere@us.army.mil>]

Sent: Wednesday, February 13, 2002 3:47 PM To: Wilmott, Shari E, CIV Fort Carson Subject: VA Study?

Shari:

I received a call today from Dr. Adler, Denver VA referencing DAMD 1701-1-0760, Impaired Auditory Gating Effects on Combat Readiness.

He said he submitted the proposal last year but with Sept 11th nothing has been done. He said MG Soriano had a copy of this proposal but we have nothing on file. He now has the funding and would like to go ahead with the

study. Does MEDDAC have a copy of this proposal?

He said that he has four years to work this study and would like the following:

1. Two rooms in a clinic.

2. An opportunity to study about 30 soldiers who are about to deploy, takes

a morning and no PT on that morning.

3. Study same group just after the deployment.

4. Relook same group 3-6 months after deployment.

5. Would like to look at groups heading out on long deployments (ODS or similar) and short deployments (NTC or JRTC).

Dr. Adler can be reached at(303) 725-5347 and (303) 393-2832

V/R

Russell D. Goemaere Major, GS Secretary General Staff Headquarters, 7th Infantry Division Building 1430, Room 253 1430 Wetzel Avenue Fort Carson, CO 80913-5000

Commercial: (719) 526-2394 DSN: 691-2394 FAX: (719) 525-1749 Cell (719) 330-5160 To: Wilmott, Shari E Ms EACH Subject: RE: Dr. Lawrence E. Adler, DOD/Ft. Carson study Thank you very much. L. Adler

Lawrence E. Adler, M.D. Professor of Psychiatry and Chief, Mental Health Service, Denver VAMC Denver VA Medical Center Mental Health Administration-116 (8C-109F) 1055 Clermont St. Denver, CO 80220

Phone: (303) 393-2832 Fax: (303) 393-4683 Email: Lawrence.Adler@med.va.gov Pager: 1-888-444-9053 (toll free with voice mail)

> -----Original Message----- **From:** Wilmott, Shari E Ms EACH [mailto:Shari.Wilmott@AMEDD.Army.Mil] **Sent:** Tuesday, March 05, 2002 11:02 AM **To:** 'Lawrence.Adler@med.va.gov' **Subject:** RE: Dr. Lawrence E. Adler, DOD/Ft. Carson study

Dr. Adler,

I have reviewed your attachment and am forwarding it on to our commander, COL James McGaha for review. Someone will be contacting you ref the issues you raised.

Shari Wilmott

-----Original Message-----From: Lawrence.Adler@med.va.gov [mailto:Lawrence.Adler@med.va.gov] Sent: Monday, March 04, 2002 10:10 PM To: Shari.Wilmott@AMEDD.Army.Mil Cc: sspincus@aol.com; ellen.cawthra@uchsc.edu; dinah.rogers@uchsc.edu; Donald.Bradshaw@Tricare.carson.army.mil; Russell.Goemaere@us.army.mil; Cass.Conaway@AMEDD.Army.Mil Subject: Dr. Lawrence E. Adler, DOD/Ft. Carson study

<<Adler DOD study-emai 1 to FT Carson.doc>> Please see attached document

FW Deployment Study.txt From: Lawrence.Adler-T@UCHSC.edu Sent: Monday, February 25, 2002 11:47 AM To: Lawrence.Adler@med.va.gov Subject: FW: Deployment Study

----Original Message----From: Lawrence.Adler@UCHSC.edu [mailto:Lawrence.Adler@UCHSC.edu] Sent: Thursday, February 21, 2002 2:38 PM To: Lawrence.Adler@med.va.gov Subject: FW: Deployment Study

----Original Message----From: Lawrence.Adler@UCHSC.edu [mailto:Lawrence.Adler@UCHSC.edu] Sent: Thursday, February 21, 2002 2:33 PM To: Lawrence.Adler@med.va.gov; Ellen.Cawthra@UCHSC.edu Subject: FW: Deployment Study

----Original Message----From: Pincus, Simon H LTC TAMC [mailto:Simon.Pincus@haw.tamc.amedd.army.mil]

Sent: Tuesday, February 19, 2002 2:24 PM To: 'lawrence.adler@uchsc.edu' Subject: Re: Deployment Study

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Simon Pincus SIMON H. PINCUS LTC, MC Chief, Outpatient Psychiatry Tripler Army Medical Center Work: (808) 433-2739 Pager: (808) 577-7674 Fax: (808) 433-3339

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Shari Wilmott DSN 691-7500

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Sir,

This study proposal was designed by Dr. Adler and Dr. Simon Pincus. COL Pittman had supported this project. I have not seen the proposal. Dr. Pincus is currently assigned to Tripler.

v/r, Jim

----Original Message----From: Conaway, Cass COL EACH Sent: Thursday, February 14, 2002 2:55 PM To: Wilmott, Shari E Ms EACH; McGaha, James F COL EACH; Wilber, Jennifer T COL EACH; Chowen, Steven LTC EACH; Polo, James A LTC EACH Subject: RE: VA Study?

I've already given my input. thanks, Cass

----Original Message----From: Wilmott, Shari E Ms EACH Sent: Thursday, February 14, 2002 1:43 PM To: McGaha, James F COL EACH; Conaway, Cass COL EACH; Wilber, Jennifer T COL EACH; Chowen, Steven LTC EACH; Polo, James A LTC EACH Subject: FW: VA Study?

Please see COL Bradshaw's note below.

Shari ----Original Message----From: Bradshaw, Donald M, COL Fort Carson [mailto:Donald.Bradshaw@Tricare.carson.army.mil] Sent: Thursday, February 14, 2002 10:37 AM To: Wilmott, Shari E Ms EACH; Bradshaw, Donald M, COL Fort Carson Subject: RE: VA Study?

Shari - he was working this with the military psychiatrist that left Carson MEDDAC and went to training (I forgot this name). We had briefed MG Soriano, COL Scott (CofS), and prior G3 (again I forget his name) and MG S had given a tentative OK.

I would support but since all players have changed what do we need to do to get it going?

Donald M. Bradshaw

FW Deployment Study.txt COL, MC, U.S. Army Director, Clinical Operations TRICARE Central Region Specker Ave. Bld. 1011 Ft. Carson, CO 80913 719-524-2613 FAX 719-524-2655 DSN: 883-----Original Message-----From: Wilmott, Shari E Ms EACH [mailto:Shari.Wilmott@AMEDD.Army.Mil] Sent: Thursday, February 14, 2002 8:39 AM To: 'COL BRADSHAW' Subject: FW: VA Study? Please see message below. Does any of this ring any bells with you? Shari ----Original Message-----From: Goemaere, Russell D, MAJ Fort Carson
[mailto:Russell.Goemaere@us.army.mil <mailto:Russell.Goemaere@us.army.mil>] Sent: Wednesday, February 13, 2002 3:47 PM To: Wilmott, Shari E, CIV Fort Carson Subject: VA Study? Shari: I received a call today from Dr. Adler, Denver VA referencing DAMD 1701-1-0760, Impaired Auditory Gating Effects on Combat Readiness. He said he submitted the proposal last year but with Sept 11th nothing has been done. He said MG Soriano had a copy of this proposal but we have nothing on file. He now has the funding and would like to go ahead with the study. Does MEDDAC have a copy of this proposal? He said that he has four years to work this study and would like the following: 1. Two rooms in a clinic. An opportunity to study about 30 soldiers who are about to deploy, takes 2. a morning and no PT on that morning. 3. Study same group just after the deployment. 4. Relook same group 3-6 months after deployment. would like to look at groups heading out on long deployments (ODS or 5. similar) and short deployments (NTC or JRTC). Dr. Adler can be reached at(303) 725-5347 and (303) 393-2832 V/R Russell D. Goemaere Major, GS

FW Deployment Study.txt Secretary General Staff Headquarters, 7th Infantry Division Building 1430, Room 253 1430 Wetzel Avenue Fort Carson, CO 80913-5000

Commercial: (719) 526-2394 DSN: 691-2394 FAX: (719) 525-1749 Cell (719) 330-5160 To: Cc:

Subject:

Shari.Wilmott@AMEDD.Army.Mil sspincus@aol.com; ellen.cawthra@uchsc.edu; dinah.rogers@uchsc.edu; Donald.Bradshaw@Tricare.carson.army.mil; Russell.Goemaere@us.army.mil; Cass.Conaway@AMEDD.Army.Mil Dr. Lawrence E. Adler, DOD/Ft. Carson study

Adler DOD ludy-emai 1 to FT C.

Please see attached document; sent previously.

Subj: Dr. Lawrence E. Adler, DOD/Ft. Carson study

Dear Ms. Wilmott:

It is now two months since our last correspondence. I have not had a reply and am therefore assuming that the command at Ft. Carson is not interested in our deployment study at the present time. Therefore, I would greatly appreciate receiving a letter to the effect that Ft. Carson cannot at this time assist me with our research. If possible, I would like to receive the letter by May 31st. I will then forward a copy of the letter to the DOD and transfer the site to Army Reserve or National Guard or Naval Reserve units in the Denver area.

Thank you for your kind attention.

Sincerely yours,

Lawrence E. Adler, M.D. CAPT, MC, USNR (IRR) Chief, MHS, Denver VA Medical Center Professor of Psychiatry, University of Colorado Health Sciences Ctr. MHS Administration-116, Room 8C109E Denver VA Medical Center 1055 Clermont St. Denver, CO 80220

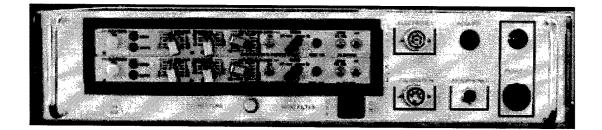
Phone: (303) 393-2832 FAX: (303) 393-4683 Pager (24 hr, toll free, with voice mail) 1-(888)-444-9053

APPENDIX II – LEA 2002 SOFTWARE OPERATORS MANUAL

LEA2002 Software Operators Manual January 2002

1 System Overview

The LEA2000 system consists of a LEA2000 Data Acquisition Frame and the LEA2002 software.



5 ((A200) 5.40				J D <u>×</u>		
	LEA 2002 Data Collection and Analysis Software					
	AMPLIFIER SETTINGS ELECTRODE HOOKUP 1/2 angl 0 +1 CH1 + GREEN - VERTEX CH2 + RED- SUPERIOR 0 1/2 angl 10 - SUPERIOR 0 SUPERIOR - SUPERIOR 0 - SUPERIOR - SUPERIOR - SUPERIOR 0 - SUPERIOR - SUPERIOR - SUPERIOR 0 - SUPERIOR - SUPERIOR - SUPERIOR - SUPERIOR - SUPERIOR 0 - SUPERIOR -					
	Data Collection		Data Review & Analysis			
	Acquire Data		View/Print Files			
	Replay Data		Filter Files			
	Replay Data (old style files	s) (Peak Find			
			Shift Files			
	Configuration Edit Settings (directories a	nd RS-232 port)	Grand Sum (Add Files)			
	Edit/Create Timing Templa		Subtract Files			
	- ,		Short Latency Subtract			
	Diagnostics		Report Writer Peak Find List			
	Run System Loopback Tes	t (with cable)				
	Run Internal Test (digital e	lectronics only)	Dateman			
	SUPER USER					

The LEA2002 software runs on a Windows 98 and higher PC with a USB interface.

The LEA2000 Frame contains an embedded processor and communicates to the PC using and RS-232 to USB adapter.

The LEA2000 Frame contains two channels of data acquisition. A high-gain, differential amplifier with selectable filtering supports each channel. Internally, the output of the amplifiers is fed to a 12-bit, Analog to Digital converter. Each channel is sampled at a rate of 1kHz or every one millisecond.

All of the setup and control of the data acquisition is managed by the LEA2002 software.

2 System Requirements

- Windows 98, ME, 2000, XP
- USB port

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- Display configuration of 1024x768 minimum
- Color inkjet or other color capable printer preferred for printing of screens

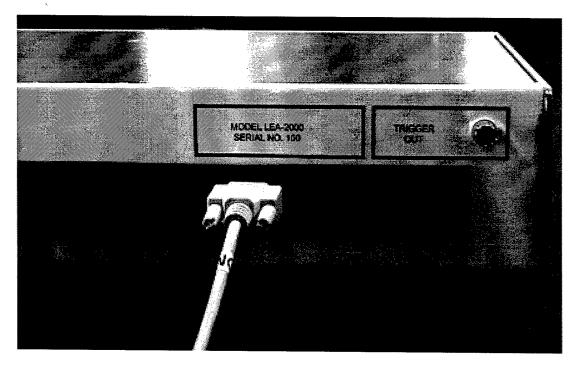
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3 LEA2002 Hardware Installation

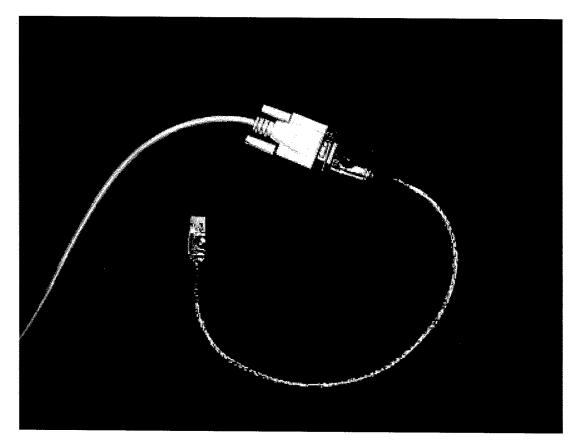
3.1.1 Installing the USB to RS-232 port cable

The LEA2000 hardware must be connected to the host computer with an RS-232 cable and RS-232 to USB adapter.

The RS-232 cable is attached to the LEA2000 on the rear panel at the connector labeled "to computer".



The USB to RS-232 adapter is attached directly to the other end of the RS-232 cable.



The USB end of the cable is attached to the USB connector on the host computer or to a USB hub attached to the host computer.

3.1.2 Powering the LEA2000

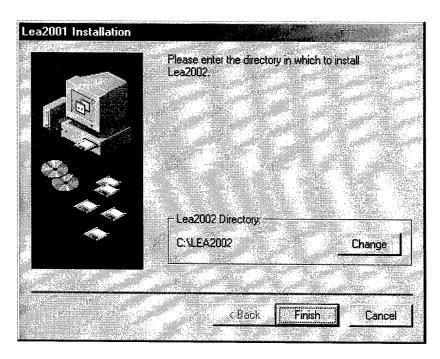
The LEA2000 Hardware is powered by a standard 110V, three-prong outlet. The power switch is located on the front panel. A red indicator above the power switch will illuminate when the power is on.

4 LEA2002 Software Installation

4.1.1 Installing the software

The LEA2002 software is installed by running the setup program on the release CD-ROM. Choose START, then RUN and then Browse to find the setup.exe file on the CD-ROM. After selecting the file, then select OK to run the file.

The program will prompt you for the installation directory. Do not change the default directory – simply select Finish and the installation will proceed.



The process will automatically install the LABVIEW runtime software. If the software requests to overwrite any existing files, click Yes. This will only happen if the software is being reinstalled on a computer.



