

**Sensor Headset™ Model 603-B
Technical Manual**

Advanced Brain Monitoring, Inc.

2850 Pio Pico Drive, Suite A

Carlsbad, CA 92008

760.720.0099

www.b-alert.com

Sensor Headset Model 603-B Technical Manual

Table of Contents

Chapter 1: Safety Information and Introduction.....	3
A. Safety.....	3
B. About Sensor Headset® Model 603-B.....	5
C. Package Contents	5
D. Minimum System Requirements.....	6
Chapter 2: Installing Software and System Set-Up	7
A. Installing Sensor Headset Software:	7
B. Preparing the Host Unit for Use:.....	7
C. Preparing the Head Unit for Use:.....	7
D. Using the Head and Host Units.....	8
E. Recharging the Batteries on the Head Unit.....	8
F. Preparing the Sensors for Use.....	9
G. Applying the Sensor Headset.....	10
H. Removing the Headset and EEG Sensors	10
I. Cleaning the Sensor.....	11
J. Sensor Care	11
K. Care for the Sensor Headset.....	12
Chapter 3: Software Options and Settings.....	13
A. Introduction to Sensor Headset Software.....	13
B. Main Screen.....	14
C. Operations	15
D. Settings	18
E. Monitor Menu	22
F. Selecting File Name.....	Error! Bookmark not defined.
G. Impedance Monitoring	27
H. Acquiring Baseline Data	28
Chapter 4: Recording and Viewing of Physiological Data	23
A. Establishing a Connection with the Wireless Headset System.....	23
B. Acquiring and Off-line Viewing of Signals.....	27
C. Applying Real-Time Classification	23
D. Applying Tech Monitoring	25
E. Generation of Baseline Files and Definition Files:...	Error! Bookmark not defined.
F. Viewing of Decontaminated Signals:	Error! Bookmark not defined.
G. Generating Output Files	32

Sensor Headset Model 603-B Specifications	37
Software.....	37
Compliance	39
A. FCC	39
B. General Compliance.....	41
Software License Agreement.....	42
Software Limited Warranty	43
Product Limited Warranty	44
Returns	45
Service	45
Customer Support.....	45
Warranty Information.....	46
Trademark Acknowledgements.....	46

DRAFT

Chapter 1: Safety Information and Introduction

A. Safety

The Model 603-B is designed to be applied by a trained technician. There are a number of warnings, and cautions throughout this manual. Read them carefully: they are important to the use of the product.

The information in this manual has been carefully checked and is believed to be accurate. In the interest of continued product development, ABM reserves the right to make changes and improvements to this manual and the products it describes at any time, without notice or obligation.

U.S. Federal law restricts this device to sale by or on the order of physician when used to monitor brain states associated with daytime somnolence in adult patients to confirm a pre-existing disorder and/or to monitor the effects of treatment.

CAUTION! Read this manual carefully before using the Model 603-B.



Contraindications

- Do not use the Model 603-B in an MRI environment.
- Do not use the Model 603-B in a situation where alarms are required. Model 603-B has no alarms.
- Electromagnetic interference from cell phones transmitting in the 940 – 950 MHz range (i.e., used for the base station to mobile station transmission of for mobile networks in Japan and Europe) may result in incorrect EEG indices and/or misclassification of brain state.



Warnings

- Explosion Hazard. Do not use the Model 603-B in an explosive atmosphere.
- Explosion Hazard. Do not use the Model 603-B in the presence of flammable anesthetics or gases.
- Explosion Hazard. Do not use the Model 603-B battery recharging system with non-rechargeable batteries.
- Permanent Damage and/or Warranty Voidance. Model 603-B must be repaired by trained ABM personnel only. Any evidence of opening the system, field service by non-ABM personnel, tampering, or any kind of system misuse or abuse shall void the warranty.
- Synapse® Conductive Electrode Cream is recommended for use with the EEG sensors. Use of any conductive gel, cream or electrolyte other than Synapse® may affect signal quality, signal accuracy or damage the EEG sensor.
- To comply with Model 603-B Transportation and Storage Environmental Condition specifications, Synapse® must be shipped separately. To order, contact Med-Tek/Synapse® at (800) 359-1326.
- Avoid placement of EEG sensors or application of Synapse cream directly into an open wound.

Cautions - General



- The Model 603-B should only be applied by a trained technician. This model is not intended for in-home use.
- Do not spray, pour, or spill any liquid on the Model 603-B, its connectors, switches, or openings, or it will cause permanent damage and void the Warranty.
- Do not use caustic or abrasive cleaning agents on the Model 603-B or on the EEG sensors or it will cause permanent damage and void the Warranty.
- This device has been tested and found to comply with the limits for medical devices to the IEC 60601 standards. These standards are designed to provide reasonable protection for safety and against harmful interference in a typical medical installation.
- Verify that all visible indicators illuminate during the startup (initialization) sequence. If any indicator is not lit, do not use the Model 603-B. Contact ABM Customer Support for repair or replacement.



Cautions - Battery

- Two 800 mA AAA Nickel-Metal Hydride rechargeable batteries are recommended for operation.
- For optimal performance, recharge the batteries immediately prior to use.
- To avoid battery leakage, do not use different types of batteries and/or mix fully and partially charged batteries at the same time.
- To avoid the risk of leakage, remove the batteries if the Model 603-B will be not be used for more than one month.
- Damage to Model 603-B resulting from battery leakage voids the warranty.
- When replacing batteries, only remove the battery covers.
- Do not recharge the Model 603-B with non-rechargeable batteries.
- Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries. Batteries might leak or explode if used or disposed of improperly.

Guide to Symbols:



Warnings are identified by the WARNING symbol shown to the left.



Cautions are identified by the CAUTION symbol shown to the left.



Type BF



Attention – See Instructions for Use is identified by the ATTENTION symbol shown to the left.

B. About the Sensor Headset Model 603-B

The Sensor Headset is an internally battery powered Type BF device intended for continuous use. The Sensor Headset provides an integrated approach for wireless acquisition and recording of electroencephalographic (EEG) and electrooculargraphic (EOG) signals. The Sensor Headset utilized the patented Sensor Headset and patent-pending disposable EEG sensors to acquire high quality EEG recordings. The Sensor Headset can be self-applied in less than five-minutes with no scalp preparation. The wireless technology allows the user to be untethered and move around the clinic while real time data is collected, displayed, and analyzed.

The Sensor Headset Model 603-B, which provides three channels of bi-polar recordings and three channels of monopolar recordings, is recommended for use with ABM's patented Sensor Headset analysis software, ERP analysis software, and Alertness and Memory Profiler™ software to quantify alertness, drowsiness, memory and/or mental workload.

The Sensor Headset Model 603-B consists of: Head and Host Units for bi-directional transmission of digitized physiological signals, a Sensor Headset that locates EEG sensors at Fz, Cz, and POz, linked mastoids for the monopolar channels, bi-polar EOG signals, 30 disposable EEG sensors, 20 disposable EEG electrodes, conductive gel, batteries, EEG Acquisition software, and users manual.

The Transceiver Unit collects signals from the sensors attached to the user, performs analog-to-digital conversion, encoding, formatting and transmitting of all signals. The signals are communicated using a 2.4 to 2.48 GHz radio transmitter. The Sensor Headset software utilizes the bi-directional capabilities of the system to initiate scalp-electrode impedance monitoring, and monitors the battery capacity in the Transceiver Unit. A standard Class 2 blue tooth dongle is used as the base unit affixed to the PC workstation.

The Sensor Headset Acquisition Software consists of several modules that allow the user to acquire, store, view, and analyze physiological signals acquired by the wireless system. The software provides a simple graphical interface for establishing and controlling data acquisition. Patented algorithms can be selected to monitor artifacts that impact signal quality in real time and sound an alarm when thresholds are exceeded. EEG Indices (Power Spectra) and brain states can be generated in real-time or off-line.

Caution: The Sensor Headset, when used according to the Technical Manual, complies with Maximum Permissible Exposure (MPE) requirements because the maximum composite output from the antenna does not exceed 0.004018 Watts EIRP and the antenna is at least 1cm away from all persons.

Caution: U.S. Federal law restricts this device to sale by or on the order of physician when used to monitor brain states associated with daytime somnolence in adult patients to confirm a pre-existing disorder and/or to monitor the effects of treatment.

C. Package Contents

Confirm that the items listed below are packed with the Sensor Headset Model 603-B. The shipment should include:

- ☐ Sensor Cap with Sensor Strip (one medium size)
- ☐ Head Unit
- ☐ Host interface
- ☐ Two AAA NiMH rechargeable batteries.
- ☐ 30 EEG sensors
- ☐ 20 disposable EEG/EOG electrodes
- ☐ **100 Sensor foam pads**
- ☐ EEG Sensor pry tool.
- ☐ Battery Charging Cable
- ☐ Sensor Headset Software CD
- ☐ User's Guide
- ☐ Warranty Form (separate from User Guide)

If any item on this list is missing or damaged, contact Advanced Brain Monitoring. Contact the carrier immediately if the shipping carton is damaged.

D. Minimum System Requirements

- Personal computer with minimum Pentium™ 450 MHz processor (recommend Pentium™ 750 MHz or higher when using technician monitoring features);
- Microsoft® Windows 98, Windows NT 4.0, Windows 2000, or Windows XP or higher;
- Minimum of 64 MB (recommend 128 MB) of installed memory for use with Windows operating system;
- Minimum 50 MB free hard disk space;
- One CD-ROM drive
- VGA or higher resolution video adapter;
- One USB port.

Chapter 2: Installing Software and System Set-Up

A. Installing Sensor Headset Software:

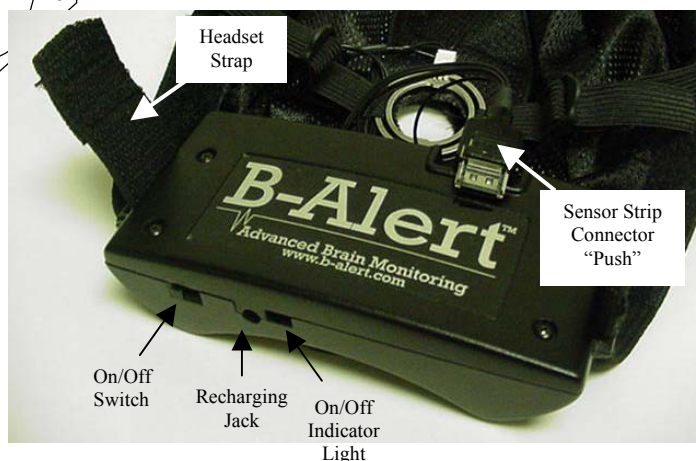
1. Place the CD in your CD-ROM drive.
2. Using Windows Explorer, create a folder called Sensor Headset on your hard disk drive.
3. Copy the file “**Sensor Headset_ACQ.exe**” from the CD to the folder labeled ABM_Sensor Headset.
4. Click on “**Sensor Headset_ACQ.exe**” to open the program.
5. Create a shortcut to Sensor Headset on your desktop.

B. Preparing the Host Unit for Use:

1. Insert a Class II Blue Tooth Dongle into a USB port of the PC workstation.

C. Preparing the Head Unit for Use:

1. Disconnect the battery covers, insert one AAA battery into each compartment, make sure + and – are properly aligned. Reattach the covers.
2. Insert the headset straps through the strap-holders.
3. Insert the **Sensor Strip** Connector into the Head Unit with the “Push” tab facing outward.



D. Using the Head and Host Units

1. Turn the Head Unit on. The green indicator light will turn on and the red indicator light will start blinking.
2. Confirm a **Host Unit (i.e., USB Dongle)** is inserted in the USB port of the PC Workstation.
3. The red indicator light on the Head Unit will turn off as soon as the wireless link is established.
4. If the red indicator light continues to blink on the Head unit, turn it off. Repeat steps 1 and 2.
5. **The absorption and reflection of the Sensor Headset wireless transmission and interference from cell phones in the 940 – 958 MHz range are affected by structures, objects and people.** To improve RF Signal Quality:
 - Make sure both Units are within 20 feet of each other.
 - **Reduce the obstructions between and avoid metal objects in the line-of sight of the head and host units.**

E. Recharging the Batteries on the Head Unit

Two fully charged 900 mA AAA Ni-MH batteries in the Head Unit can provide sufficient power for seven hours of continuous use. To recharge batteries:

1. **Make sure the Head Unit is turned off (both green and red indicator lights should be off).**
2. **Connect the Type “A” connector of the charging cable into a USB port of a PC workstation.**
3. **Remove the Sensor Strip Connect from the Head Unit and insert the opposite end of the charging cable.**
4. Turn on the Host Unit. The green Charging Indicator LED on the host unit will automatically turn On when charging starts and turn Off when charging has completed.
5. When the Charging Indicator LED turns off, and remove the recharging cable from the Head Unit.
6. **The capacity of recharged batteries declines as a function of time. Approximately one week after a recharging the batteries will loose about 30% of recording time (from 7 to 5 hours). Recharge as needed to record for the necessary length of time.**
7. **A slight recharging memory effect can occur when Nickel-Metal Hydride batteries are not fully drained between charges. If you notice a significant reduction in the amount of continuous recording time after each charge, leave the head unit on until the batteries are fully drained, and then recharge. If the problem persists, replace the batteries**

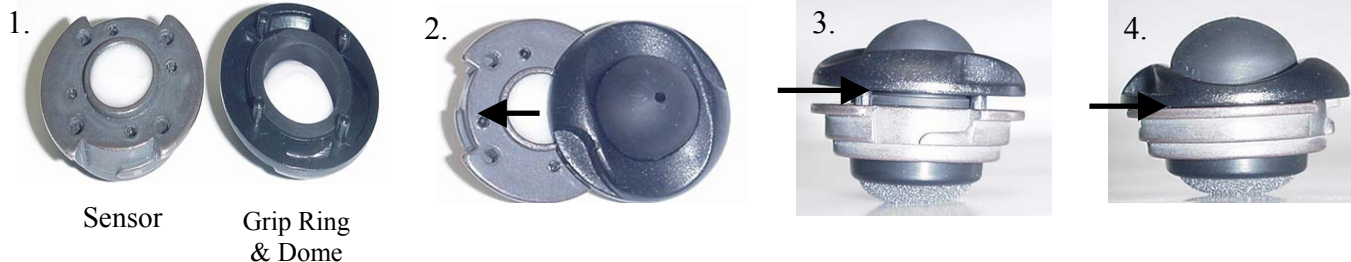


Caution:

- Two AAA Nickel-Metal Hydride rechargeable batteries are recommended for operation in the Head Unit. **If Nickel-Cadmium batteries are used, the batteries must be fully drained before recharging to avoid an immediate recharging memory effect.**
- To avoid battery leakage, do not use different types of batteries and/or mix fully and partially charged batteries at the same time.
- To avoid the risk of leakage, remove the batteries if the Model 603-B will not be used for more than one month.
- When replacing batteries, only remove the battery covers.
- Do not use the Model 603-B battery recharging system with non-rechargeable batteries.
- Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries. Batteries might leak or explode if used or disposed of improperly.
- Patient should never be connected to Sensor Headset when recharging batteries.

F. Preparing the Sensors for Use

1. **Replace the sensor foam and firmly seat the foam ring.**
2. Fill the sensor cavity level with the top edge and the dome between $\frac{1}{3}$ and $\frac{1}{2}$ full with conductive cream. Do not overfill!
3. Align the sensor holes and the grip ring pegs so that the cut-out edge of the sensor matches the shape of the grip ring as shown in the photo below.
4. Press down slightly on the dome to make sure it is seated around the lip of the sensor. This step reduces the chance of conductive cream leaking out.
5. Firmly press together the grip ring and sensor so the edges are flush.
6. Sensors can be filled with gel and stored upright in an air-tight container for later use. The conductive cream is water-based so some evaporation may occur. Do not store for more than one week.
7. Align cut-out edge of the sensor with the notch on the stainless steel ring and insert. Twist the sensor clockwise slightly approximately 2 mm. Do not over-tighten the sensor.
8. Add a small amount of conductive cream to the electrodes to be used for the mastoid and EOG sites. **Note: To avoid DC potentials, the same conductive cream should be used with all sensors and electrodes.**



G. Applying the Sensor Headset

1. Measure the distance from the nasium to theinion and select the appropriate Sensor Headset size.

Size	Nasium - Inion
Small	32.0 – 34.5 cm
Medium	35.0 – 37.0 cm
Large	≥ 37.5 cm

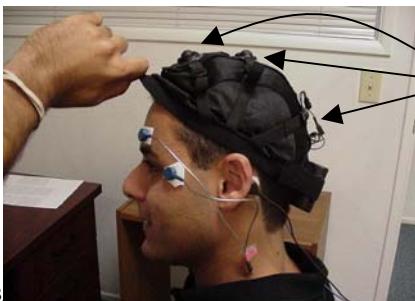


2. Make sure all of the sensor straps are loose. Place the headset on from front to back, center the sensor holes, and adjust the Sensor Headset until you can feel the inion below the alignment hole (under the Head Unit).
3. Tighten the headset straps until the Headset is secure, yet comfortable.
4. Lift up on the conductive rings so that the Sensor is approximately 1/4 inch above the hair. With your finger over the dome hole, press slowly on the rubber dome until the conductive cream is felt on the scalp. Release the conductive ring.
5. Pull gently outward on the sensor straps to increase tension on the Sensor against the scalp. Lift up on the quick-release strap holder to decrease tension.



H. Removing the Headset and EEG Sensors

1. After testing is complete, turn off all equipment.
2. Disconnect the EOG and mastoid EEG cables from the headset (if applicable).
3. Keeping the sensors attached, Slowly remove the headset.
4. Disconnect the Sensor strip from the Headset by pressing on the release button and gently pulling the connector straight out.
5. Remove the EEG sensors from the strip and set aside for cleaning.
6. Clean the conductive rings on the Sensor Strip with an alcohol wipe.



Keep
sensors
attached



Push down
to release

I. Cleaning the Sensor

Warnings:

- Proper cleaning of the sensors is required prior to reuse.
- Do not reuse sensors that have been exposed to an open wound or a head disease.

1. What you need to start

- Latex gloves.
- Electrode cleaning tool.
- Anti-bacterial soap – “Dial Complete” with foaming dispenser.