Click Next to proceed. The installer will display the Destination folder for the Labview run-time software.

nation Folder elect a folder where the application will be insta	illed.	La	bVI	
The Installation Wizard will install the files for N Engine 6.0 in the following folder,	lational Instr	uments Lab	VIEW Run•T	ïme
To install into a different folder, click the Brows	e button, ar	nd select an	other folder.	
You can choose not to install National Instrum	ents LabVIE	W Run-Tim	e Engíne 6.0	l by
	State of Milling States			
Destination Folder C.\Program Files\National Instruments\			Biowse	
Destination Folder			Biowse	
Destination Folder			Biowse	
Destination Folder			Biowse	

Click Next and accept the default path.

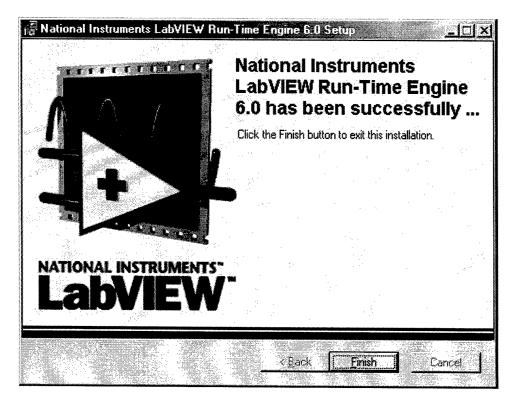
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National Instruments LabVIEW Run- Ready to Install the Application Click Next to begin installation.	lime Engine 6		INSTRUMENTS"
Click the Back button to reenter the inst	allation informati	on or click Cancel to) exit
the wizard.			
	<u> </u>	k Next>	Cancel

Click Next to continue the installation. The installer will copy files to the appropriate directories.



After all the files are copied, click Finish to exit the installation.

4.1.2 Installing the USB to RS-232 port driver

1. With the computer on, plug the USB side of the adapter into your computer or hub's USB port. Once the USB connector is inserted into the PC, the "New Hardware Wizard" should appear – click NEXT to continue.

2. A new dialog box should appear, make sure the default setting is selected ("Search for the best drivers for your device") and click NEXT to continue. Insert the installation CD into your computer's CD-ROM drive. In the new dialog box, select the CD-ROM drive and click "NEXT" to continue.

3. In the ready to install...dialog box that comes up, click on "Next" to continue. Files should now be copied to your hard disk.

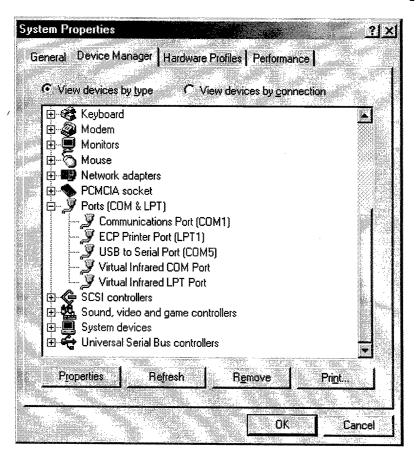
4. Windows will now finish the installation process.

4.1.3 Checking the Installation

1. Open the My Computer folder

- 2. Open the Control Panel
- 3. Open the Systems Folder
- 4. Click on the Device Manager Tab
- 5. Click on the "+" sign of the Ports (COM & LPT) line

You should see an entry for "USB to Serial Port" with a COM number in parenthesis. This is the COM port assigned to USB adapter and to the LEA2000Hardware. Write this COM port address down – you will need to select this COM port address in the LEA2002 software Edit Settings Menu.



6. Click OK and exit the system pop-up. Close the control panel by clicking the "X" in the upper right hand corner.

5 Running the LEA2002 software

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The software installation creates a software group LEA2002 in the Programs Group. To run LEA2002, press Start, Programs, LEA2002, LEA2002.

The first time the software is run, the user needs to assign the LEA2000 hardware COM port address. This is established using the Edit Settings Menu and selecting the COM port address found in the System Properties menu as described in the installation section of this manual.

6 Directory Structure and File naming conventions

6.1 Directory Structure

HOME

To simplify the collection, storage and management of data, the LEA2002 software maintains a strict directory structure. This directory structure and the associated file naming conventions provide a file system that is easy to use and yet maintains strong data integrity. The software remembers the last "legal" directory accessed by the user and uses that directory for future file functions. The Replay "old style" function does not understand the LEA2002 file structure and does not maintain a last-used directory setting.

Rather than rely on the user to create and maintain filenames that have meaning and consistency, the LEA2002 software creates a file naming system that encodes the essential file information into the directory and actual filenames.

The directory naming convention contains 5 levels:

STUDY LOCATION RESEARCHER SUBJECT ID

- <u>HOME path</u> this is the highest level directory and by default is C:\LEA2002
- <u>STUDY NAME</u> this is the level that names the study the data is collected for or the type of study being conducted.
- <u>LOCATION</u> this level names the physical location the data is collected from.
- <u>RESEARCHER</u> this is the name of the person collecting the data of the name of the researcher the data is collected for.
- <u>SUBJECT ID</u> this is the identifier for the subject from whom the data is collected. All of the data files for a particular subject are saved under the particular Subject ID directory. The ID can be any combination of letter and/or numbers that conform to the Microsoft Windows naming convention.

For example, with these names HOME: LEA20001 STUDY: VA2002 LOCATION: UCHSC RESEARCHER: ADLER SUBJECT ID: SUBJECT B

Files would be stored under this directory

C:\LEA2002\VA2002\UCHSC\ADLER\SUBJECT B

All files for SUBJECT B would begin with SUBJECT B and be appended with the specific file typing extensions. For example, the set of files for single run acquisition with 10 sweeps would generate these files:

C:\LEA2002\VA2002\UCHSC\ADLER\SUBJECT B\SUBJECT B_1.%PA C:\LEA2002\VA2002\UCHSC\ADLER\SUBJECT B\SUBJECT B_1.12.RAW1 C:\LEA2002\VA2002\UCHSC\ADLER\SUBJECT B\SUBJECT B_1.12.RAW2 C:\LEA2002\VA2002\UCHSC\ADLER\SUBJECT B\SUBJECT B_1.12.RAW3 C:\LEA2002\VA2002\UCHSC\ADLER\SUBJECT B\SUBJECT B_1.12.RAW4 C:\LEA2002\VA2002\UCHSC\ADLER\SUBJECT B\SUBJECT B_1.12.RAW5 C:\LEA2002\VA2002\UCHSC\ADLER\SUBJECT B\SUBJECT B_1.12.RAW6 C:\LEA2002\VA2002\UCHSC\ADLER\SUBJECT B\SUBJECT B_1.12.RAW6 C:\LEA2002\VA2002\UCHSC\ADLER\SUBJECT B\SUBJECT B_1.12.RAW6 C:\LEA2002\VA2002\UCHSC\ADLER\SUBJECT B\SUBJECT B_1.12.RAW7 C:\LEA2002\VA2002\UCHSC\ADLER\SUBJECT B\SUBJECT B_1.12.RAW8 C:\LEA2002\VA2002\UCHSC\ADLER\SUBJECT B\SUBJECT B_1.12.RAW9 C:\LEA2002\VA2002\UCHSC\ADLER\SUBJECT B\SUBJECT B_1.12.RAW10 C:\LEA2002\VA2002\UCHSC\ADLER\SUBJECT B\SUBJECT B_1.12.RAW10 C:\LEA2002\VA2002\UCHSC\ADLER\SUBJECT B\SUBJECT B_1.12.RAW10

The next run for the same subject would increment the number following the subject so the files would begin with SUBJECT B_2.

The names used for each of these items follow the standard Microsoft Windows long naming convention. The names can contain letters, number and spaces. The names should be kept as short as possible, otherwise the complete name may not be displayable in some LEA2002 file name displays.

When establishing names, the user should follow the naming convention established by the research organization conducting the testing.

The software does not try to make sense of the names, but does require that a name exists at each level in the hierarchy. The user cannot create a Subject Id until the higher order paths have been established. When the software requests a file name, a pop-up provides a display of the existing directory structure and the tools to create additional elements.

6.2 File types

This section discusses the various file types used by the LEA2002 software. See the File Structure Details chapter for a description of the contents of the files.

6.2.1 Acquire data Types (%PA,ASC,FLA,RAW,SWP)

The acquire data software creates several different type files as part of an acquisition run. All files are created under an existing Subject ID path or a new one created by the user.

6.2.1.1 Header Only file (%PA)

This file only contains the header information and no data. There is only one %PA file per acquisition run.

Filename Format:

<Subject>_<RUN#>.%PA

Example:

SUBJECT B_1.%PA

6.2.1.2 Sweep File (SWP)

The sweep file records the numbers of the sweeps accepted during an acquisition run. These refer to the sweeps that are summed in the Accumulated Sum Files and the Filtered files. There is only one Sweep file per acquisition run.

Filename Format:

<Subject>_<RUN#>.SWP

Example:

SUBJECT B_1.SWP

6.2.1.3 Raw Data Files (RAW)

Raw data files contain the complete raw data record of an acquisition sweep. For the standard P50 acquisition, this is 950 ms worth of data and includes both channels. There is a separate file generated for each sweep in a run.

Filename Format: <Subject>_<RUN#>.RAW<Sweep#>

Example: SUBJECT B_1.RAW1 - for the first sweep SUBJECT B_1.RAW2 -for the second sweep

6.2.1.4 Accumulated Sum File (ASC)

The Accumulated Sum File contains the sum of all the accepted sweeps for a particular Condition-Test pair. Before display, the sum values are divided by the number of accepted runs to obtain the correct values.

One file is generated at the end of a run for each Condition-Test pair specified in the timing template. The standard P50 template only specifies the click 1 -click 2 pair or "12" suffix on the file name.

Filename Format: <Subject>_<RUN#>.<Condition #><Test#>.ASC Example: SUBJECT B_1.12.ASC SUBJECT B_1.13.ASC - File if there was a "13" measurement pair

6.2.1.5 Filtered files (FLA,FLD,FLG,FLS,FL1)

Filtered files contain data that is filtered by software high-pass and low pass filters. The file extension indicates the source of the unfiltered data. The most common filtered file type, FLA, is automatically generated by the software at the end of an acquisition run.

The FLA file is simply a filtered version of the ASC file and must be divided by the number of accepted runs before display. An FLA file is generated for each ASC file generated.

Filename Format: <Subject>_<RUN#>.<Condition #><Test#>.FLA

Example:SUBJECT B_1.12.FLA-Filtered file for the "12" pairSUBJECT B_1.13.FLA-File if there was a "13" measurement

There are several other filtered file types used. These are generated by using the Filter File function. The internal format of the files is the same as the FLA file. These file extensions are used to differentiate the source of the filtered data.

Filtering a SUB (Difference) file will produce an FLD file (Filtered Difference). The filename will be the same as input file name with an FLD extension rather than an SUB extension.

Filtering a GD1 (Grand Sum) file will produce an FLG file (Filtered Grand Sum). The filename will be the same as input file name with an FLG extension rather than a GD1 extension.

Filtering and SFT (Shifted) file will produce and FLS file (Filtered Shifted). The filename will be the same as input file name with an FLS extension rather than an SFT extension.

6.2.1.6 Difference File (SUB)

One file can be subtracted from another to produce a difference file. The internal format of the file is the same as an ASC and FLA file. The SUB extension is used to differentiate the difference file from any other type of file. The user creates a filename for the output file and the software adds the SUB extension.

6.2.1.7 Grand Sum File (GD1)

Files can be added together to produce a Grand Sum file. The internal format of the file is the same as an ASC and FLA file. The GD1 extension is used to differentiate the grand sum file from any other type of file. The user creates a filename for the output file and the software adds the GD1 extension

6.2.1.8 Shifted file (SFT)

The data within a file can be shifted to align the peaks to another file or peaks within the same file. The resulting shifted file will have the same name as the input file but will have an SFT extension. The internal file structure is the same as the ASC and FLA file. The SFT extension is used to differentiate the shifted file from any other type of file.

6.2.2 Old Style File Compatibility

The goal of the LEA2002 software was to improve data acquisition flexibility, ease of use and data integrity. Old data files can be accessed by the LEA2002 software if the user understands how to bring the files into the new environment.

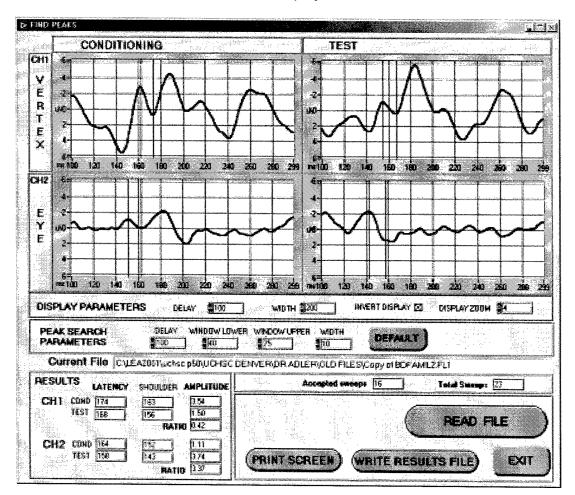
The biggest issue in bringing old files into the LEA2002 software environment is dealing with the new directory structure. All LEA2002 files fit under a tightly structured directory structure (See Directory Structure Discussion) and files not under that structure are not visible to the software. The easiest way to make the old files visible to LEA2002 is to create a new Subject ID (like Old Files) under the appropriate file path and copy all of the files to that directory.

The new Subject ID can be created by using the standard Microsoft Windows File functions to create a new directory under the appropriate Researcher level. A new Subject ID can also be created by performing a run under the acquisition function and creating the new directory using the file pop-up. The pop up will allow you to cancel the run without generating any files.

Once the old files have been copied to the new directory using Microsoft Windows File functions, the files will be accessible in the LEA2002 functions by choosing the Subject ID created by the process above.

7 Using the Graph Display Parameters

All of the graphs use a common set of Display Parameter Controls. These controls allow the user to control which portion of the acquired waveform is displayed and the magnification of the display.



7.1 Display units

The horizontal display units are in milliseconds. The acquisition resolution is 1 millisecond. The vertical display is in microvolts.

7.2 DELAY and WIDTH

The Delay and Width controls determine which portion of the acquisition is displayed by controlling the X axis or horizontal axis of the graphs. The Delay control sets the beginning of the waveform window and the Width control sets the width of the window. The controls default to show the entire captured waveform.

7.3 INVERT DISPLAY

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The Invert Display checkbox controls the polarity of the vertical (Y) axis of the graph. The normal display displays positive signals up and negative signals down. Checking the Invert Display box simply inverts the vertical scale for the graph. The acquisition data is not modified by this inversion – it just changes the display.

NOTE: The convention for the P50 waveform display is that the waveform is a deviation below the axis. To accomplish this and to maintain compatibility with previous versions of the software, the default graph display is inverted.

7.4 DISPLAY ZOOM

This control sets the vertical magnification of the graphs.

8 Main Menu

8.1 Overview

The Main Menu contains the controls to access all of the LEA2002 functions. Those functions are divided into 4 groups – Data Collection, Configuration, Diagnostics and Data Review and Analysis. The Main Menu also displays the amplifier settings for the LEA2000 hardware and the electrode connections for the standard P50 acquisition.