2. Disassembling the Sensor

- Place the flat edge of the electrode tool between the sensor body and the grip ring and gently begin to pry the grip ring from the sensor body.
- Work both sides of the grip ring loose and separate the dome from the grip ring.
- **Place the flat edge of the electrode tool between the sensor body and the foam ring and gently begin to pry the foam ring from the sensor body.**
- **Remove the foam ring and discard the foam.**

3. Removing the gel

- Using warm running water, the electrode cleaning tool and the anti-bacterial soap, wash the gel out of the sensor components.
- Pay special attention to the following areas where the gel can get trapped.

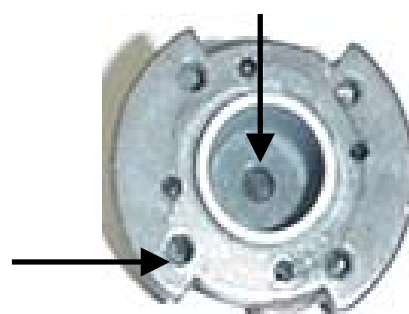
4. Final rinsing

- Remove and rinse the components under warm running water.
- Allow the parts to drip dry on a paper towel.
- **When dry, affix a new sensor foam piece and reassemble the sensors.**



J. Sensor Care

1. If cream dries on the foam inside the sensor cavity, use soap and warm water to remove before reusing the sensor.
2. Avoid use of sharp or metal objects that may scratch the sensor. **Scratched sensors should not be reused.**
3. Remove the sensors from the stainless steel rings after use or discoloration may occur. **Discolored sensors should not be reused.**



K. Instructions for Cleaning the Sensor Headset

1. Disconnect the **sensor strip connector** from the Head Unit.
2. Disconnect the four snaps between the Sensor Cap and Sensor Strip and remove the Sensor Strip.
3. Hand-wash the Sensor Cap with Woolite or mild laundry detergent. Rinse thoroughly with warm water. Air dry.
4. Clean the Sensor Strip with an alcohol wipe to remove any gel.
5. When the Sensor Cap is dry, confirm the Sensor Cap and Sensor Strip are the same size (e.g., small, medium or large) and reconnect.



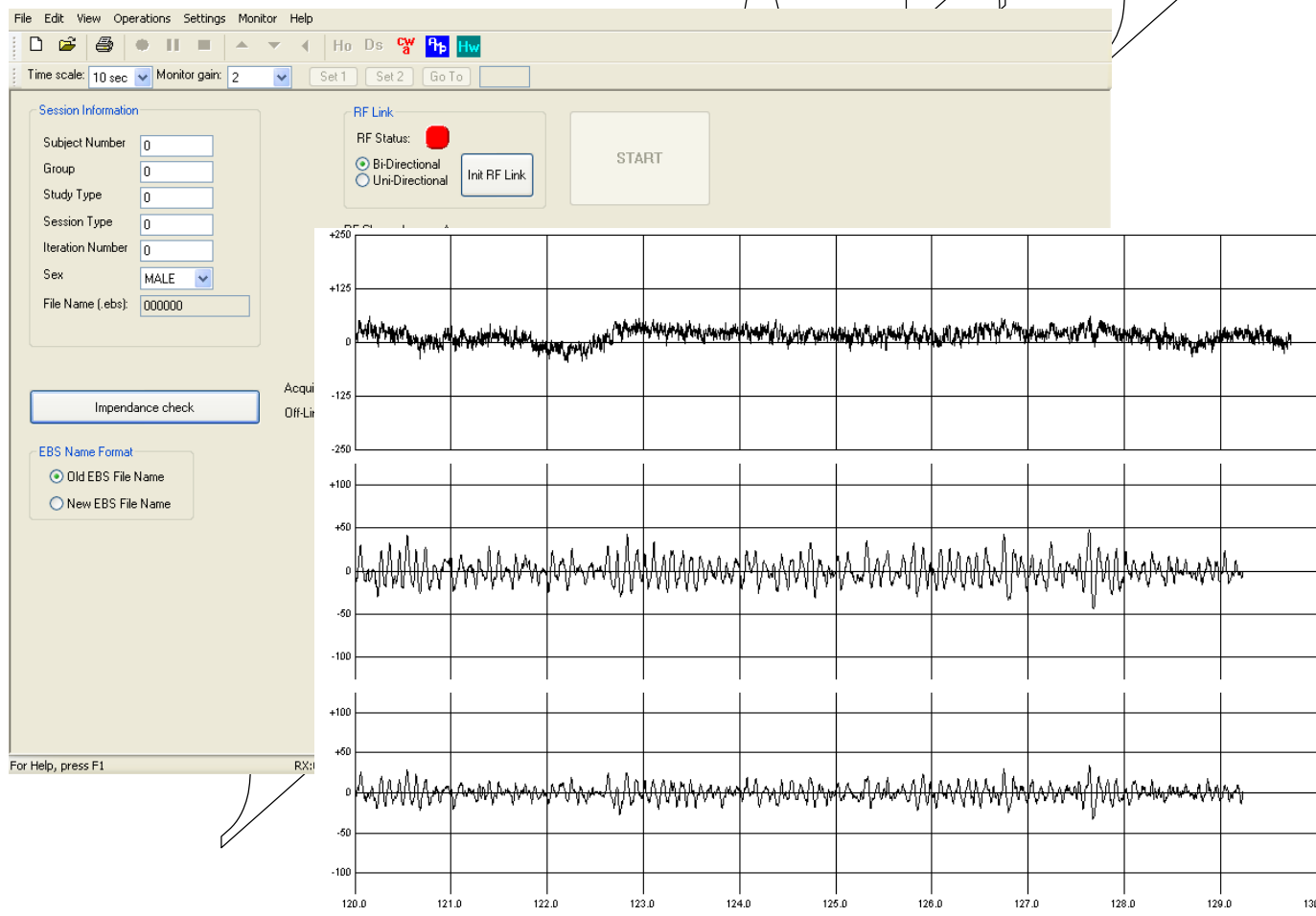
Cautions:

- For optimal recordings, clean the sensor immediately after use.
- Sensors are recommended for a maximum of 20 uses.
- Discolored or scratched sensors will affect signal quality and must be replaced.
- When removing the sensor strip from the headset, do not pull or jerk the connector.

Chapter 3: Software Options and Settings

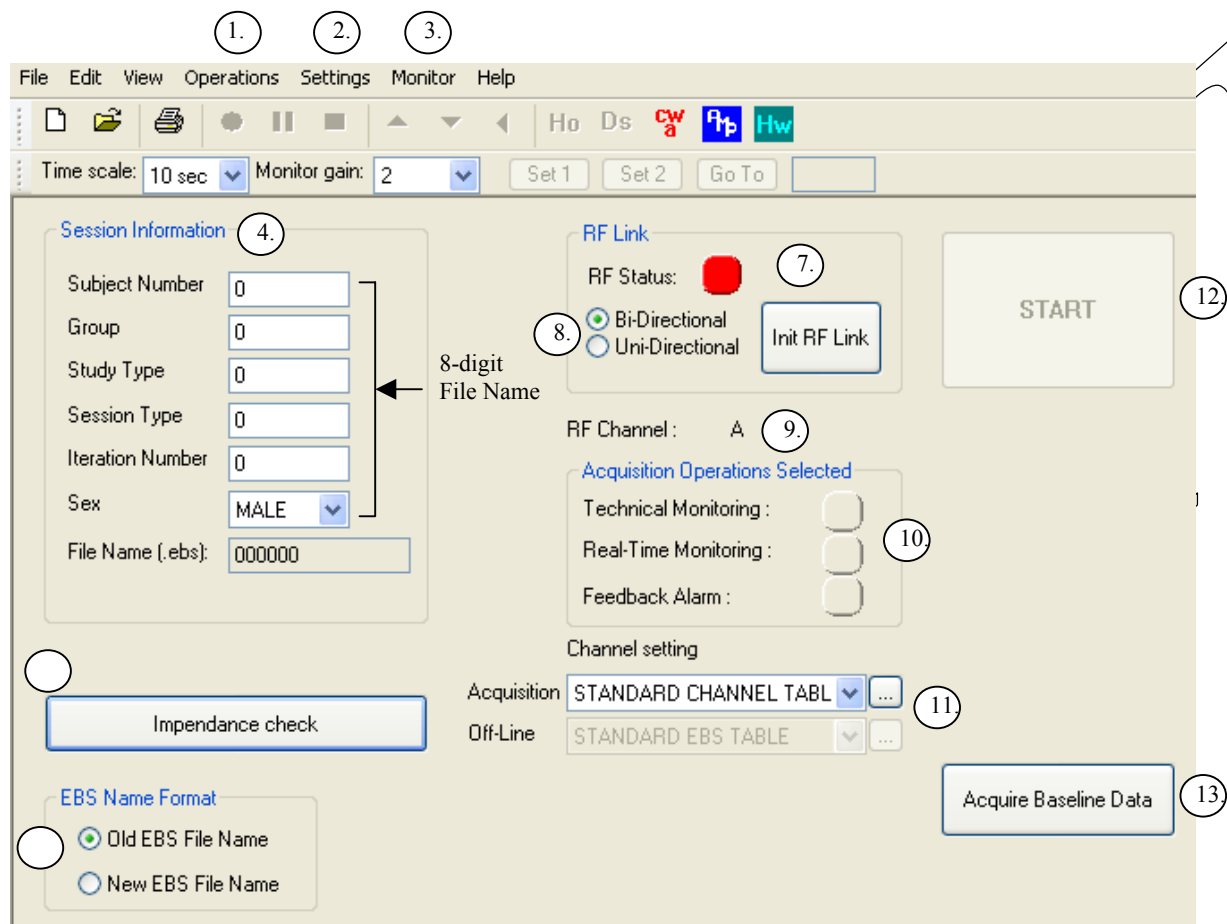
A. Introduction to Sensor Headset Software

The Sensor Headset Software provides the capability to acquire, store, view, and analyze analog signals during acquisition. In addition to viewing the EEG and EOG signals, the software provides the capability to analyze the signals in real time, allowing the user to monitor artifacts and other problems that can affect signal quality. This feature allows analog signals to be optionally monitored after identification and decontamination of eye blinks, muscle artifacts, amplifier saturation and dropped packets across the RF link. Thresholds can be selected to trigger an alarm that alerts the technician when excessive amounts of artifact are being recorded. In addition to monitoring artifact, the Sensor Headset software can notify the technician of low battery levels in the Head Unit and high scalp-electrode impedances. The program can also present vertical marks in the record during certain tasks to identify when a stimulus is presented and when the user responds.



B. Main Screen

The features of the Main Screen for the Sensor Headset Software include:



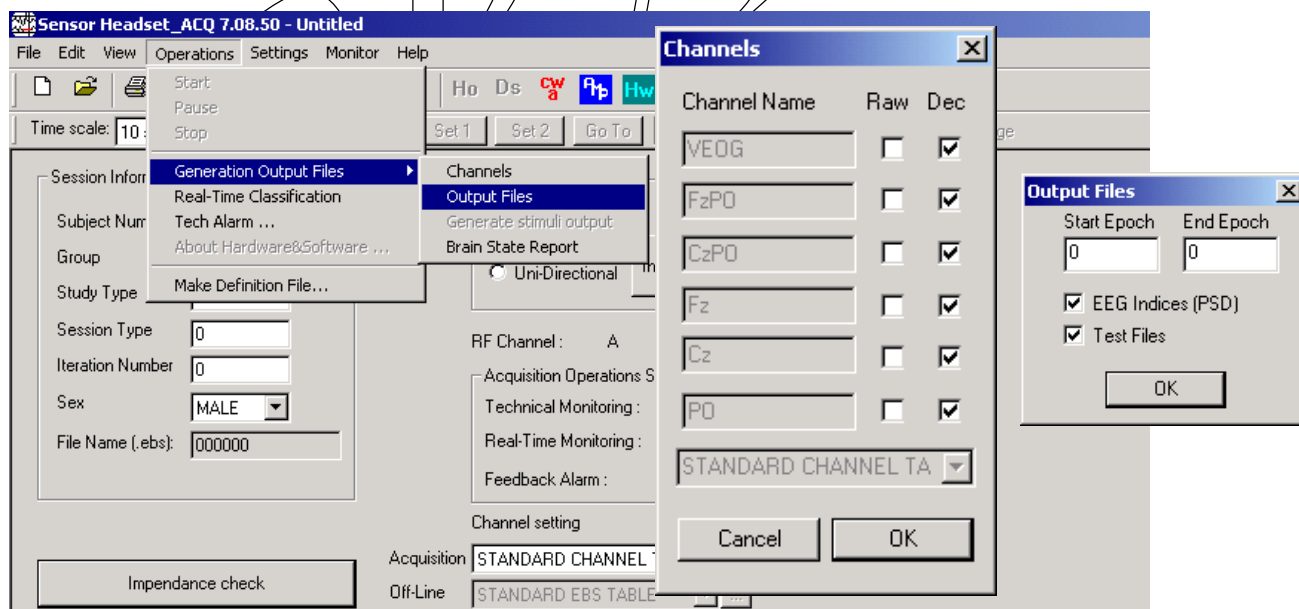
1. The “Operations” menu allows the user to select among various acquisition and analysis functions.
2. The “Settings” menu option provides the capabilities to configure the hardware.
3. “Monitor” allows adjustment to the presentation of the signals during recording.
4. “Session Information” is designed to generate a unique 8-digit file name for the recording.
5. The “Impedance Check” button will initiate the automated measurement of all scalp/skin- electrode impedances.
6. The “EBS Name Format” will provide the option to select between two different EBS file-naming conventions. This feature is not yet implemented.
7. The “Initiate RF Link” button will ensure that the wireless systems are initiated and functional. The “RF Status” button will be red if an RF link is not established, and will turn green after the RF link has been initiated.
8. “Bi-Directional” wireless transmission mode should normally be selected, so that the host computer can provide commands to the Head Unit. The “Uni-Directional” mode should only be used to monitor signal quality in conjunction with ABM’s Alertness and Memory Profiling Software.

9. “RF Channel” shows the channel selected in the “Wireless Set-Up” menu option.
10. The “Acquisition Operations Selected” identifies the menu options that were selected for monitoring artifact (Technical Monitoring), real-time **brain state** monitoring, and/or real-time monitoring with feedback alarms.
11. “Channel Setting” allows the technician to select the channel configuration set up with the “Channel Map” menu option.
12. The “Start” button will begin acquisition or open a data file for offline analysis.
13. The “Acquire Baseline Data” button will create an individual’s baseline data to be used in the creation of definition files for real-time classification. Baseline files are required for all real-time classification.

C. Operations

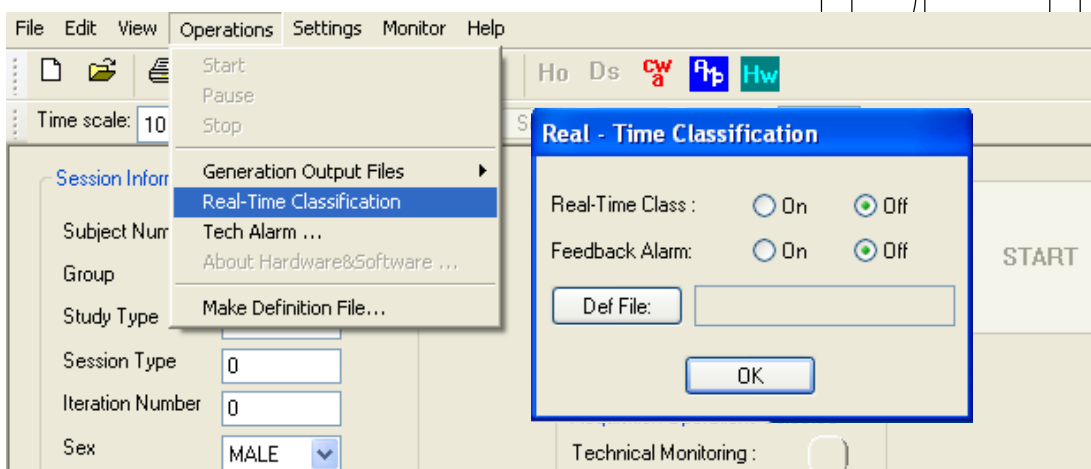
1. Generation of Output Files

- The Sensor Headset software provides the capability to generate output files that can be used in data analysis. Output files include EEG Indices (i.e., power spectral density (PSD) calculations) for each one Hz bin from 1 to 40 Hz, and the types and locations (in the record) of Artifact that was detected (see Chapter 4, section G for additional information on generating output files).
- Channels: This allows selection of channels that will be used in the .PSD file generation.
- Output Files: allows user to: 1) select which portion (defined by 1 second epochs) of the data should be analyzed, and 2) select what type of output file should be generated (i.e., EEG Indices and/or Brain State).



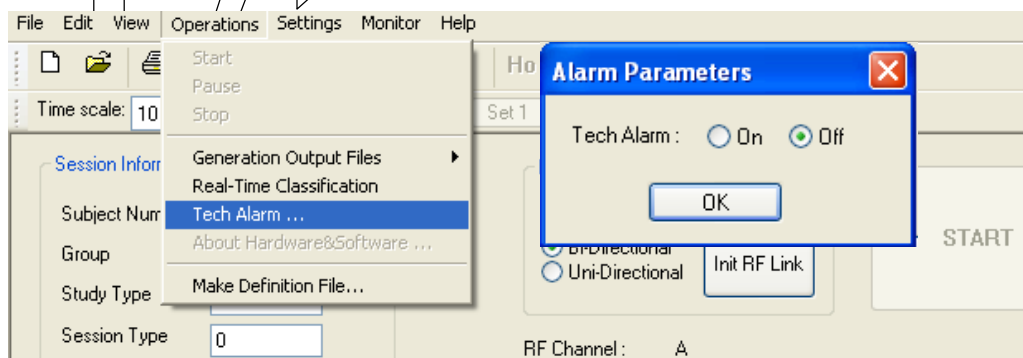
2. Real-time Classification

- The Sensor Headset software contains specific algorithms that are capable of classifying each second of EEG data into various brain states. Classifications can be viewed in real-time (with a two-second processing delay) or in offline-analysis. Since each person has unique EEG characteristics, definition files must be created before applying classification (see Chapter 4, section E for more information on generating definition files).
- **Real-Time Class:** assigned each second of EEG into brain states based on alertness – drowsiness and mental workload.
- **Feedback Alarm:** initiates an alarm that will sound if too many seconds of EEG are classified as drowsy.
- **Def File:** allows user to select the subject's unique definition file to be used in classification.