MAIN MENU			12
LEA 2002 Data Collection and Ar	nalysi	is Software	
AMPLIFIER SETTINGS ELEC 1/2 ampl:0 =1 1/2 amp.Hil = 308 amplification=180 CH1 + GREEN - VERTEX - BLVE + VERTEX		E NOOKLIP CH2 + RED- SUPERIOR BRINT BLACK - LEFT EAR	
Data Collection Acquire Data		Data Review & Analysis View/Print Files	
Replay Data Replay Data (old style files)		Filter Files Peak Find	
Configuration Edit Settings (directories and RS-232 port)		Shift Files Grand Sum (Add Files) Subtract Files	
Edit/Create Timing Templates Diagnostics		Short Latency Subtract Report Writer Peak Find List	
Run System Loopback Test (with cable) Run Internal Test (digital electronics only)			
SUPER USER			

8.2 Amplifier Settings and Electrode Hookup

The upper portion of the Main Menu screen lists the amplifier settings for the LEA2000 hardware and electrode hookup for the standard P50 waveform collection. These settings must be used to produce the correct results.

8.3 Super User Indicator

The Super User indicator shows the current status of the Super User Mode. In Super User Mode, all of the analysis features of the LEA2002 software are made available to the user. When disabled, the Grand Sum, Shift Files, Subtract Files and Edit/Create Timing Templates functions are not displayed and are not available. The Super User mode is controlled in the Edit Settings menu.

8.4 Data Collection section

The Data Collection section includes Acquire Data, Replay Data, and Replay Data (old style files) functions. Acquire Data is the program that acquires the EEG data from a subject and stores the data to files on the PC.

Replay Data and Replay Data (old style files) both read subject data that is already stored in a file on the PC and allows the researcher to replay the data and choose a new output file. Replay Data only reads the new "RAW" files, which were acquired by the LEA2002 software. Replay Data "old style" reads the "%1A" and "%2A" created by PEP97 and older versions of LEA2002.

8.5 Configuration section

The configuration section contains the functions to set the default directory path, default timing template, the communication port address and enable/disable the super user mode. These settings should be set before using any of the other software functions.

This section also contains the Edit/Create Timing Templates (Super User Mode only) function. This function allows the user to create the number, amplitude and timing of the stimulus clicks and the timing of the measurements to be collected.

8.6 Data Review and Analysis section

This section contains all of the software functions that are used to display and analyze the collected data.

View/Print Files is used to display averaged (*.ASC) and filtered (*.FL*) data files one at a time.

Filter Files is used to re-filter averaged files (*.ASC). The function contains controls to set the filter parameters and select a list of files to be filtered. The display show the existing averaged and filtered files on the same graph for comparison.

Peak Find is used to set the peak find parameters, display the peaks found and to save the results to a log file. (*.STT).

Shift Files (Super User Mode only) allows the user to shift the data from multiple runs to align the peaks.

Grand Sum (add Files) (Super User Mode only) allows the user to sum the data from multiple runs into a single file.

Subtract Files (Super User Mode only) allows the user to take the difference between two data files and save the result to a new file.

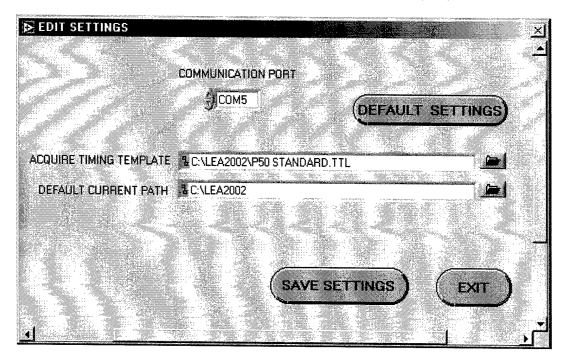
Short Latency Subtract (Super User Mode only) allows the user to subtract the Condition portion of a file from the Test portion of another file.

Report Writer and Group Peak Find function allows the user to build a report on a list of data files. The report contains the parameters selected by the user and can be printed or saved to a spreadsheet-type file for further analysis. A peak-find is performed on the selected files using the parameters selected by the user and the results may be included in the report.

9 Edit settings

9.1.1 Overview

The Edit Settings menu allows the user to select the basic setup parameters for the LEA2002 installation. These parameters include the RS-232 Communication Port setting, the acquire timing port setting, the default file path for all LEA2002 files and the Acquire Timing Template file name. In addition, the user may select the Super User mode by scrolling down and entering the proper password.



9.1.2 Communications Port

This control allows the selection of the RS-232 port that is assigned to the LEA2002 acquisition hardware. See the installation section for determining the proper setting for this port.

9.1.3 Acquire Timing Template

The acquire timing template is a special file that contains all of the timing parameters required to control data acquisition. The file folder button to the right of the filename activates a file dialog box to allow file selection.

It is unlikely that you will need to change the default template. In general, only the default template will exist on the system. You will only change the template if directed by the specific instructions of a particular study or you are a researcher conducting a study using custom acquisition settings.

9.1.4 Default Current Path

This is the default top-level directory used by the software for file operations. The file folder button to the right of the filename activates a file dialog box to allow file selection.

This path should not be changed unless specifically directed as part of a study. The establishment of study name, location, researcher and subject is performed in other menus.

9.1.5 Default Settings

This button returns the settings to the default values and saves them to the configuration file. The default settings are:

Communication Port: COM5 Acquire Timing Template: C:\LEA2002\P50 STANDARD.TTL Default Current Path: C:\LEA2002

9.1.6 Save Settings

This button saves the current settings to the configuration file. The settings must be saved to retain any changes made by the user.

9.1.7 Exit

Closes the Edit Settings menu and returns control to the main menu.

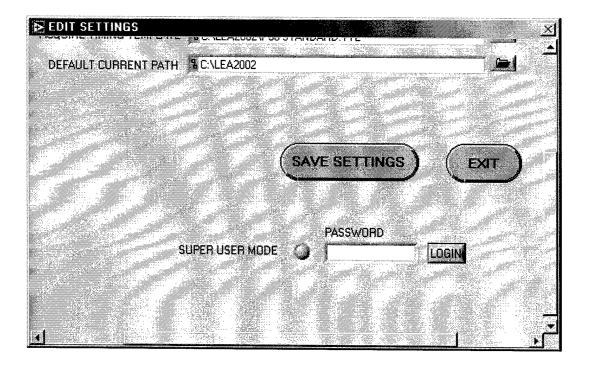
9.1.8 Super User Mode

The Super User Mode controls can be revealed by scrolling the display down to reveal the password and login controls. The Super User Mode indicator displays the current mode. If Super User Mode is enabled, the indicator will be green.

9.1.8.1 Password

Upon installation, Super User mode is disabled. To enable Super User mode, the user must enter the proper password and then press login. The software will verify the password and then prompt the user to enable or disable Super User Mode. Do not press "enter" in the password field, this will result in an invalid password. The password is case sensitive so pay attention to capitol letters.

NOTE: Be sure to scroll back up to show the main portion of the display before exiting – the display position is saved upon exit.



10 Edit/create templates (Super User Mode Only)

10.1 Overview

The Edit/Create timing template function allows the user to control all of the timing parameters related to creating the stimulus clicks and acquiring the EEG data. All of the timing and stimulus level information is stored in a file called a Timing Template file (file type TTL). Information is extracted from the template file by the data acquisition software to setup the LEA2000 hardware and to control how the data is collected and stored. The Test function allows the user to view the timing and levels on the graph for verification.

All of the parameters associated with a particular click appear in the columns below the Click Timing parameters.

The template file (*.TTL) should only be edited using the template Edit/create software. Editing the file in any other way could result in corrupt settings that will not be detected by the acquisition software.

Refer to the System Overview section for a detailed discussion of the data acquisition system.

The screen below shows the Edit/Create Timing menu with the default timing template loaded.

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10.2 Loading and Saving a timing template

When timing templates menu is called, the default timing template is loaded and its parameters displayed. The default timing template file name is set in the Edit Settings menu.

By pressing the load template button, the user can view the available template files. In the standard software release, there is only one template – the P50 STANDARD.TTL template. Selecting the template from the pop-up will load the desired file.

After editing the settings, a new template can then be created by using the Save Template button. The settings are checked for consistency before a template is saved. The user may choose to overwrite and existing template, but will be prompted by the software for permission. Templates should always be saved in the home directory – default C:\LEA2002.

10.3 Editing timing parameters

10.3.1 Acquisition Length

The Acquisition Length field sets the length of acquired raw data records. The default is 950 ms. The hardware sample rate is 1ms so the default number of data samples is 950 per channel. The maximum acquisition length is 10,000 ms or 10 seconds.

The Condition and Test measurement windows are a fixed 450 ms in length, 100 prior to and 350 ms after each respective click.

10.3.2 Number of Clicks

The Number of Clicks field sets the number of stimulus clicks occurs during a sweep. The default is 2 and the maximum is 8. For each click there is an associated click timing, click width and measurements field displayed.

10.3.3 Click Timing

The Click Timing fields program the click delays in milliseconds from the beginning of a sweep. There is a box for the number of clicks selected. Each click delay must be later than the previous click plus its width. The following screen shows 8 clicks being programmed, each 100 ms apart.

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10.3.4 Click Width

The LEA2000 hardware has the capability to generate click widths in 1ms increments. By default, the width is fixed to be constant for every click and the click width is 1ms. The click generated is a single pulse square wave.

With the Fixed Width box checked, all clicks generated will be the width specified for the first click – so click width only shows one column. If the Fixed Width box is unchecked, Click Width will show a column for every click. This allows the user to program a different click width for every click.

The screen below shows the width of the first click to be 10 ms and the width of the second click to be 1 ms.

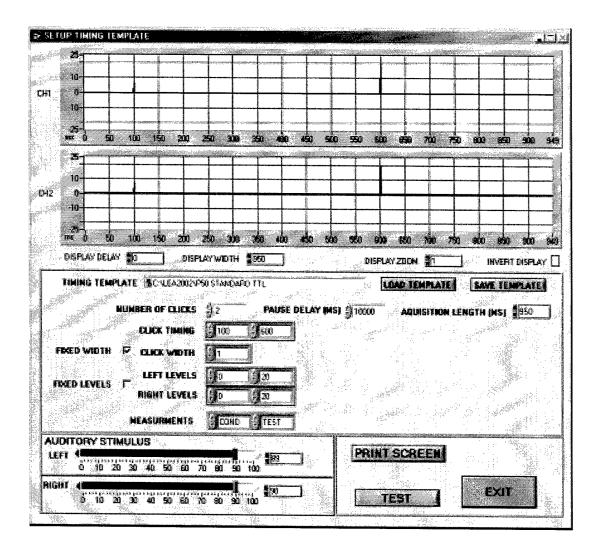
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10.3.5 Levels

If the Fixed Levels box is checked, the click level (intensity) is constant for all clicks.

If Fixed Levels is unchecked, then the stimulus levels for each click can be specified individually. Fields for Left Levels and Right Levels are displayed with boxes for each click. The levels are "relative" settings, that is the value in the box will be added or subtracted to the stimulus levels set by the operator at run time. The settings are in dB. The maximum stimulus level is 100, so the levels set in the template and the levels set by the operator at run time cannot exceed 100 or clipping will occur. A run time message is generated if clipping is detected.

The screen below shows variable level clicks with the second click set at 20 dB above the first click.



10.3.6 Measurements

All acquisition data files (other than RAW) are stored as Condition-Test pairs. These pairs are 450 ms wide windows of data collected around each of the specified clicks. The Measurements settings tell the acquisition software which clicks to acquire data around and which click is the Condition or reference click. A measurement column appears for each click. The choices are COND for Condition, TEST, or OFF.

There can be only one Condition click but there can be up to 7 Test clicks. The acquisition software generates a set of data files for every Condition-Test pair and re-uses the Condition data if multiple Tests are specified.

The screen below shows a template with 8 clicks 100 ms apart and 4 Condition-Test pairs. Note that measurements could not be made on click 7 and 8 because the acquisition length does not allow the standard 350 ms post click data collection.

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10.3.7 Test Button

Pressing the Test button analyzes the settings for consistency and if the LEA2000 hardware is connected, will run an acquisition. If the acquisition is run, the LEA2000 hardware is configured in loopback mode, so the relative amplitude and timing of the clicks will be shown on the graph. The click levels are relative to the Auditory Stimulus level settings.

10.3.8 Auditory Stimulus

The Auditory Stimulus settings are used to set the base click levels for testing in this menu only. The actual base click levels are set by the operator during data acquisition. Like during an actual acquisition, these click levels are added/subtracted to the template click levels if variable levels are specified.

10.3.9 Print Screen

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This button will cause the Template screen to be printed to the selected printer. This provides a convenient method to document the template settings for future reference.

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11 Acquire data

11.1 Overview

The Acquire Data function allows a user to acquire subject data using the LEA2000 hardware acquisition system. Before beginning an acquisition, the operator must:

- Set up the LEA2000 hardware. The LEA2002 software main menu shows the proper amplifier settings.
- Establish the communication port setting if not already done so. See the Installation section on how to perform this step.
- Establish the proper timing template setting. In most cases the default setting is the only one available and no action is required. See the Set up Menu for this step.
- Connect the electrodes to the subject using the proper skin preparation method and conductive paste. Electrodes should be sterilized between uses. The LEA2002 main menu shows the proper lead configuration for the P50 protocol. When connected the leads should have an impedance of 10k Ohm or less. This can be measured with a digital or analog ohmmeter between each lead-pair.
- Place the earphones on the subject and establish the proper Auditory Stimulus levels. The threshold varies for each patient, so this step needs to be performed before beginning a run.

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Upon initialization, the Acquire Data menu loads the timing template selected in the setup menu and display the Measurements on the screen. The example above shows the standard P50 template loaded. The Measurements indicator shows the first click being the Condition click and the second Click being theTest click.

11.2 Setting the Auditory Stimulus Levels

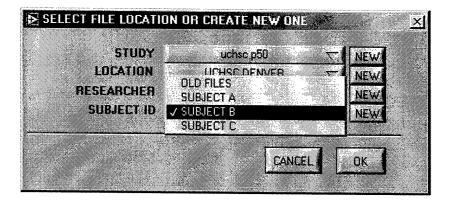
The Auditory Stimulus controls set the amplitude of the clicks sent to the earphones. Each subject has a different hearing threshold, so this threshold needs to be established.

The TEST LEFT and TEST RIGHT buttons send clicks to the respective ear, but do not acquire data. The Left Audio and Right Audio sliders set the amplitude of the clicks independently for each ear.

The threshold can be determined by incrementing and decrementing the Audio level for each ear and performing tests until the subject barely hears a click. The Audio controls can be set by sliding the bar with the mouse, or by clicking on the arrows at the end of each slider. Once a threshold has been established, the audio level should be set to 45dB above the threshold for each ear respectively. If the acquired waveform shows a startle response, then the audio levels should be reduced until the subject does not show a startle response.

11.3 Acquiring Data - Run

The Run button initiates an acquisition and prompts the user for a subject name. The pop-up menu allows the user to choose from existing subjects, or to create new Studies, Locations, Researchers or Subjects. Please refer to the File naming conventions section for more detail on the file directory structure.



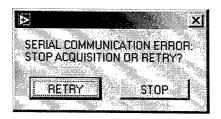
The output file name is automatically created by incrementing the extension on the filename until one is found that does not already exist.

After choosing the subject, the user is prompted to add comments to file header. The header is preloaded with the current data and the Study, Location, Researcher and Subject ID.

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FILE	HEADER INFORMATION
DATE	12/18/2001. SPEC
STUDY	uchsc p50
LOCATION	UCHSC DENVER
RESEARCHER	DR ADLER
SUBJECT ID	SUBJECT BELLER BELLER
FILE NAME	SUBJECT B_1
	ENTER COMMENTS RESS ENTER WHEN DONE
COMMENTS	

After any comments are entered, the software then begins the acquisition.

If the software is unable to communicate to the LEA2000 hardware, a message is displayed.

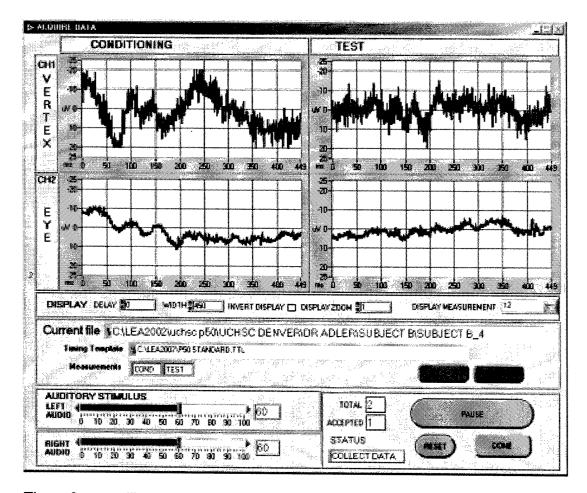


If the hardware was turned off, or the communication cable was disconnected, then the problem could be corrected and a Retry may be successful.

If the problem is due to an incorrect serial port address, then the user must Stop the acquisition, exit the acquisition menu and correct the problem in the setup menu.

See the troubleshooting section for more suggestions.

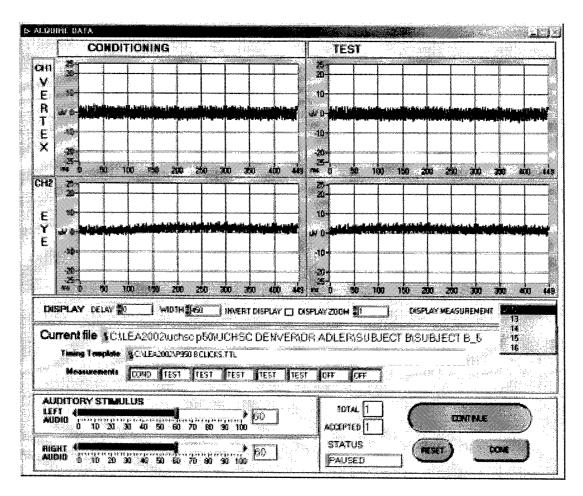
Assuming a successful communication with the hardware, the software will display the data and prompt the user to accept or reject the sweep. If the user does not make a choice within 4-5 seconds, the software will automatically accept the data and begin another acquisition



The software will pause for a predetermined time before making the next sweep. This pause time is specified in the timing template and is editable in the Edit/Create timing template menu. The default is 10 seconds between runs and that includes the time to accept or reject the sweep.

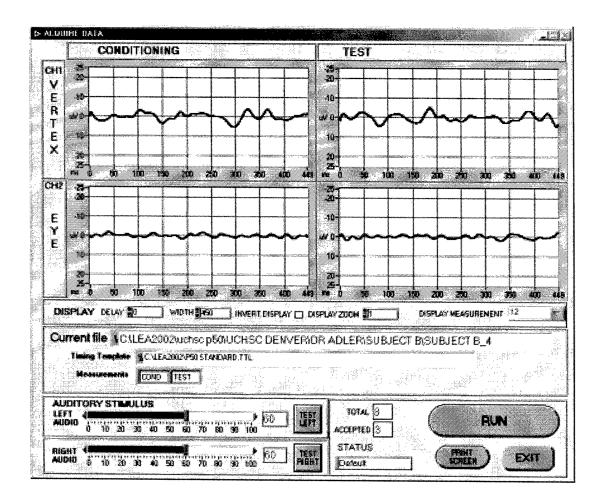
The software will continue to acquire successive sweeps in this manner until all the maximum number of sweeps have occurred, or the user presses the Reset, Pause or Done button.

The Reset button resets the acquisition and empties any files that were created.



The Pause button allows the user to suspend the acquisition and examine the current sweep in more detail. The examples above shows the acquisition paused and the Display Measurement pop-up visible. If the timing template contains multiple Condition-Test pairs, then the user can view the different pairs using the Display Measurement control. The numbers refer to the click numbers of the Condition-Test pair. "12" means click 1 is the Condition Click and click 2 is the Test click. The file name extensions follow the same naming convention to identify the Condition-Test Pair. The standard P50 template only creates/uses the "12" pair.

The Done button terminates the acquisition and completes the processing of the accepted sweeps by filtering and saving the data. The graph displays will be updated with the filtered and averaged data from the accepted sweeps.



The filter parameters are hard-coded into the software. The filter parameters are "0.95" with a gain of "1" for the high pass filter and "3" for the low pass filter.

If there are multiple Condition-Test pairs, then their filtered data can be viewed by selecting them in the Display Measurement control.

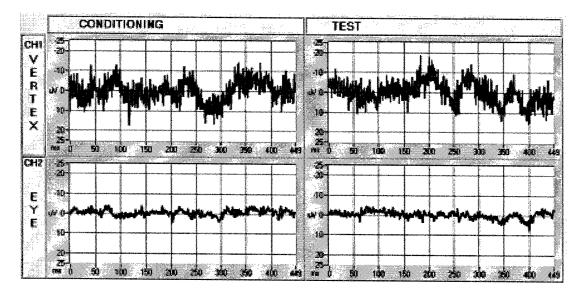
The Print Screen button will print the current screen to a user specified printer. This is a good way to preserve a record of the acquisition settings and the filtered result all on one page.

12 Good Sweeps vs. Bad Sweeps

Collecting good sweeps requires judgment on the part of the operator to choose the sweeps that are most likely to contain the best responses and are not corrupted by muscle response or other noise. Accepting sweeps with these problems will reduce the magnitude and quality of the desired evoked response. Here are some examples of some good sweeps that should be accepted and some bad sweeps that should be rejected.

12.1 Good Sweeps

Good sweeps are characterized by relatively flat Vertex response and little eye channel response. Neither channel should show any saturation.



12.2 Bad Sweeps

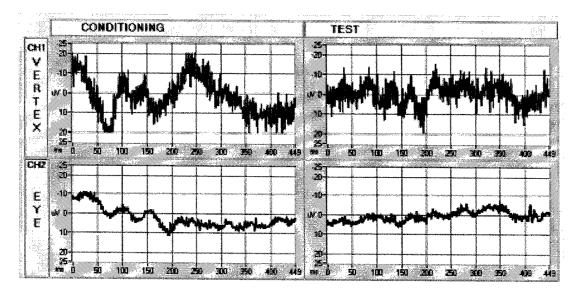
Bad sweeps are characterized by large eye channel (muscle) response, saturation of either channel, or potential Alpha wave response.

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This first example shows saturation of both channels.

This next example shows potential Alpha wave content – most likely due to the subject drifting into sleep. The Alpha wave is the large low frequency content present in the conditioning portion of the vertex channel.

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13 Replay Data

13.1 Overview

The Replay Data function allows a user to re-acquire subject data from previously recorded raw data files. This gives the user a chance to re-choose the sweeps to be included in the resulting averaged and filtered files.

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Another reason for using replay data is to apply a different timing template to previously recorded raw data files. This allows conducting different types of analysis without acquiring new subject data.

The user interface is very similar to the acquire data screen, but the data is coming from files stored on the computer rather than from a subject.

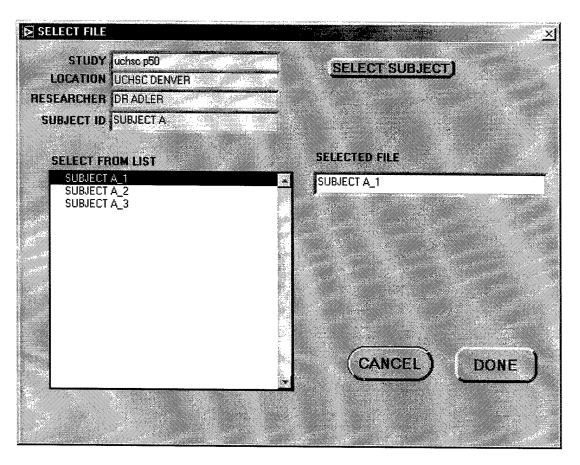
The Replay Data function also loads the default timing template that is specified in the setup menu. The display shows the measurements that were specified in the template.

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13.2 Beginning Replay

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The Begin Replay button initiates the Replay and prompts the user for a file to replay. The pop-up menu allows the user to choose the subject and specific file to replay.



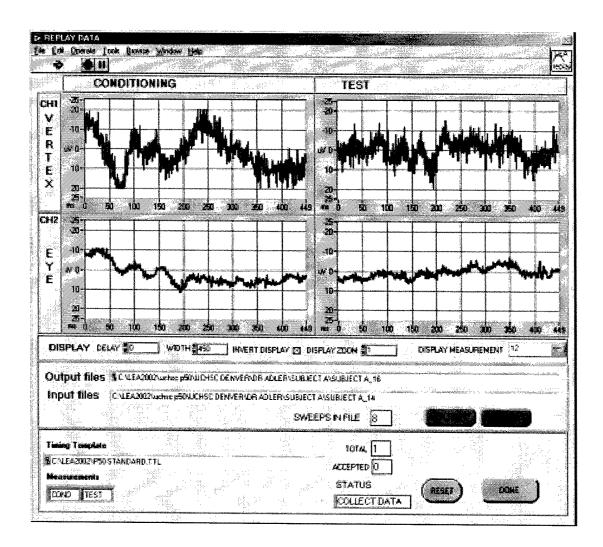
The output file name is automatically created by incrementing the extension on the filename until one is found that does not already exist. In the above example, output files will be named "SUBJECT A_4" with the appropriate extensions.

After choosing the file to replay, the user is prompted to add comments to file header. It is recommended that the user add a specific comment as to the reason this replay is being done. This will allow the file to be distinguished from other files in the future. The date is automatically updated and the file path is filled in.

DATE	12/13/2001
STUDY	uchsc p50 and and a set of a set
LOCATION	UCHSC DENVER
SEARCHER	DRADLER
SUBJECT ID	SUBJECT A
PI Comments	ENTER COMMENTS RESS ENTER WHEN DONE

After any comments are entered, the software then displays the first sweep from the specified file. Sweeps In File displays the number of sweeps contained in the input file.

The user is prompted to accept or reject the sweep. If there is more than one measurement pair, the user can choose which pair to display from the Display Measurement control on the bottom right of the display.



After Accepting or Rejecting the sweep, the software will continue to display successive sweeps until all the sweeps have been examined, or the user presses the Reset or Done button.

The Reset button resets the replay to the beginning of the sweeps and empties any files that were created.

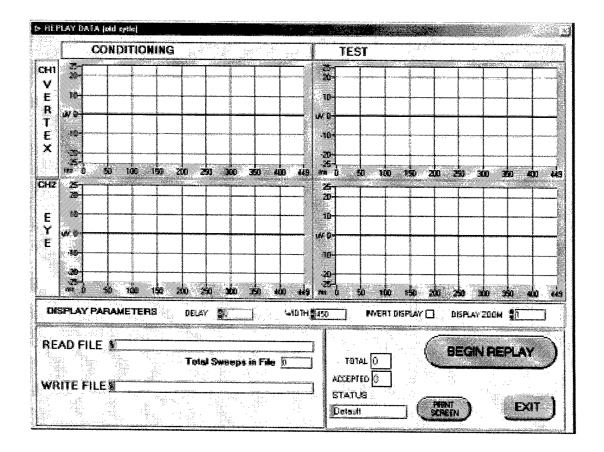
The Done button terminates the replay at the current sweep and completes the processing of the accepted sweeps. When completed, the display shows the filtered data. The filter parameters are hard-coded into the software. The filter parameters are "0.95" with a gain of "1" for the high pass filter and "3" for the low pass filter.

14 Replay Data old style

14.1 Overview

The Replay Data (old style) function allows a user to re-acquire subject data from previously recorded *.%1A and *.%2A files. These files were created by PEP97 and previous versions of LEA2002. A specific Replay function is required for these files because previous versions of software did not use timing templates and only recorded data for the standard P50 Condition-Test pair.

The user interface is very similar to the acquire data screen, but the data is coming from files stored on the computer rather than from a subject.



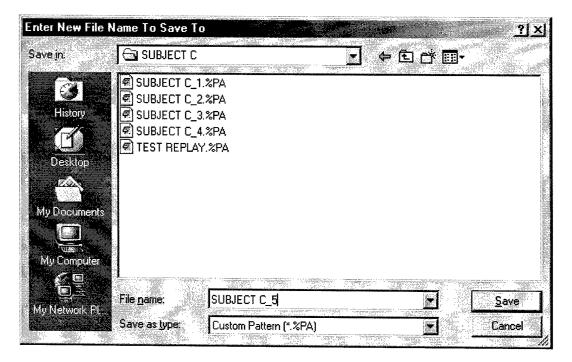
14.2 Beginning Replay

The Begin Replay button initiates the Replay and prompts the user for a new file name to save the output to. The file type prompted for is the %PA file since this is the core file type for the old-style acquisition.

The software will not allow the user to overwrite acquisition files so a new file name must be chosen.

The Replay Data (old style) function produces averaged and filtered files that are compatible with all LEA2002 analysis functions. To be accessible to those functions, the Replay output files must be manually placed into the STUDY\LOCATION\RESEARCHER\SUBJECT directory structure. If the target SUBJECT directory already exists, then the user can select that subject directory and then type in the proper filename. Review the file naming conventions section of this manual to understand how to accomplish this.

The example below shows creating an output file name that is compatible with the new directory structure and is not a duplicate file.



After choosing the file destination, the user is prompted to add operator name, location and comments to file header. It is recommended that the user add a specific comment as to the reason this replay is being done. This will allow the file to be distinguished from other files in the future. The date is automatically updated and the file path is filled in.

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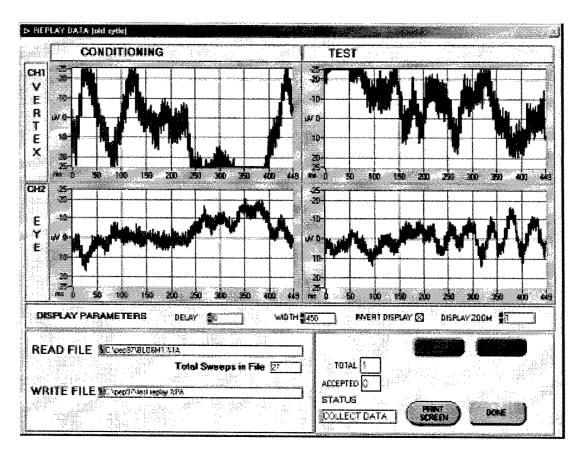
After any comments are entered, the software then prompts the user for the file to replay.