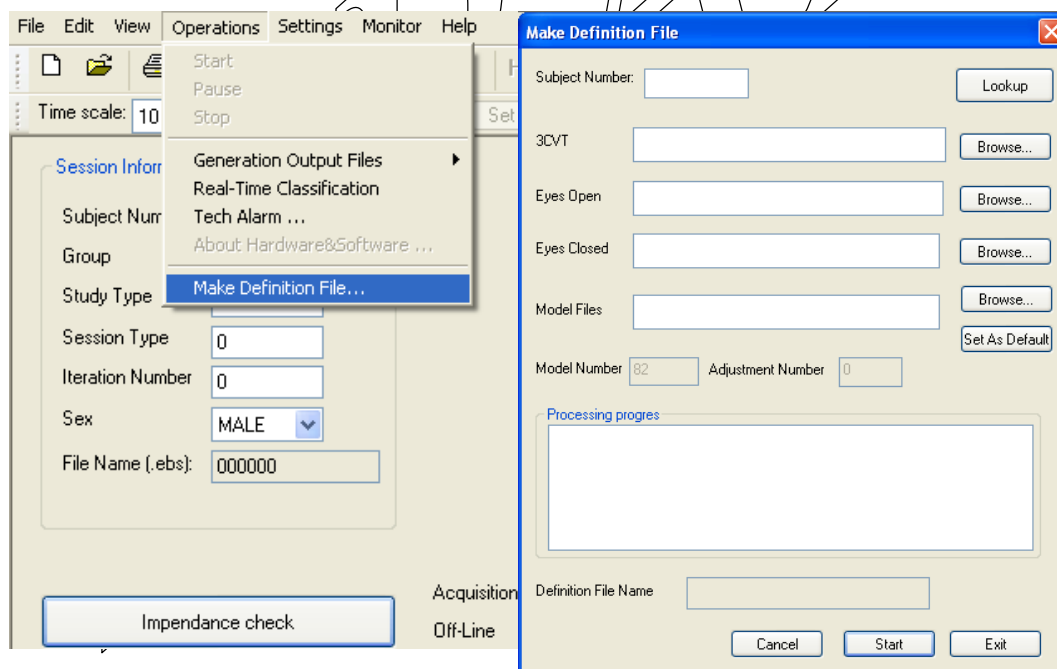
3. Tech Alarms

- The Tech Alarm feature will assist a technician in monitoring artifacts and signal quality, and notify the technician when data quality is poor. When the Tech Alarm is turned “On”, an audio Tech Alarm will sound and the Tech Alarm icon will flash when high levels of artifact and impedances, or low battery voltages are measured.



4. Make Definition File

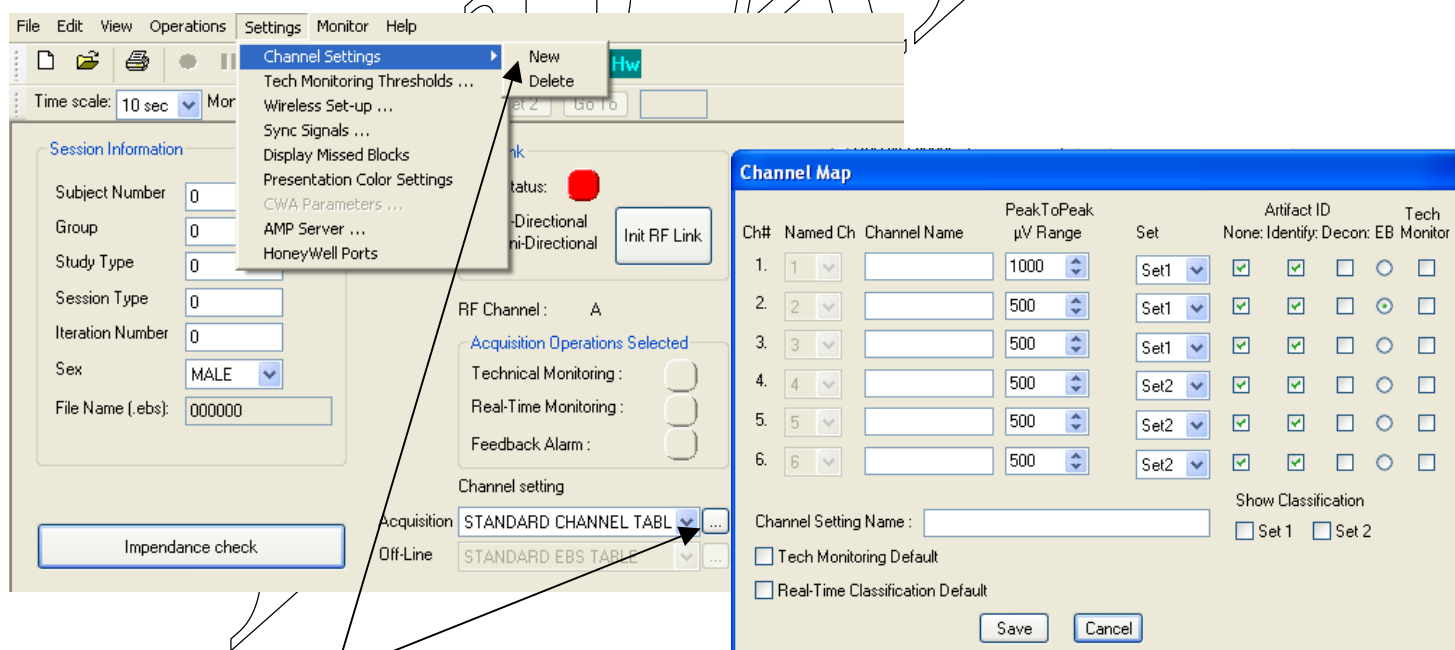
- This feature will create unique individual EEG definition files to be **used for brain-state classifications** applied in either real-time or offline analysis. The real-time classification feature cannot be used without a subject definition file.
- The definition files represent a unique EEG model for the individual based on their specific EEG patterns while performing three different baseline conditions
- A definition file is automatically created when baseline sessions are recorded (see Chapter 3 H.).
- To create a new definition files from previously completed baseline data (i.e., (3CVT, Eyes Open, and Eyes Closed complete the following steps:
 1. Select “Make Definition File” from the “Operations” menu.
 2. Enter the subject number.
 3. Select the 3 baseline files that were created.
 4. Select the model files to be used in the definition file creation.
 5. Press start.
 6. A window will appear to indicate that the definition files have been created.
 7. Press “exit”. The definition file is now available for loading for use with the real-time classification feature or the off-line Brain State Classification feature.



D. Settings

1. Channel Settings

- The Channel Map screen allows the six physical channels to be assigned channel numbers (Named Ch.) that orders the presentation of each channel.
- The Peak-Peak setting determines the initial dynamic range of the channel when presented to the monitor.
- Channels can be grouped into Set 1 or 2, allowing the technician to toggle between either group of channels during data acquisition.
- Each channel can be configured depending on the amount of Artifact Identification to be presented and whether to apply tech monitoring:
 - “None”: the raw signal is presented after application of a 60 Hz notch filter.
 - “Identify”: colors the regions identified with artifact.
 - “Decon”: colors the signals after decontamination.
 - “Tech Monitor”: applies set thresholds to artifacts that occur within the channel
- The user can select which channel is used for eyeblink (EB) decontamination.
- A Channel Map can be designed as the default to be used each time an operation is selected. To create a default Channel Settings, simply select the variables desired, assign a Channel Setting Name and Save. The saved channel setting will then appear as one of the options in the “Acquisition” tab under “Channel Setting” on the main screen.



The Channel Map can be accessed from the “Settings” menu or from selecting the “Acquisition” type on the main screen.

- The recommended Channel Map for Tech Monitoring and Real-Time Classifications are presented below.

Channel Map

Ch#	Named Ch	Channel Name	PeakToPeak μV Range	Set	Artifact ID None: Identify: Decon: EB Monitor	Tech Monitor
1.	1	VEOG	1000	Set1	☒ ☐ ☐ ☐	☐
2.	2	FzPO	500	Set1	☐ ☒ ☐ ☒	☒
3.	3	CzPO	500	Set1	☐ ☒ ☐ ☒	☒
4.	4	Fz	500	Set2	☐ ☒ ☐ ☐	☒
5.	5	Cz	500	Set2	☐ ☒ ☐ ☐	☒
6.	6	PO	500	Set2	☐ ☒ ☐ ☐	☒

Channel Setting Name: Tech Monitoring

Show Classification: ☐ Set 1 ☐ Set 2

☒ Tech Monitoring Default

☐ Real-Time Classification Default

Save Cancel

NOTE: The FzPOz and CzPOz channels are used as inputs for the Real-Time Classification. Because zero-values are inserted as part of some of the decontamination routines, it may be useful in presenting FzPOz and CzPOz in both the “Identify” and “Decon” modes during this operation.

NOTE: The processing power of the CPU will affect how many channels can be presented in the decontamination mode. Additional instructions are provided in Chapter 4 for selection and configuration of the tech monitoring and real-time classification modes.

2. Tech Monitoring Thresholds

- The Tech Alarm Thresholds allows the user to adjust the settings for marginal, poor and bad levels of artifact, impedance levels or battery voltage that triggers the Tech Alarm.