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Look jn:	Сарер97		
History History Desktop My Documents	I don't know what this is-do not delete ref_file test_files 1VOLT.%1A 36790.%1A ACCEPT.%1A aheadtst.%1A anred.%1A asdfasdf.%1A asdfghj.%1A	 a bandwidth.%1A bavd.%1A bbbb.%1A betst.%1A better.%1A better.%1A BLOGM1.%1A BLOGM3.%1A blom61_leamain.%1A bw.%1A cal.%1A 	ال ده ده ده ده د د د د د د د د د د د ا د ه د ه
My Computer	* BL06M1.%1A Files of type: Custom Pattern (*.%)	1A)	Dpen Cancel

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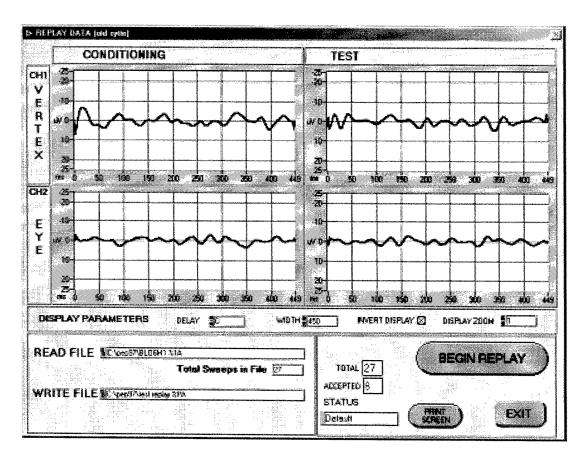
After selecting a file, the software then begins to replay the data. The number of sweeps contained in the input file is displayed in the Total Sweeps in File indicator.

The user is prompted to accept or reject the sweep. The current sweep number and the accepted number of sweeps is displayed on the screen.



After Accepting or Rejecting the sweep, the software will continue to display successive sweeps until all the sweeps have been examined, or the user presses the Done button.

The Done button terminates the replay at the current sweep and completes the processing of the accepted sweeps. When completed, the display shows the filtered data. The filter parameters are hard-coded into the software. The filter parameters are "0.95" with a gain of "1" for the high pass filter and "3" for the low pass filter.



The Print Screen Button allows the user to print the displayed screen to a user specified printer.

15 View/Print Files

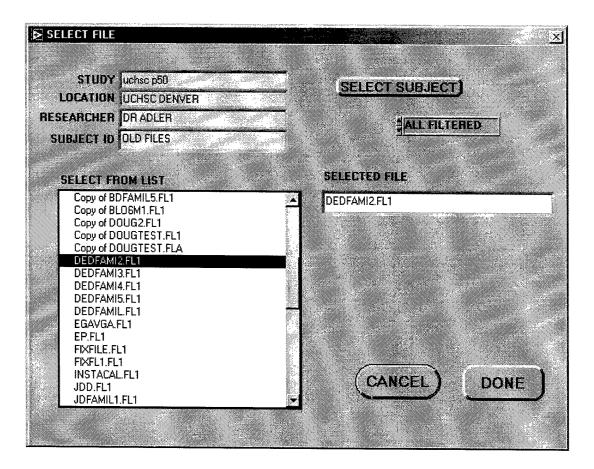
This menu allows the display of files that are stored under the LEA2002 directory system. This menu allows the display of Accumulated Sum or Averaged files (ASC), Filtered files (FLA,FLG,FLD,FLS and FL1), Grand Sum files (GD1), Subtracted files (SUB) and Shifted files (SFT).

Raw files (RAW), Data files (%1A, %2A), Header Files (%PA), Sweep files (SWP), Grand Sum List files (GDL), and Peak Find Result files (STT) are not displayable in this menu.

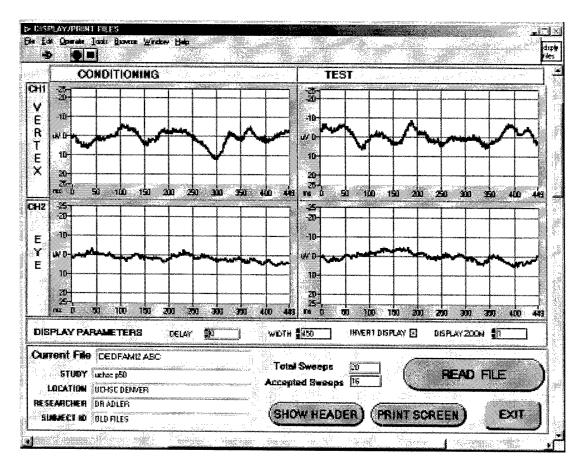
The display uses the standard graph presentation and also shows the file path in detail.

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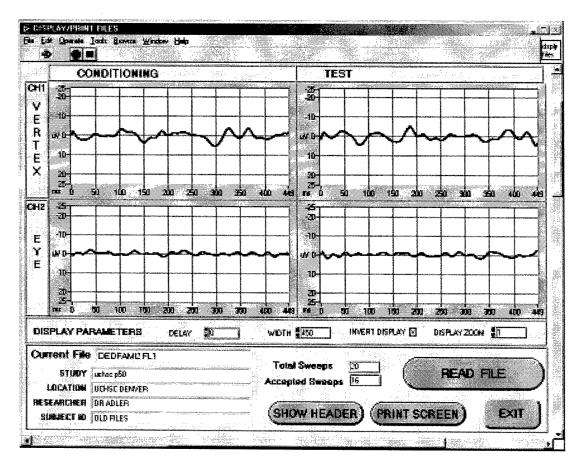
The Read File button brings up the Select File pop-up. The Select Subject control pops up a control to choose the complete Subject ID path. The file type control selects the type of files to be displayed in the select list. The types to choose from include "ALL" files, "All Filtered" files, "Averaged" files, "Grand Sum" files, "subtracted" files, and "Shifted" files.



Once a file is selected, it is displayed on the graph. This example shows an averaged file (ASC).



The example below shows the filtered version of the same file.



The display can be printed to a user specified printer by pressing the Print Screen button.

The Show Header button brings up a display of the header information in the file. The header contains details on the conditions the file was created and any comments the user has added.

This example shows the header of a filtered file.

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DATE 12/11/2001			
TEMPLATE		·	
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Files acquired by PEP97 or CEPAN contain less information than files created by LEA2002. This example shows the header display for an older style filtered file. Notice that the older software did not use a template.

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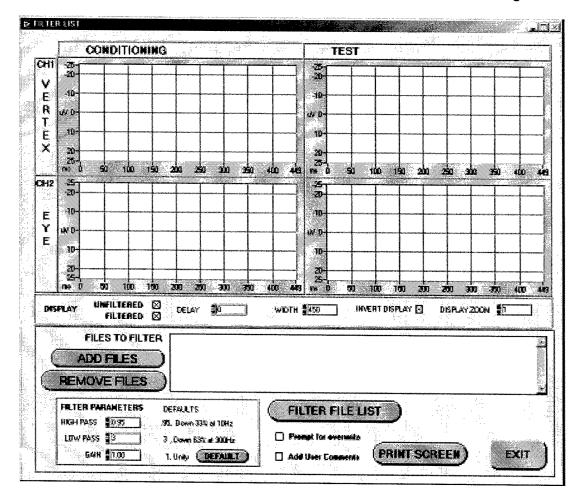
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16 Filter Files

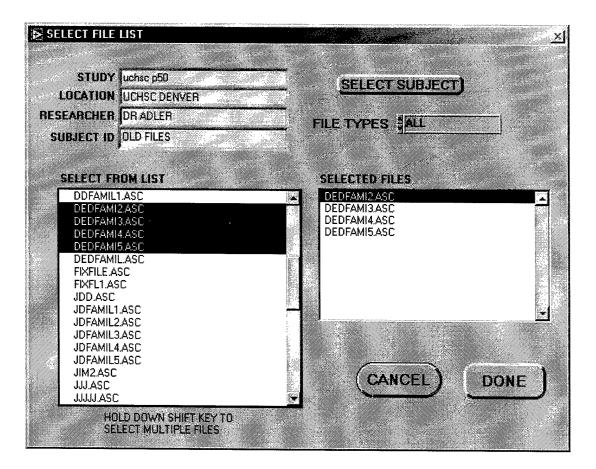
16.1 Overview

The Filter Files function allows a user to filter a list of files and specify parameters for that filtering. The function is able to graph data before and after filtering.

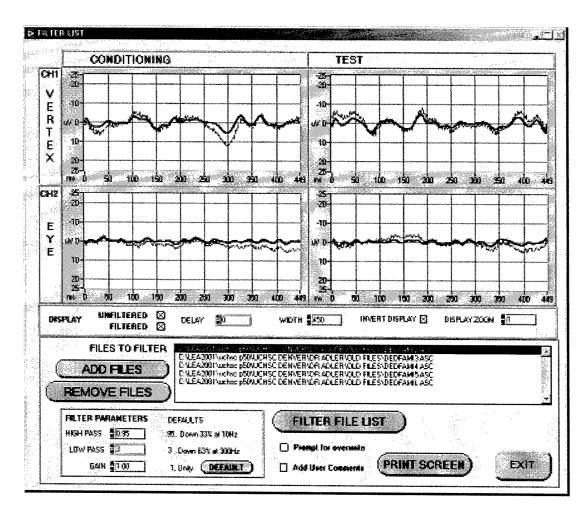


16.2 Filtering Files

The filtering process is started by adding files to the file list using the Add Files button. The Select File List pop-up allows multiple files to be selected at the same time by using the shift key.



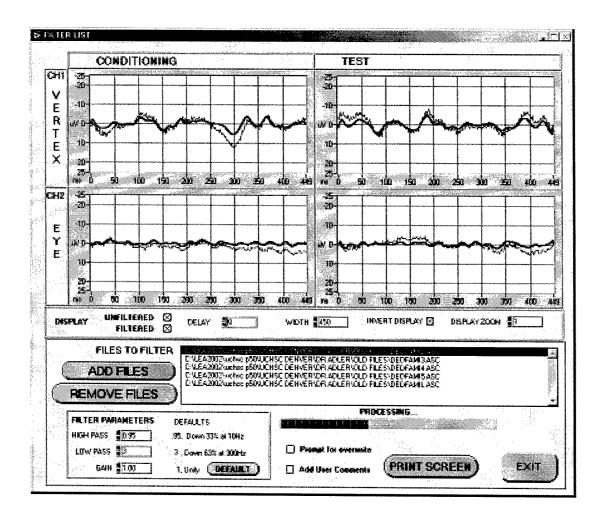
Once the file list is established, the function automatically displays the file highlighted in the file list if the Unfiltered display box is checked. If the Filtered display box is checked, it will also display the filtered version of the highlighted file, using the filter parameters chosen in the Filter Parameters box.



The display automatically updates if new Filter Parameters are chosen or a new file is highlighted.

The Remove Files button will delete the currently highlighted file from the file list.

Pressing the Filter File List begins the processing of the files. The display will show a progress bar showing the percentage of files that have been processed.

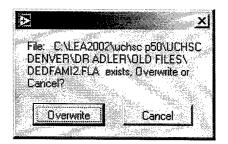


If the Add User Comments box is checked, the user is prompted to add comments to every file in the list.

≥ ADD OPERATO	DR COMMENTS
FILE	HEADER INFORMATION
DATE	12/18/2001
STUDY	uchsc p50
LOCATION	UCHSC DENVER
RESEARCHER	DRADLER
SUBJECT ID	
FILE NAME	DEDFAMI2.ASC
PI Comments	ENTER COMMENTS RESS ENTER WHEN DONE
	ENTER

If the Prompt for Overwrite box is not checked, the software will overwrite the existing filtered file for the file being processed. See file types for detail on the various filtered file types. Filtering an old style file will produce an FLA type file and not overwrite an existing FL1 type file.

If the Prompt for Overwrite box is checked, the user will be prompted to approve any overwrite or cancel the overwrite for that file. The user cannot choose another name for the output file. There can be only one filtered output for any particular unfiltered file.



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If the user needs to have other filtered versions of the same file, then the unfiltered files would have to be manually copied to another Subject ID directory to keep them separated.

17 Peak Find

17.1 Overview

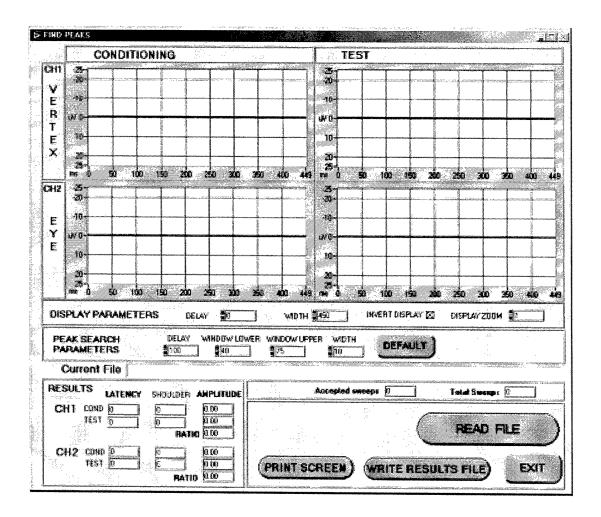
The Peak Find function searches for peaks in the data and then measures the peak amplitudes and ratios. The results can be written to an STT type file.

17.2 Peak Search Parameters

The peak find starts searching at the Window Upper point plus the Delay. It searches for a minimum point (slope goes from negative to positive) and marks that point as a peak. It saves that point and it is called the Latency. It then searches for a maximum point (slope goes from positive to negative) and marks that point as the Shoulder. It records the difference between the two points as the amplitude. It continues to search downward in the window until it reaches the Window Lower plus Delay bounds or finds another minimum. If another minimum is found, it then searches for a maximum and compares the amplitudes. The latencies and amplitude of the larger peak are retained. The search progresses from

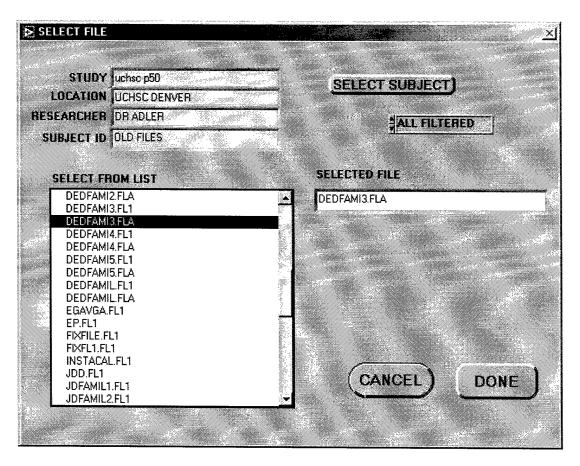
If a peak is found in the condition array, then a search for the peak in the test array is centered around the latency of the condition array plus or minus the window width.

Latencies displayed are time in msec from the delay point.