Tech Monitoring Thresholds

Interval Thresholds

	Marginal	Poor	Bad
EMG - %/Min	2	4	5
Saturation - %/Min	2	4	5
Excursion - %/Min	2	4	5
Missed Blocks - %/Min 1-2	2	4	5
Missed Blocks - %/Min 3+	2	4	5

Impedance - kΩ High: 200

Battery Voltage Low: 1

Eye Blink Thresholds

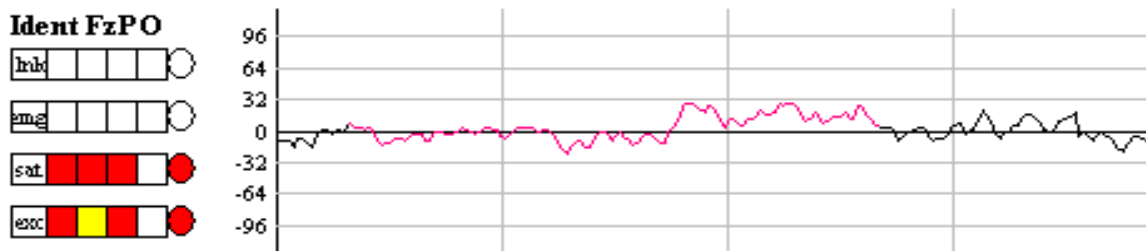
	Identify	Emg Thresholds	Decon	Norm 2-4	Norm 1-2Hz	Norm 4-8
Identify	2	3.5	0.5	75	150	150

Session Threshold

	Marginal			Poor			Bad		
	M+	P+	%S	M+	P+	%S	M+	P+	%S
EMG	2.0	1.0	3.0	3.0	2.0	4.0	5.0	3.0	5.0
Satur	2.0	1.0	3.0	3.0	2.0	4.0	5.0	3.0	5.0
Exc	2.0	1.0	3.0	3.0	2.0	4.0	5.0	3.0	5.0
Blocks	2.0	1.0	3.0	3.0	2.0	4.0	5.0	3.0	5.0
Total	2.0	1.0	3.0	3.0	2.0	4.0	5.0	3.0	5.0

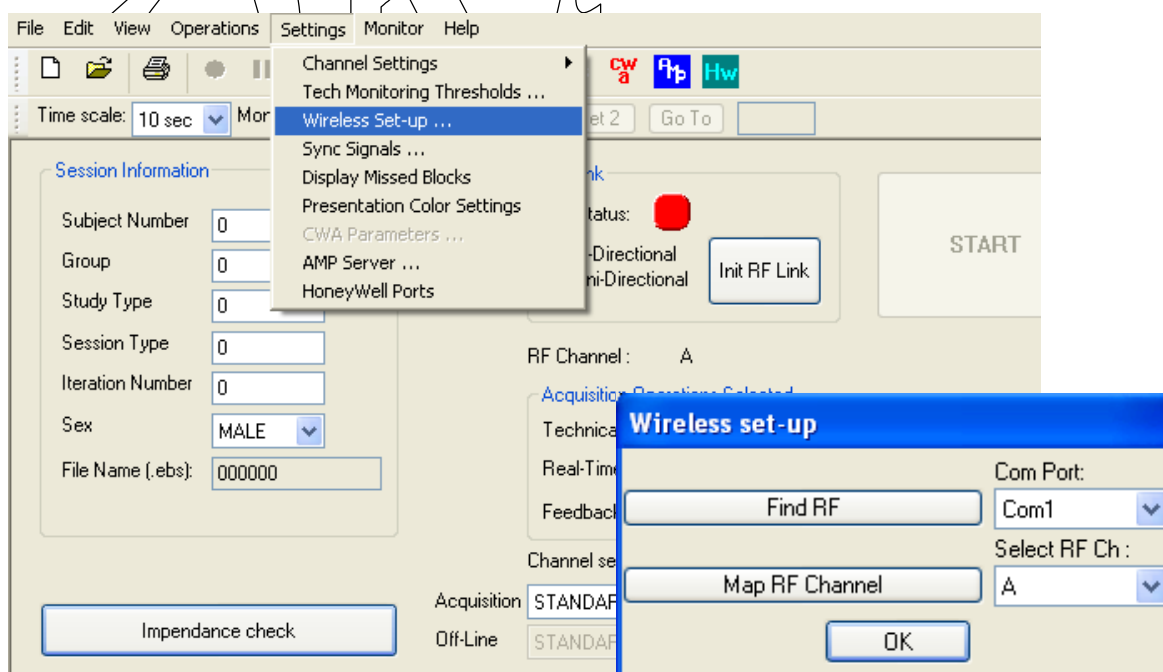
Cancel OK

- The audio Tech alarm sounds and the Tech Alarm icon flashes when high levels of artifact and impedances, or low battery voltages are measured.
- Setting a threshold to zero means that that threshold will not trigger the Tech Alarm.
- When the tech monitor feature is selected from the channel map, a box showing a five-minute history of signal quality for each type of artifact will appear to the left of the EEG signal.



3. Wireless Set-Up

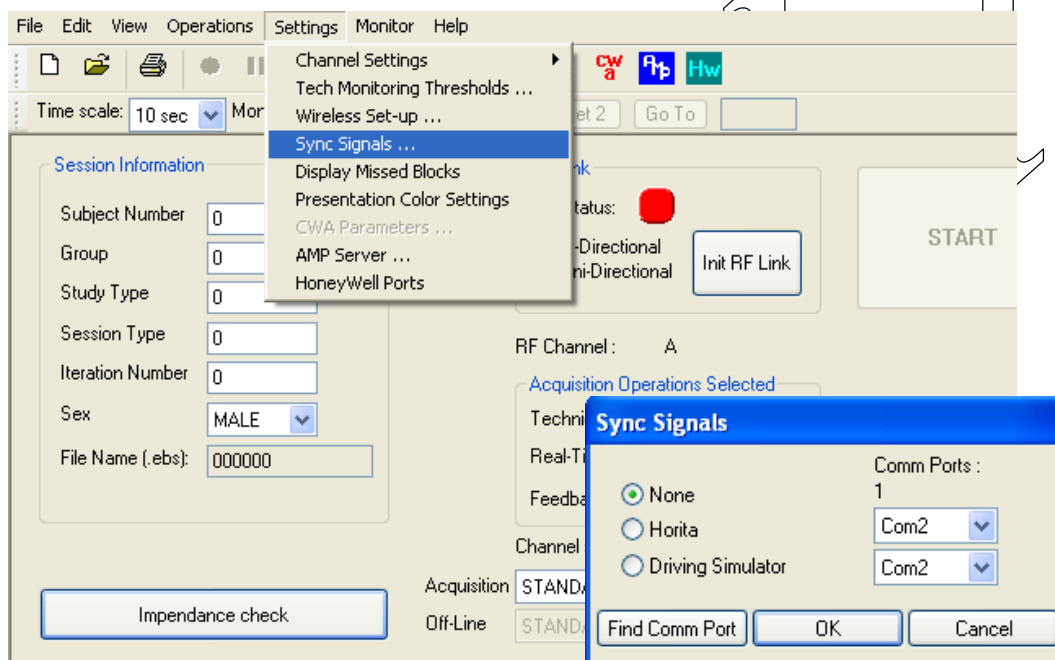
- The Head Units are pre-set to provide high quality wireless transmission. The Wireless Set-up menu allows the user to assign a Com Port and RF channel for the system before beginning data acquisition.
- When the user clicks on Find RF, the program will automatically select what Com Port the systems are plugged into.
- If more than one system will be used at a site, you should assign different RF channels to each unit by selecting from the scroll down Select RF channel menu.
- Click OK and close program to save changes.



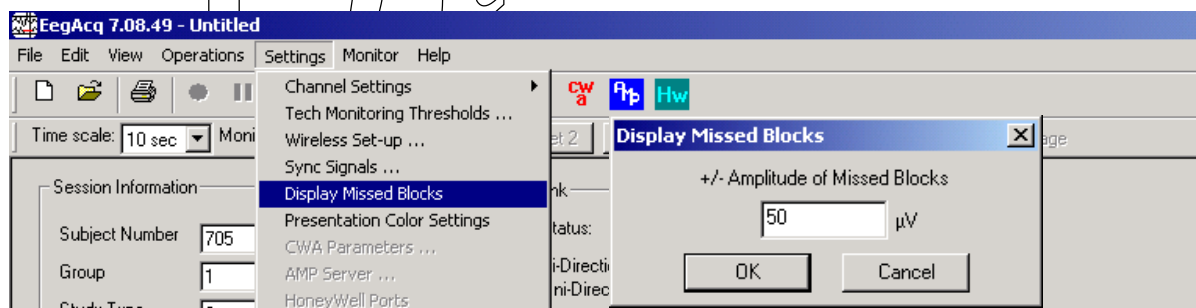
4. Sync Signals

- The Sensor Headset software can incorporate additional serial inputs into the EEG record to assist with file synchronization during off-line analysis. Press the Default button to set the standard configuration that is applied each time the software is opened.
- The Horita option incorporates time codes generated by the Horita TRG-50 PC that can be simultaneously recorded on VHS tape. (see: <http://www.horita.com>).
- The Driving Simulator option incorporates performance measure outputs from STISIM program (see: <http://www.systemstech.com>).

Selecting Find Com Port while Horita or Driving Simulator is running will find appropriate Com Port.



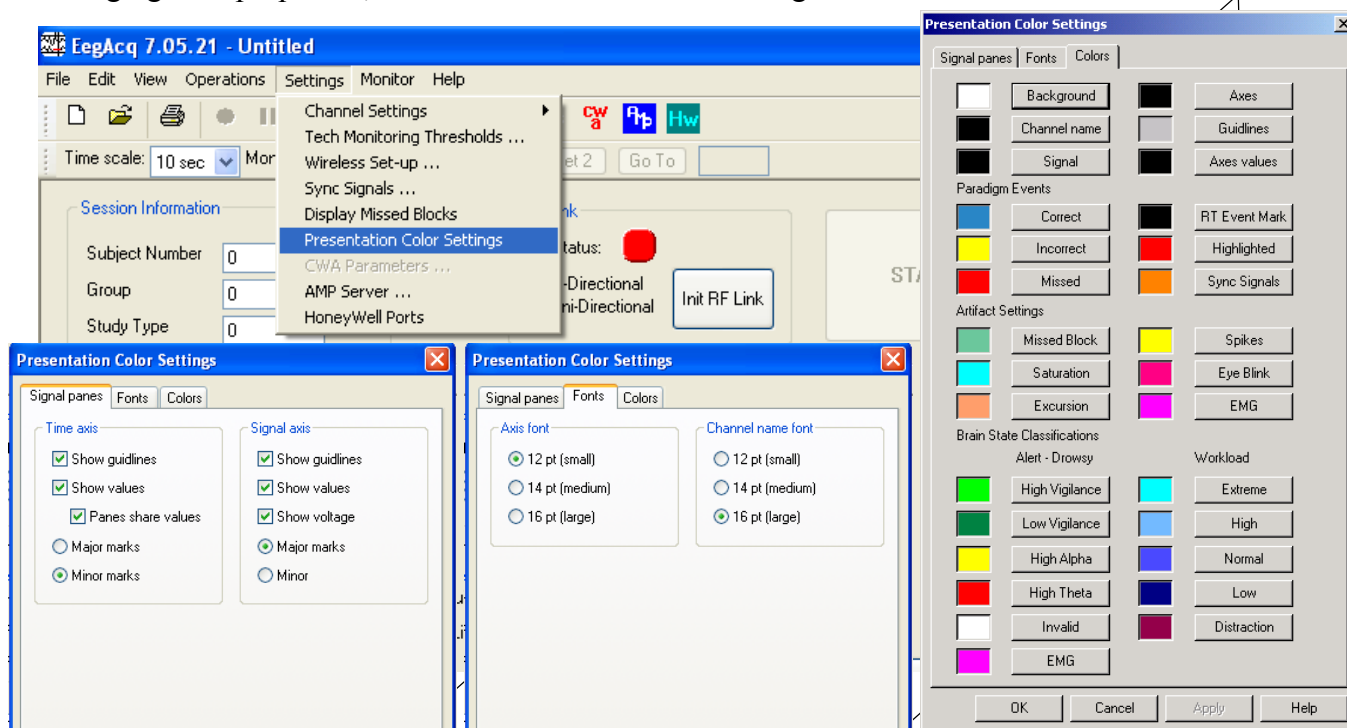
5. Display Missed Blocks



- The amplitude of the signal that you wish to have presented when dropped blocks occur is adjustable to make it easier to recognize.
- The amplitude of the signal is only used for presentation purposes and does not affect the saved recordings.

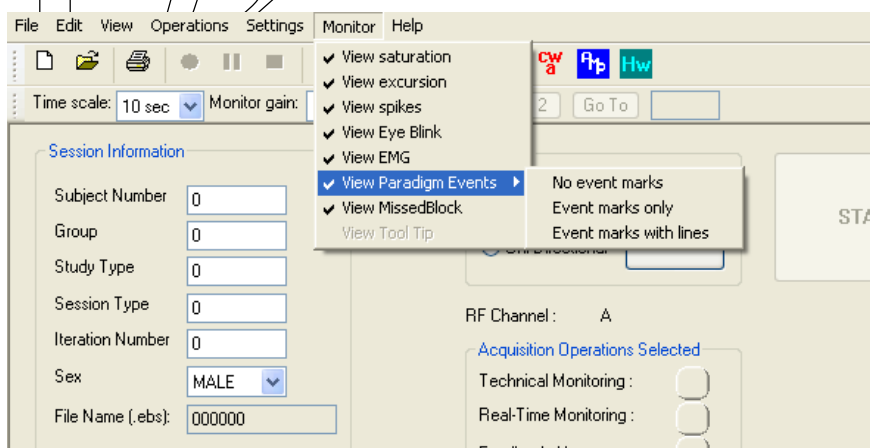
6. Presentation Color Settings:

The Presentation Color Settings allows for customization of the EEG presentation. This includes changing axes properties, fonts and colors for artifact recognition and brain state.



E. Monitor Menu

- The monitor menu allows selection of the artifact routine that you wish to have visually presented. These selections apply to both the real time and off-line modes.
- The monitor menu provides the option to present stimulus and/or response markers generated by the Alertness and Memory Profiling (AMP) Software.
- To select an option to monitor:
 1. Left click on the item you would like to view.
 2. A check mark should appear next to all items that have been selected for viewing.



Chapter 4: Recording Physiological Data

A. Establishing a Connection with the Wireless Headset System

Prior to acquiring any data with the head and host units, the Sensor Headset Software needs to assign a Com Port to the system. Follow the steps below to assign a Com Port:

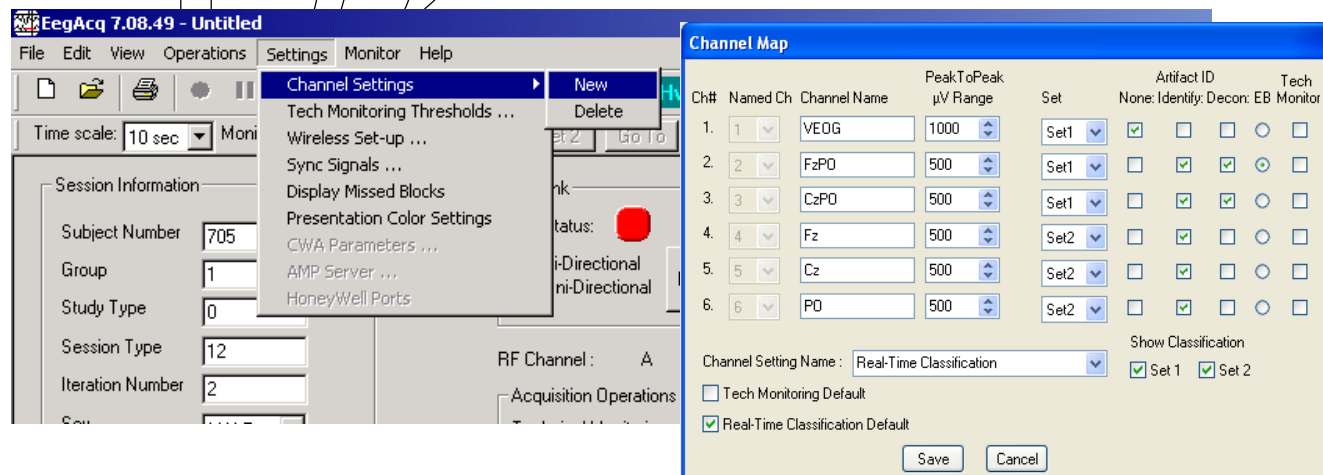
1. Plug the host unit (Class 2 Blue Tooth Dongle) into the desired USB Port. The host unit should be within 30 feet of the head unit to ensure proper data transmission.
2. Turn the head unit on. Wait until the green light appears indicating the two units are linked and functional.
3. Click on Settings, Wireless Set-Up and Find RF. The program will automatically select what port the host unit is assigned.
4. Select OK and close the software program to save the changes.

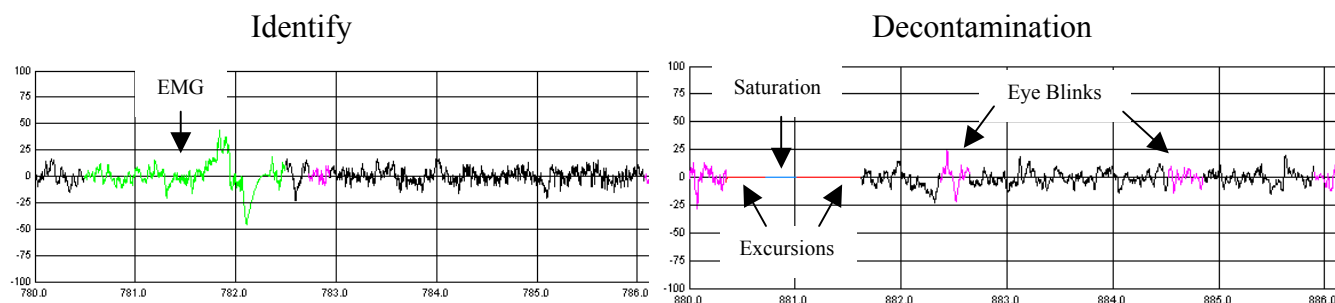
The firmware automatically assigns alternate channels when more than one Sensor Headset are used in the same vicinity.