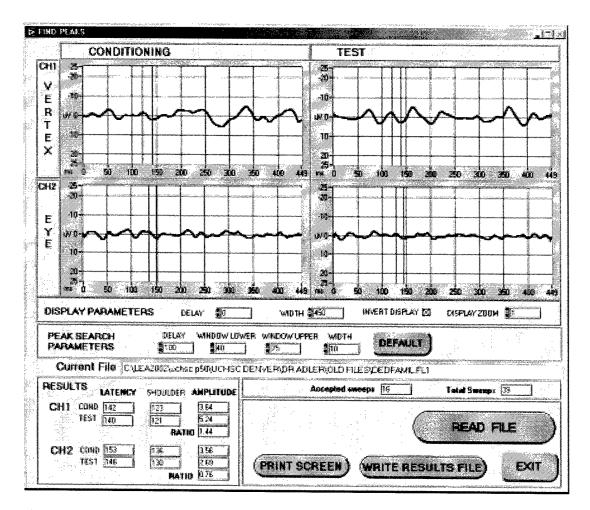


17.3 Peak Search

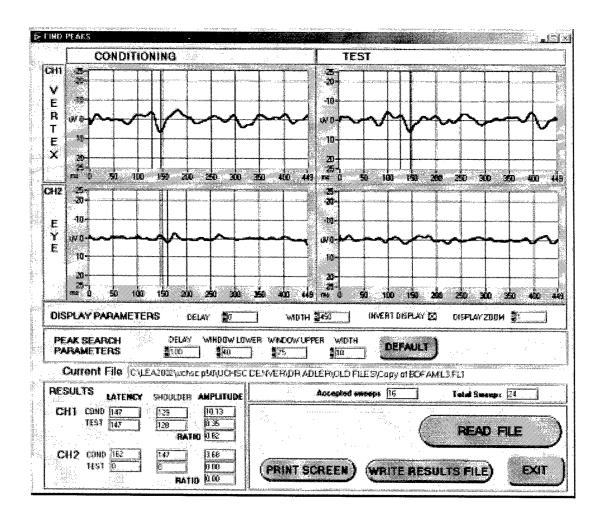
A peak search is initiated by reading an input file. The Read File button will show the Select File pop-up. The default file type shown is All Filtered. Selecting ALL from the file type control will show all filtered and unfiltered file types. An ASC file type can be chosen, but performing a peak find on unfiltered data is meaningless because of the noise in the data.



Once a file has been selected, the data will be displayed and a peak find will be performed. The display will show the numeric results and the graph will show markers for the computed Latency and Shoulder. A new peak find will be performed if the peak search parameters are changed of the file is changed.



If the peak search does not find a peak, the amplitude and ratios are set to zero and the markers are moved to the left hand side of the display. The below example shows that a peak was not found for the Test sweep of channel 2. A peak was not found because there is not a peak within the +/- 10 ms of the peak found in the conditioning sweep.



The Write Results File button initiates creating an output file (STT) that contains a text report of the peak find. If the file already exists, a pop-up requests overwrite permission. Only one STT file can exist for any particular file name.

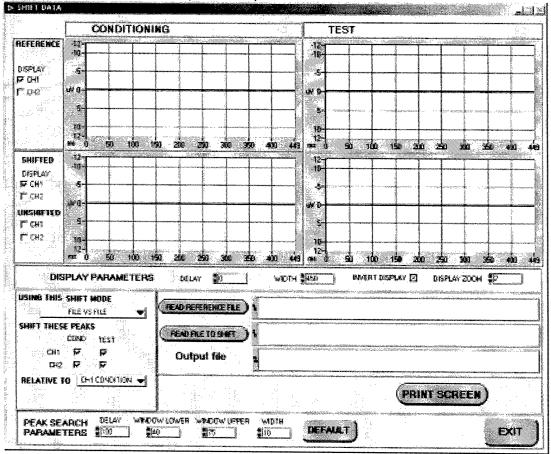
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	Arie Martin			

The Report Writer performs the peak find function on a list of files and does not write/overwrite the STT files.

18 Shift Files (Super User Mode Only)

18.1 Overview

The Shift file function shifts the data in a file to align with the peak(s) found in another file or a specified peak within the file. The Shift function relies on the peak find method used in the Peak Find function. The Shift function window contains controls to set the peak find parameters.



18.2 Shift Controls

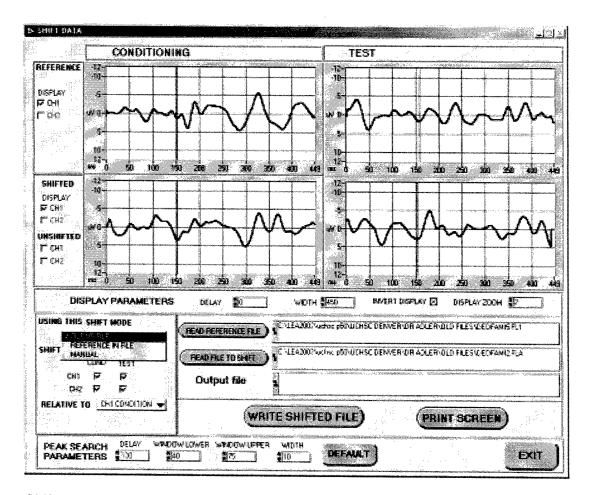
The shift controls set the basic parameters of the shift function – the source of the reference peak(s) and which portions of the data file to shift.

Using This Shift Mode control has three options – File VS File, Reference In File, and Manual.

File VS File establishes that the reference peak(s) are in a separate reference file.

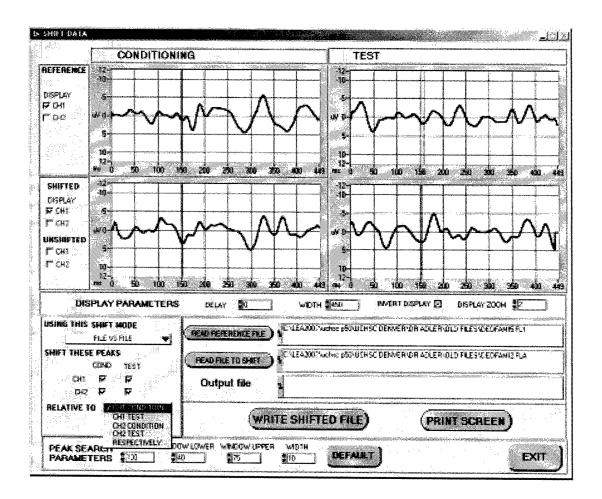
Reference In File mode establishes that the reference peak to be used in the shift is one of the peaks within the file.

If Manual mode is selected, the peaks will be moved using a value the user enters manually.



Shift These Peaks check boxes establish which portions of the data file will be shifted.

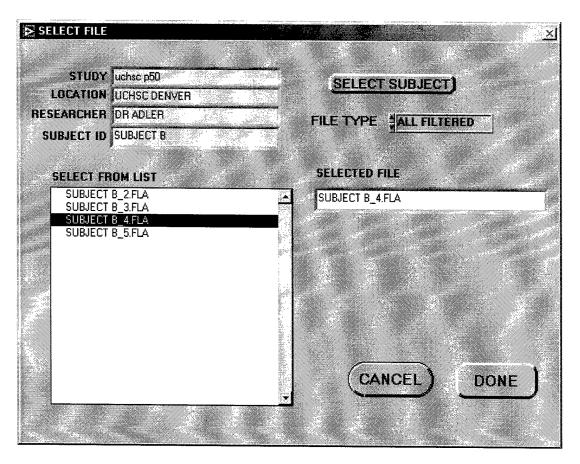
The Relative To control establishes which peak is the reference peak. The "Respectively" selection specifies that all of the selected peaks will be shifted to align with the respective peaks in the reference file. For example CH1 condition is moved relative to CH1 condition, CH1 Test is moved relative to Ch1 Test and so on.



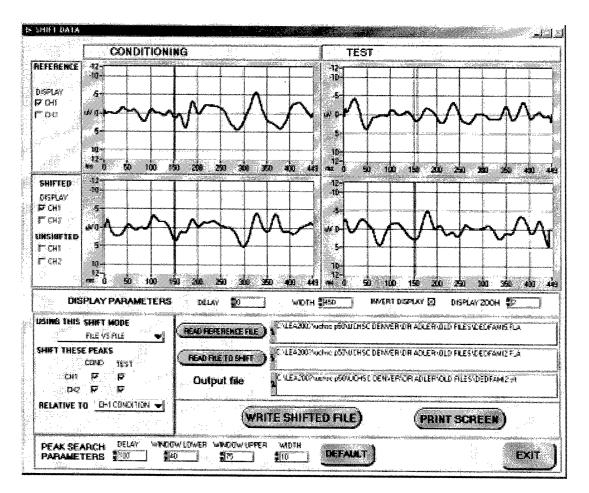
18.3 Shifting Files

The shifting process begins by setting the shift parameters to the desired settings. If File Vs File mode is chosen, the Read Reference File button will be displayed.

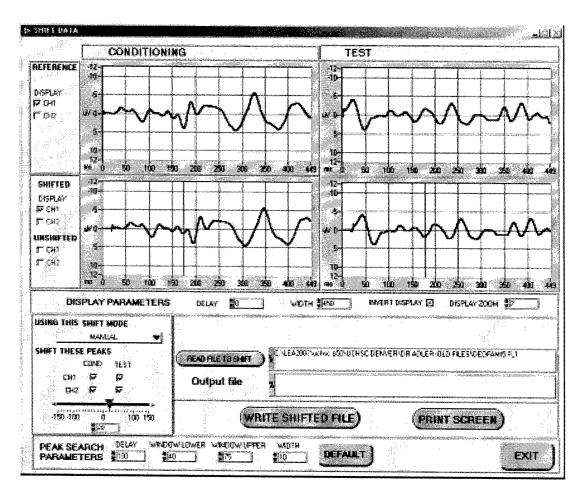
Read Reference File and Read File To Shift will open the Select file pop-up.



After the files are chosen, the display will show the sweeps for the boxes that are checked on the left of the graph. The screen below shows CH1 of the shifted file with the peaks shifted to align with the condition peak of the reference file.



If Manual mode or Reference In File is chosen, the reference data (and the upper display) will be the original file before shifting. If manual mode is chosen, a manual control appears in place of the Relative To control.



Zeros are used to fill the gaps at the ends of the data where there is no data.

Write Shifted File initiates saving the shifted file. The user is prompted to add comments to the header before saving. The shift software also records the shift parameters into the header for future reference.

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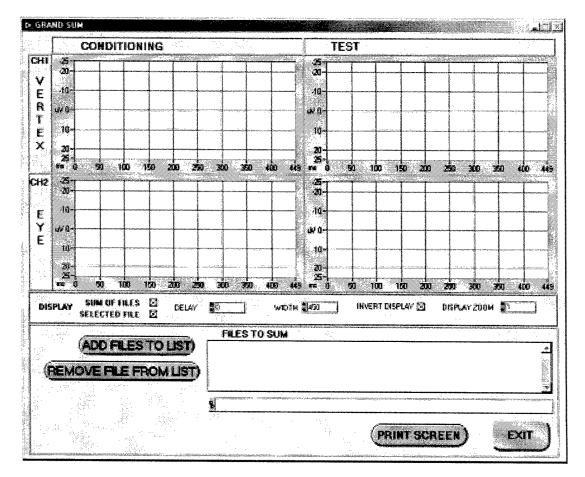
If an SFT file of the same file name does not exist, then one is created. If an SFT file does exist, then the user is prompted to either create a new file name, or chose a file to overwrite.

select existing	file or create new	r file. do not add file ex	tension.		· 기치
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My Computer	File <u>n</u> ame:	DEDFAMI2.sft			Save
	Save as type:	Custom Pattern (*.sft)			Cancel

19 Grand Sum (Super User Only)

19.1 Overview

The Grand Sum function simply adds the data within a list of files and creates a new output file (GD1). The number of sweeps in the output file is the sum of the number of sweep in the Files To Sum list. The function also creates a file that lists the files that were summed (GL1). The sum file may include filtered and/or unfiltered data.



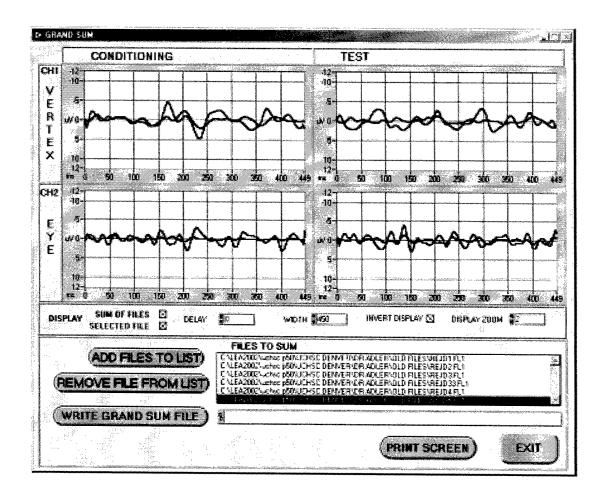
19.2 Selecting Files to Sum

The operation begins by Adding Files to the List. This button brings up a Select file list. The File Types control shows the type of files that will be displayed in the SELECT FROM list. The Select Subject button will bring up the directory control to choose the complete file path.

Multiple files can be chosen at one tome by holding down the shift key and selecting the files with the mouse. If multiple file types are to be chosen, then set File Types to All and select the files of interest. If files from multiple subjects are to be used, select all of the files from one subject, select done in the select file popup and then press the Add Files to List button again to choose the other subject files.

SELECT FILE LIST	
STUDY uchsc p50 LOCATION UCHSC DENVER RESEARCHER DR ADLER SUBJECT ID DLD FILES	SELECT SUBJECT)
SELECT FROM LIST KB2R.FL1 KB3.FL1 KB4.FL1 LARSIT1.FL1 LITT.FL1 MDFAMIL1.FL1 MDFAMIL2.FL1 MDFAMIL5.FL1 PEP97.FL1	SELECTED FILES REJD1.FL1 REJD2.FL1 REJD3.FL1 REJD3.FL1 REJD4.FL1 REJD5.FL1
REJD1.FL1 REJD2.FL1 REJD3.FL1 REJD3.FL1 REJD4.FL1 REJD5.FL1 TMSRB.FL1 HOLD DOWN SHIFT KEY TO SELECT MULTIPLE FILES	CANCEL DONE

After closing the Select File pop up, the chosen files appear in the Files To Sum list on the display. The highlighted file will be displayed on the graph. The display control section contains check boxes to display the Selected File and the Sum Of Files.



Any file in the list can be displayed by clicking on the file name in the Files to Sum list.

Any file can be deleted from the list by clicking on it and then clicking the Remove File From List button.

19.3 Writing Grand Sum Files

Once the file list is complete, the output file can be written by pressing the Write Grand Sum File button. There is not a predefined naming convention for Grand Sum files since the data can come from files of many different names. The user must either choose an existing GD1 file name or create a new one.

Select File or C	hoose New File Name. DO NOT ADD EXTENSION
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My Network PL.	File name: sum of rejd4
	Save as type: Custom Pattern (*.GD1)

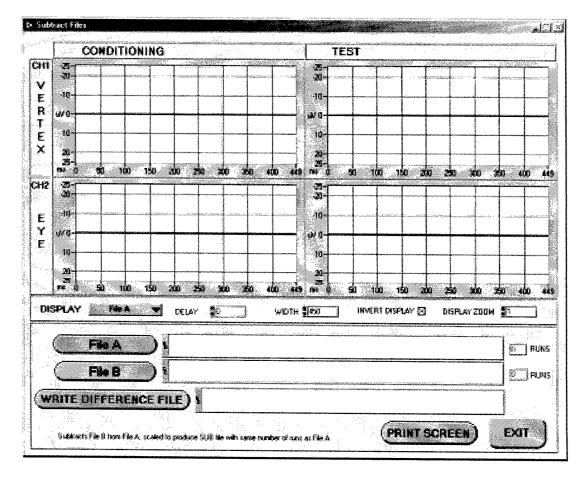
The user is offered a chance to add comments to the header in the GD1 file.

DAY Month	18	OTHER INFORMATION		
YEAR	12 2001		, kan manana ing kanana manana sa sa kanana na kanana na kanana na kanana na kanana na kanana na kanana kanana k kana manana kanana na kanana kanana kanan	
TOTAL SWEEPS	Change and the second		eren anderen a Terre anderen an	
NCEPTED SWEEPS TIME DELAY	Contraction of the second s			
	EDITABLI	EINFORMATION		
OPERATOR	:	L		
LOCATION				
	INTS HERE			
LOCATION	TS HERE			
LOCATION	ENTS HERE			

20 Subtract Files (Super User Only)

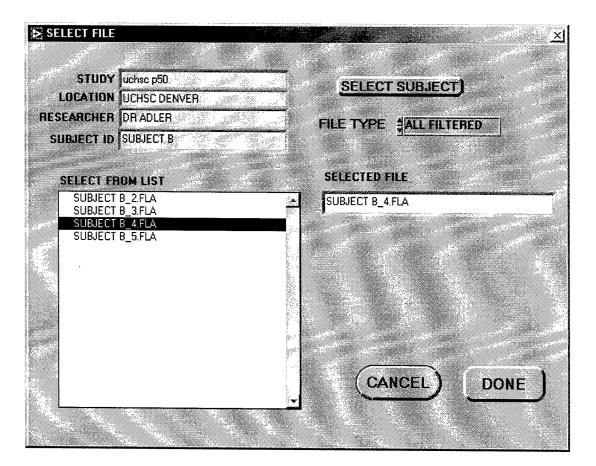
20.1 Overview

The Subtract Files function takes the difference between two data files. The files can be filtered or unfiltered data. The function subtracts File B from File A. The data is normalized before subtraction to account for differences in the number of runs in each file. The Output file is scaled to contain the same number of runs as the input File A.

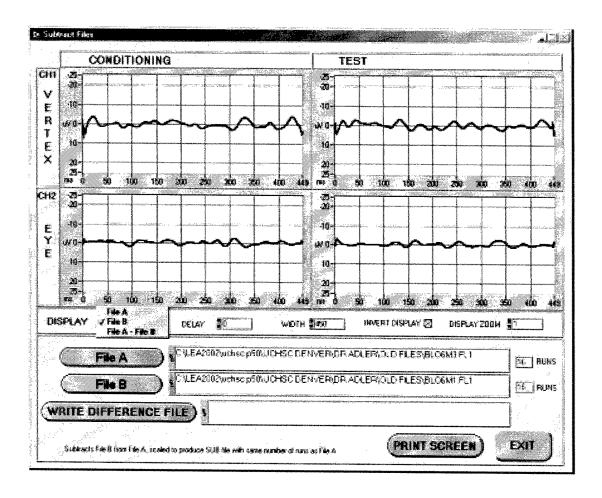


20.2 Subtracting Files

Each file is read by pressing the Read File A and Read File B buttons. These buttons display the Select File pop up. The File Types control shows the type of files that will be displayed in the SELECT FROM list. The Select Subject button will bring up the directory control to choose the complete file path



Once the files are selected, the graph will display either File A, File B or the difference between the files. The Display control selects which file to display.



The subtracted file is written by pressing the Write Difference File button. There is not a predefined naming convention for Subtracted files since the data can come from files of many different names. The user must either choose an existing SUB file name or create a new one.

Enter New Fi					1 শ
Save jn:			- E	E 🕈 🔳	
History History Desktop My Documer	Jeannie SAVE	NCE SUB			
My Compute	Filename:	TEST DIFFERENCE.	···· *···×: ·········· ··········		<u>Save</u> Cancel

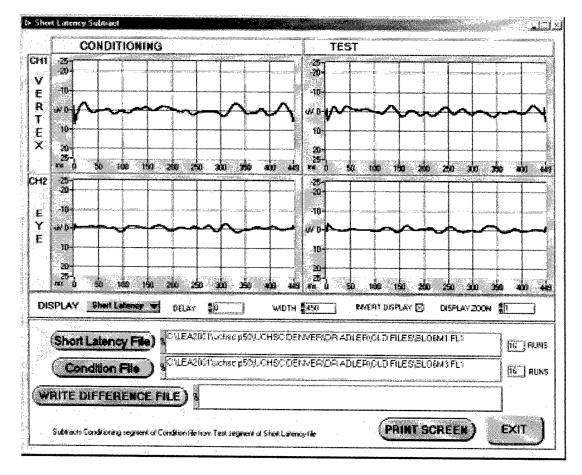
.

The user is offered a chance to add comments to the SUB file header. Notice that the header contains the names of the subtracted files in the Other Information section.

FILE NAME	A MERCULTUCKS	e pSINUCHSC DENVERIOR ADLERIOLD FILESITEST DIFFERENCE SUB
DWY	18	OTHERINFORMATION
MONTH	12	
YEAR	2001	
TOTAL ALCON		
TOTAL SWEEPS	China and C	DIFFERENCE BETWEEN:
THE DELAY	C. C. C. C. Constanting of the C	CALEA2002/uchic pSONUCHSC DERIVERIUM ADLERIUND FILESVAEJD2 PL1
		CNEA2002/uchic p00/UCHSC DENVER/OR ADLER/OLD FILES/REJD337L1
	COLLARIE	INFORMATION IN
	FURAME	
OPERATOR	EUHABLE	INFORMATION
OPERATOR	CUITABLE	
LOCATION	2 <u></u>	
	2 <u></u>	
LOCATION	2 <u></u>	
LECATION	2 <u></u>	
LOCATION	2 <u></u>	

21 Subtract Short Latency

The Subtract Short Latency function is identical in operation to the Subtract function except the Condition portion of the Condition file is subtracted from the Test portion of the Short Latency File. The Condition portion of the Short Latency File is written unaltered to the .SUB file.



To create a difference file using the short latency subtract function the user chooses the Short Latency file and the Condition file and then uses the Write Difference File button to write the .SUB file to the desired directory and file.

The display selection allows the user to display the Short Latency file, the Condition file or the difference between them.

22 Report Writer

22.1 Report Writer Overview

The Report Writer function generates printed reports and tab-delimited report for a list of files selected by the user. The reports include the information details selected by the user. The Peak Find results included in the reports are generated by a new peak find performed on any filtered type file when generating the report. Existing Peak Find STT files are not read or overwritten during the report process.

Because a peak find is performed every time a report is generated, it is simple to run multiple reports with different peak find parameters and compare the results.

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FILES TO SUM			· .		·				
								ADD FI	· · · · · · · · · · · · · · · · · · ·
FEAR FMD Par	UNETERS	SEFAULTS 180	PRINT	REPOR	Ð	PRINTEP) Town 20		a.va.	

22.2 Report Elements

Each potential report element is shown on the report menu and has a select button beside them. Any item selected will be included in the report. The user should limit the number of element for a printed report so all items can fit across one page.

There are two groups of elements on the display. The upper box contains items that will always appear as columns in the printed report and the export file. The

printed report will contain a header for each file in the report. The export file will contain only a single header at the beginning of the file.

The items in the smaller box will appear as individual lines in the printed report and as columns with header names in the export file.

<u>Full Filename</u> – The complete file name <u>Study</u> – The Study portion of the file name <u>Location</u> – The Location portion of the file name <u>Researcher</u> – The Researcher portion of the file name <u>Subject ID</u> – The subject ID of the file name <u>Filename</u> – The file name itself

Date – The date the file was created – from the header

<u>Accepted Runs</u> – Number of run accepted during the acquisition – from the header

<u>Total Runs</u> – total number of runs during the acquisition – from the header

<u>Peak Find Results</u> – all of these parameters are derived from a peak find performed as part of the report process

<u>Researcher Comments</u> – any comments recorded in the header file by the researcher when the file was created.

<u>Usage Comments</u> – any comments recorded in the header by the software when the file was created.

<u>Filter Parameters</u> – the filter parameters recorded in the header by the software when the file was generated. Older files do not contain this information

<u>Peak Find Parameters</u> – the peak find parameters shown on the menu when the report was generated

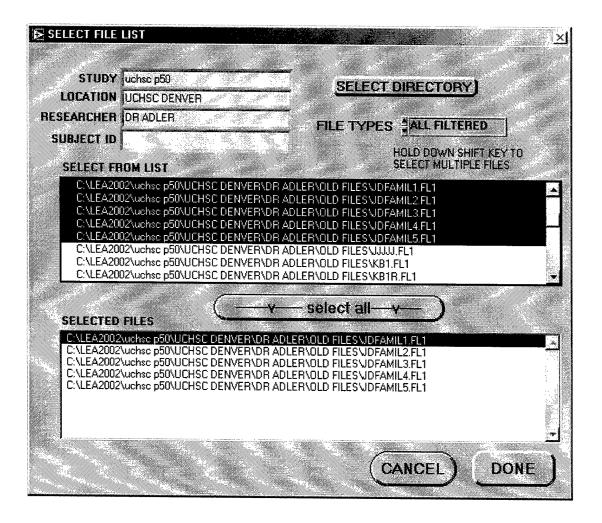
<u>Timing Template Name</u> – the timing template in use when the file was created. This is recorded in the header. Older files do not contain this information.

Blank Line Separator – when checked, the printed report will contain a blank line prior to the subsequent file record

22.3 Selecting files for the Report

The Add Files button displays the Select File list pop up. Multiple files can be selected at one time by holding down the shift key and clicking on multiple files

with the mouse. It may take a moment to fill the Select From List when directories containing a large number of files are accessed.



The Select Directory button displays the Select File or Wildcard pop up. This pop up can select a particular Subject ID path or can choose the files below a selected level in the directory structure. The example below shows ALL Subject Ids selected for the Dr Adler Researcher level.

Номе	DIRECTORY SCILEA20	02\	
STUDY	uchse p50		ALL STUDIES
LOCATION	UCHSC DENVER		ALL LOCATIONS
RESEARCHER	DR ADLER	-10	ALL RESEARCHERS
SUBJECT ID	OLD FILES	- O	ALL SUBJECT IDS

.

The selected files will be displayed in the Files to Summarize List. Multiple Add File operations can be performed until the file list contains all of the desired files.

" TULL PRË MAME	C CATE	ACCEPTED M.M.	12 TOTAL M.M.S	PEX PHOPESOL	nanining 1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 199 Nanining 1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999	allinininin tarihoosaana	arananan secondara S
STLOY LOCATION MESEARCHEN				ohi fi rand	i condition - Angulud 1953 - Angulud		
" SUBJECTIO E FILINIAE				or cand	CIRCRIPION ← ANFUTUD TEST ← ANFUTUD		/ 8
RESEARCHER (D URAGE COMMENT RELER PARAMETI PEAR FRID RERAM THING TEMPLATI BLAYK LINE SEFA	s PS QTERS Charge						44. 54,5 ,4.9 (1997) (1997) (1997)
ILES TO SUM		and and a considerably and a second	antimum		and the second	***	72
C. C. C. Station of the second	NOUTING THE	ATPORANTRAUAITE Mandrautrauaite Atrorautrauaite Atrorautrauaite	IN-SUBJECTN JFLA IN-SUBJECTN JFLA IN-SUBJECTN JFLA IN-SUBJECTN JFLA			ADO FIL	<u>BS</u>)
CULAMINAN	NOUTING THE	ACCIDENCEDICIST	I SICILLETTS SELE			ADD FE	

Files may be deleted from the list by clicking on the file and pressing the Remove File button.

The Peak Find Parameters box contains the settings for the peak find performed on filtered files in the report.

22.4 Creating a report

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A report can be generated after selecting the report elements, adding the files to summarize and setting the peak find parameters.

The Export File button will initiate creating a tab delimited style report file. A file pop up will request an output file name. An existing file can be overwritten with permission.

ENTER REPO	IRT FILE NAME				<u> </u>
Save in:			-	3 d¥ 🔳•	
History History Desktop My Documen					
My Compute	File name:	TEST REPORT] Custom Pattern (*.TXT	[]		Save Cancel

The generated file will contain a TXT extension. This file can be read by word processing programs or can be imported into a spreadsheet. Below shows an example file imported into Microsoft Excel.

	und Ayons. Juie Si	di man (n. 1997) 19 an					
N Parsan	E Carama	217080 8 - 215910	€	ing the second state			
3 8. 364731.1 4 8. 664731.1 4 8. 764731.1	1 ja 1 331 1 27, 1	K, ≩wi 8, 3≩1, 8, 5¥1	\$73 288 8 8 191 94	63 63 64 6 74 7	2 2 7	and the state of a sta	A N 201 20 20 20 20 20 20 20 20 20 20 20 20 20
a e a sil visi an Desti					(a.,		

A report can be printed by pressing the Print Report button. The report will be printed to the printer selected on the screen. The report will be printed in landscape mode. Below is an example of a printout.

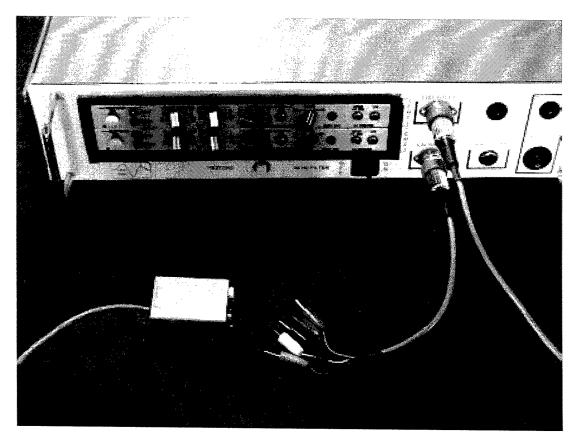
23 Diagnostics

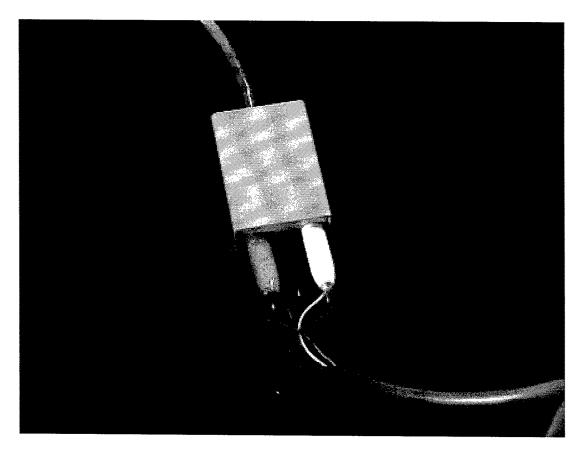
23.1 System Loopback

The system loopback test provides a complete functional test of the LEA2002 hardware. This is accomplished by feeding the output of the click tone generator back into the electrode inputs. When the test is run, the tone generator output is internally fed to the calibration output connector. Using the calibration cable, the signal is fed into the electrode inputs.

23.1.1 Running the test

Connect the calibration cable to the LEA2002 calibration connector and to the electrode box as shown. The loopback cable has 5 plugs on one end and a green DIN circular connector on the other end.

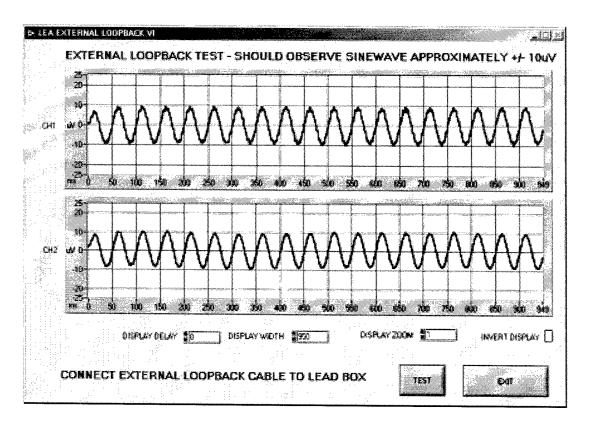




Each plug on the end of the loopback cable plugs into a socket of the same color.

From the LEA2002 main menu, select Run System Loopback Test (with cable). Press the TEST button.

A sine wave of approximately +/- 10mV should appear on both channels.



Red and White are channel two, Green and Blue are channel one. If either channel does not show the correct waveform then check for the proper connections. If the connections are good, then swap the electrode cable and the loopback cable with another set of cables and test again. If swapping cables does not solve the problem then the unit may require repair.

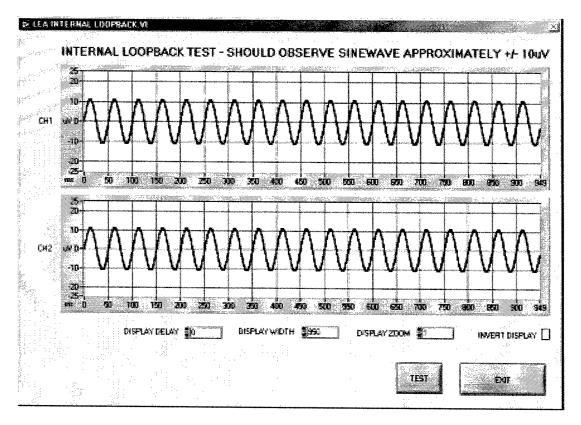
23.2Internal Test

The Internal Test exercises the acquisition control board electronics only. It does not test the electrode cable or the input amplifiers and filters. It accomplishes this by feeding the click tone generator output to the analog input of the acquisition control. The LEA2002 software sends commands to the acquisition system to properly configure the board for this test.

23.2.1 Running the test

From the LEA2002 main menu, select the Run Internal Test (digital electronics only) function. Press test in this menu. If the headphones are plugged into the LEA2000 hardware, a tone will be heard - this is normal.

The graph should display an approximately +/- 10mV sine wave for each channel. If there is no communication error and the display is incorrect, then the



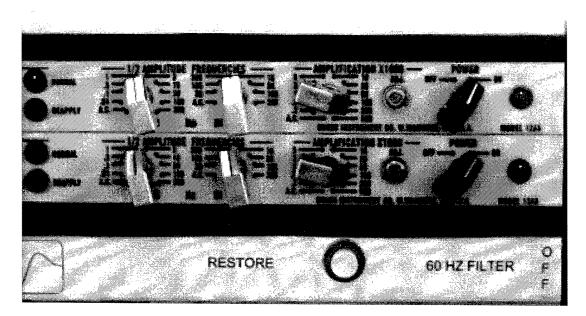
unit requires repair. If there is a communication error, refer to troubleshooting communication errors.

23.3 Calibration

CAUTION: Calibration should only be attempted by a skilled technician with the proper tools. Calibration levels are set during construction and are not likely to require resetting.

The External loopback function can be used with an external signal source for a true calibration check. The external source can be connected to one channel at a time and the test run to check the acquired signal.

A 10uV, 20Hz sine wave makes a good calibration source. The gain can be calibrated on the front of each channel amplifier using the ADJ control and a small tip screwdriver.



A resistor divider can be used to reduce the signal output of a function generator down to +/-10uV. A 100,000 divider (100K Ohm and a 1 Ohm resistor) will reduce a +/- 1V signal to +/-10uV. The accuracy of the signal will depend on the accuracy of the resistors used for the divider.

24 Troubleshooting Communication Errors

There are two potential error messages that are reported by LEA2002. The first message "device not found" means that the communication port number that LEA2002 is trying to access does not exist. This means that the communications port number selected in the Edit Settings menu does not exist and must be changed. Refer to the software installation section and select the proper communication port.

The other error "serial communication error" is reported when LEA2002 software does not receive a proper response from the LEA2011 hardware. This can for a number of reasons:

- LEA2002 hardware is unplugged or the power switch is off. Check the power connection and power switch. The power light should be on. If the unit is plugged in, the power light is on and the power light is off, then refer to troubleshooting the LEA2002 hardware.
- The communication cable is not connected. Check the cable connections. Run the Internal Test program and observe the LED on the USB-RS232 adapter. The LED should flash every time the TEST button is pressed. If the LED does not flash, then the adapter is not properly installed or the proper port is not selected. Refer to the installation for the hardware and software and ensure the adapter is properly installed and the proper port has been selected.

The communication is through a straight RS-232 connection rather than a USB-RS-232 adapter. The straight RS-232 connection to a computer can randomly produce byte errors when running with acquisition times greater than 950ms. Even with shorter acquisition times, an error may occur every 30 or 40 sweeps. These errors can be ignored – the data for that one sweep will be lost, but the acquisition can continue.

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25 File structure details

25.1 Header File

Filename.%PA contains the raw header information only. ASC files, filtered files, grand sum and difference files all include the header information at the beginning of the file (internally).

Line	Content				
1	FILE TYPE: 3				
2	Length: 450				
3	TEMPLATE: C:\LEA2002\P50 STANDARD.TTL				
4	DAY: 12				
5	MONTH: 10				
6	YEAR: 2000				
7	TOTAL SWEEPS: 24				
8	ACCEPTED SWEEPS: 16				
9	TIME DELAY: 100				
10	FILTER PARAMETERS: DEFAULT REPLAY				
11	0				
12	0				
13	RESEARCHER: DR ADLER;				
14	LOCATION: UCHSC DENVER;				
15	COMMENT LINE #1: ;				
16	LINE #2: ;				
17	LINE #3: ;				
18	LINE #4: ;				
19	SUBJECT ID: SUBJECT A;				
20	FULL FILE NAME: C:\LEA2002\uchsc p50\UCHSC DENVER\DR				
	ADLER\SUBJECT A\SUBJECT A_2;				
21	0				
22	0				
23	0				

File Type = 3 for all old style files. New files will contain the file extension like .ASC or .FLA.

Lines 2,3,10 will contain "0" in old file types.

Line 13 is labeled OPERATOR in old file types.

If SUB file type: Line 21:"Difference between:" Line 22: <FILE A> Line 23:<FILE B> <u>If SFT (shift) file type:</u> Line 21:<shift mode>,<relative to> Line 22: <ch1condshift>,<ch1testhsift>,<ch2condshift>,<ch2testshift>

25.2 RAW data files

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Filename.RAW# contains the acquired data for one sweep

Example: FILE TYPE: RAW LENGTH:950 TEMPLATE: C:\LEA2002\P50 STANDARD.TTL 89 -92 81 - 100 13 - 103 55 -65 31 - 73 18-100 68 - 88 17 - 77 6 -66 18-102 41 - 79 70-85 61 - 64 7 -65 -40 -65 .

25.3 Sweep File

Filename.swp - list of all accepted sweeps

Example:

1 2 4

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- 6
- 9
- 11
- 16

25.4 SUM File

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<u>Filename.ASC</u> contains header and the sum of all the selected sweeps. To display, the values must be divided by the number of accepted runs from the header.

```
[header -- see description above]

1 364 625

2 1055 -239

3 -827 -2428

. sums of all the selected sweeps

.

.

898 1903 180

899 625 -272

900 -1356 -473
```

25.5 Filtered files

<u>Filename.FL1</u> is the same format as .ASC but it contains the filtered version of the sum file. Must divide by the number of accepted sweeps to get actual value.

There is only one filtered file for a particular .ASC or .GD1 and they are written over with permission.

.ASC will now produce .FLA (Filtered ASCII) .SUB will now produce .FLD (Filtered difference) .GD1 will now produce .FLG (Filtered Grand sum) .SFT will now produce .FLS (Filtered Shifted)

old FL1 files will still be read and all filtered files will be grouped as .FL* for file display purposes.

25.6 Grand Sum Files

Filename.GD1 same format as .ASC but contains the sum of a files.

25.7 Grand List Files

<u>Filename.GL1</u> contains the filenames of the files summed for the Grand Sum file of the same name.

Example: ALLFINE2.ASC ALLFINE3.ASC BLO6M1.ASC BLO6M2.ASC

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25.8 Raw Data Files (old style)

Filename.%1A contains sweeps 1..32 [blank] SWEEP # 1 [blank] 320 -612 -951 -116 first 450 samples .106 116 551 -151 2048 - 640 2048-535 second 450 samples .-587 -268 -881 -89 SWEEP # 2 913 - 193 155 105 -131 230 265 - 20 Filename.%2A contains sweeps 33..64 _____ [blank] SWEEP # 33 [blank] 320 - 612 -951 -116 first 450 samples . .106 116 551 - 151 2048 - 640 2048-535 second 450 samples .-587 -268

-881 -89

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25.9 Peak find results file

Filename.STT contains the results of peak find. Written over with permission.

File Name DEDFAMI2.FL1								
Sweeps Accepted	Delay	Left Window Edge	Right Window Edge	Window Width	Amplitude			
16	100	40	75	10	1.000000			
Channel	Cond. Lat.	Condition Shoulder		Test Shoulder	Condition Amplitude	Test Amplitude	Ratio	
1 2	52 48	27 33	60 47	24 31	4.988235 1.788235	4.341177 1.376471	87.028297 76.973686	

25.10PEP97 and CEPAN definition files

.DEF files are used by PEP97/CEPAN to set the operating parameters and directories. These parameters are either set in the setup file/function of LEA2000 or shown as defaults in the individual screen. LEA2000 also offers full pop-up file control of path and directories.

These files are not used and are not created by LEA2000

%%CREATE.DEF %%CHNL.DEF %%PATH.DEF %%PKPARM.DEF %%TIME.DEF

25.11 File Usage by Function:

25.11.1 Acquire data

Process creates:%PA, SWP, RAW (one for each sweep), ASC and FLA

25.11.2 Filter data

INPUT FILES: Sum files: .ASC Grand Sum Files: .GD1 Subtracted files: .SUB Shifted files: .SFT

OUTPUT FILES:

3

Filtering an ASC file will produce an FLA file. The filename will be the same as input file name with an FLA extension rather than an ASC extension.

Filtering a SUB (Difference) file will produce an FLD file (Filtered Difference). The filename will be the same as input file name with an FLD extension rather than an SUB extension.

Filtering a GD1 (Grand Sum) file will produce an FLG file (Filtered Grand Sum). The filename will be the same as input file name with an FLG extension rather than an GD1 extension.

Filtering and SFT (Shifted) file will produce and FLS file (Filtered Shifted). The filename will be the same as input file name with an FLS extension rather than an SFT extension.

Currently CEPAN filtering writes over old file without asking.

Filtered file will contain filename of the unfiltered source and the filter parameters used.

25.11.3 Shift data

INPUT FILES: Sum files: .ASC Grand Sum Files: .GD1 Subtracted files: .SUB Filtered files: .FL1

OUTPUT FILE: inputfilename.SFT which will overwrite existing file with permission (if exists).

Currently CEPAN overwrites existing file without asking.

Shifted file will contain filename of the unshifted file, shift mode and amount of shift in the comments.

25.11.4 Grand Sum data

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INPUT FILES: Sum files: .ASC Grand Sum Files: .GD1 Subtracted files: .SUB Shifted files: .SFT Filtered files: .FL1

OUTPUT FILE: newfilename.GD1 contains the sum, format same as .ASC OUTPUT FILE: newfilename.SWP contains the list of files in the sum.

25.11.5 Subtract/Short Latency Subtract data

INPUT FILES: Sum files: .ASC Grand Sum Files: .GD1 Subtracted files: .SUB Shifted files: .SFT Filtered files: .FL1

OUTPUT FILE: newfilename.SUB contains the sum, format same as .ASC

File will contain names of files subtracted in the header.

Filename: Directory: Template:	LEA2001_OPERATORS_GUIDE.doc C:\projects\uchsc\MANUAL C:\WINDOWS\Application					
Data\Microsoft\Templates\Normal.dot						
Title:	Data Collection					
Subject:						
Author:	Jim Graydon					
Keywords:	-					
Comments:						
Creation Date:	11/29/2001 10:09 AM					
Change Number:	31					
Last Saved On:	1/13/2002 2:05 PM					
Last Saved By:	Jim Graydon					
Total Editing Time:	2,199 Minutes					
Last Printed On:	1/13/2002 2:06 PM					
As of Last Complete Printing						
Number of Pages: 104						
Number of Words: 11,459						
Number of Characters: 56,781						

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APPENDIX IV – PUBLISHED ABSTRACT

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Abstract Title

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Impaired Auditory Sensory Gating in Soldiers Preparing for Extended Deployment to Bosnia

Author Names

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Abstract Text (250 Words)

<u>Background</u>. Establishing valid neurophysiologic parameters to measure deployment stress is relevant both to combat readiness at the unit level and long-term health consequences for military service members.

<u>Methods</u>. 27 soldiers were evaluated four weeks prior to a scheduled six-month deployment to Bosnia. Two separate neurophysiologic techniques (P50 sensory gating and pre-pulse inhibition of acoustic startle) were used to measure auditory information processing. Biological measures included plasma-free catecholamines. The Symptom Checklist 90-Revised (SCL-90-R) was used as an objective psychological measure.

<u>Results</u>. Approximately half of soldiers (n = 26) evaluated during pre-deployment have P50 auditory sensory gating impairment compared with only 10% of individuals in the normal population. In contrast, most soldiers (n = 25) maintained some pre-pulse inhibition of acoustic startle. Pre-pulse inhibition was consistent within soldiers when comparing two blocks of pre-pulse startle trials (Pearson's correlation coefficient is 0.4, p=0.04). Mean plasma-free MHPG for pre-deploying soldiers (n = 23) was 16.8 +/- 4.5 s.d. ng/ml, four times as high as levels previously measured in normal controls. On the SCL-90-R, t-scores scales of anxiety, hostility, and somatization were highly correlated.

Conclusions.

Soldiers experiencing pre-deployment stress may have diminished P50 auditory sensory gating. Pre-pulse inhibition in this population is a reliable measure, which does not change in parallel with P50 gating. P50 gating may be more sensitive to increased

catecholaminergic neuronal transmission. Soldiers may express their symptoms somatically rather than talking about their underlying anxiety. Deployment stress does result in symptomatic and neurophysiological changes, which can be measured by several different techniques.

Presentation

Poster

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Category

Electrophysiology

Presentation Exclusion Date

May 5, 2000