B. Selecting Signals to be Presentation

The signals can be presented in one of three levels of Artifact identification: “none” is the original signal, “Identify” displays the signal with artifact affected regions colored and “Decon” displays the signal after decontamination of the artifact. See the example below. Artifact will be presented using the coloring scheme selected with the “Presentation Color Settings” option. To make the Channel Settings Map:

1. Select Channel Settings and New.
2. Select the Peak to Peak μV range for each channel.
3. Assign each channel to Set 1 or Set 2.
4. Select the signals to be presented based on the level of artifact identification.
5. For EB, check FzPO and CzPO, the two channels needed for identification of eye blinks.
6. Select the channels that the tech monitoring feature should be applied to.



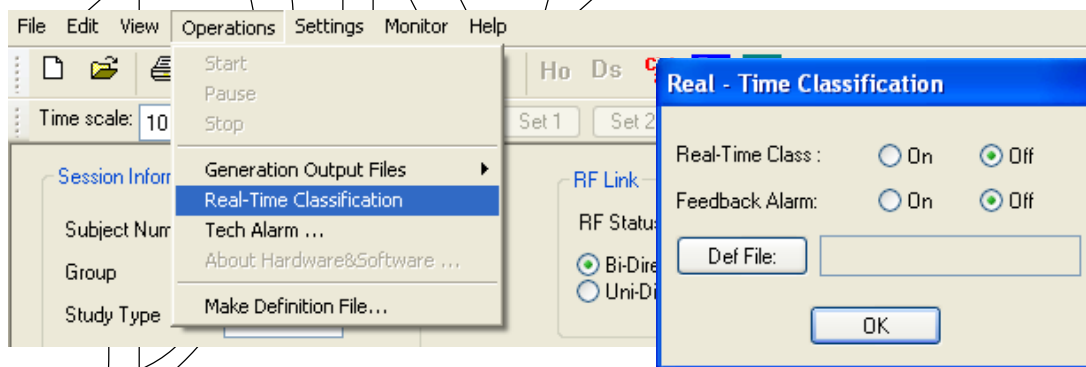


C. Selecting Real-Time Classification

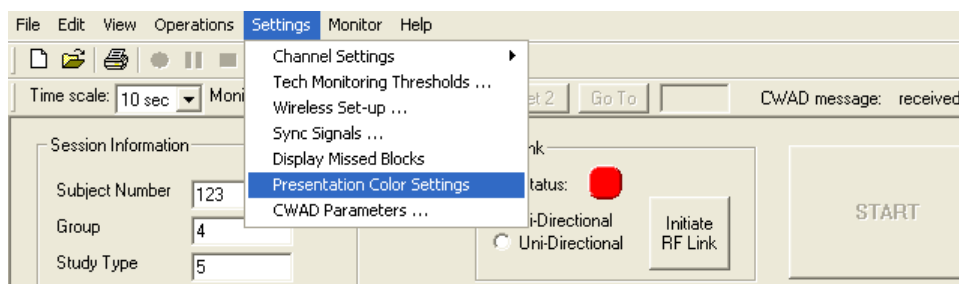
The Sensor Headset software contains specific algorithms that are capable of classifying each second of EEG data in various brain state classifications. Classifications can be viewed in real-time (with a two-second processing delay) or in offline-analysis. Since each person has unique EEG, definition files must be created before applying classification (see Chapter 4, Section E for information on definition files).

Follow these steps to enable Real-Time Classification:

1. Select “Real-time Classification” from the Operations menu.
2. A “Real-time Classification” box will appear. Select “On” to turn the Real-Time Classification On. There is also an option for a Feedback Alarm. Turn this on to hear an alarm when a large amount of EEG is being classified as drowsy.
3. Definition files must be created to apply real-time classification of an individual’s data. Click on the “Def File” box to select the definition file that corresponds to the individual that is performing the task. For more information on creating definition files the next section.
4. Click OK.



5. Verify that the “Real-Time Monitoring” box is highlighted in the Acquisition Operations Selected box of the main screen. If the Feedback alarm was enabled, the “Feedback Alarm” box should also be highlighted.
6. Select the Real-Time Classification channel setting from the Channel Setting Acquisition box on the main screen.
7. Select the “Presentation Color Settings” from the Settings menu. Select the “Colors” tab and choose the colors to be used in Real-Time Classification.



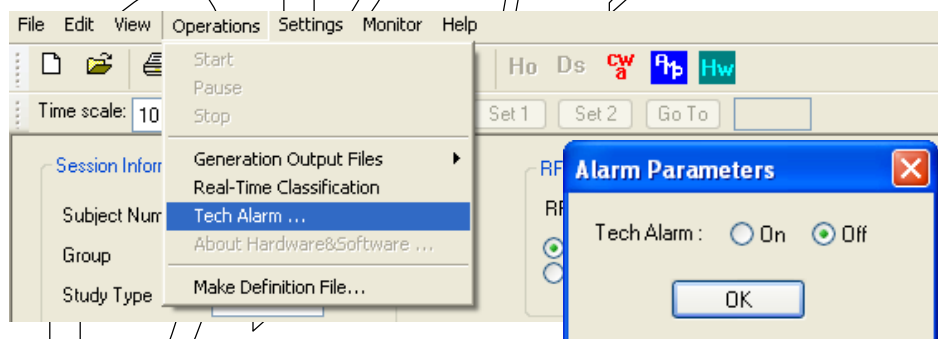
8. When the Real-Time Classification feature is enabled and EEG Data Acquisition has been initiated, a colored box will appear at the bottom of the acquisition screen that represents the particular classification for that second (epoch) of EEG. There will be a two second lag in real-time classification.

C. Selecting Tech Monitoring

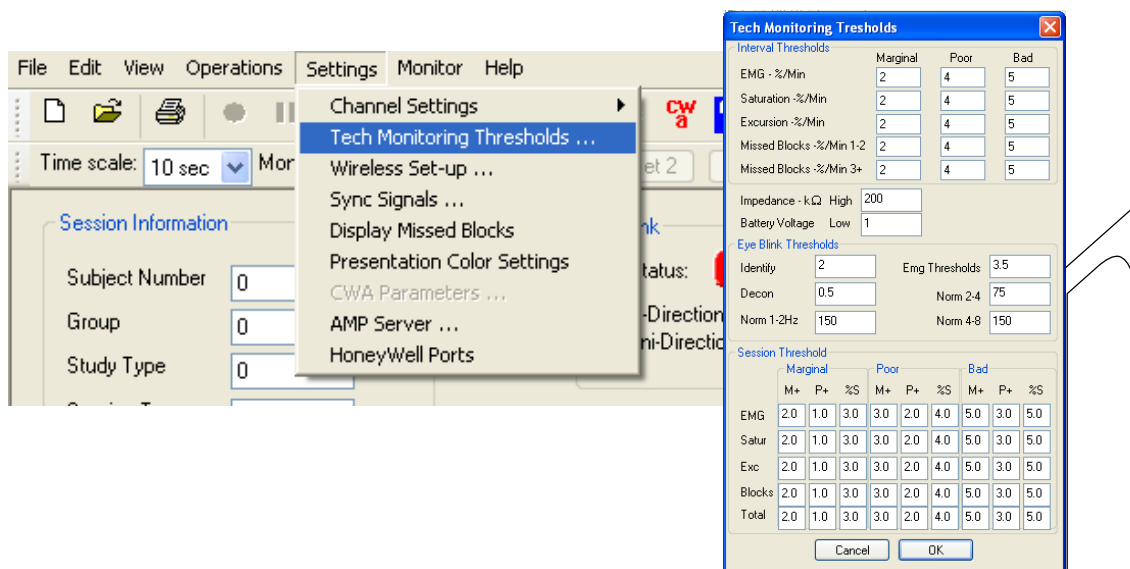
The Tech Alarm Thresholds provide the capability to adjust the settings for high and low levels of artifact, impedance levels or battery voltage that triggers the Tech Alarm. The audio Tech alarm sounds and the Tech Alarm icon flashes when high levels of artifact and impedances, or low battery voltages are measured.

Follow these steps to enable Tech Monitoring Alarms when acquiring data:

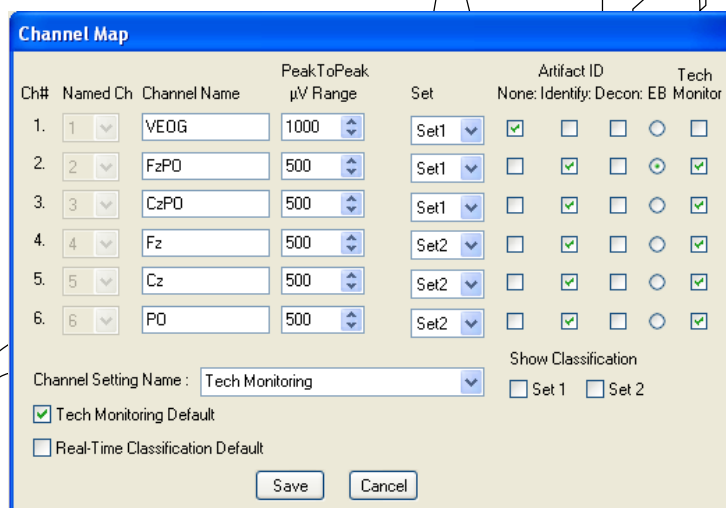
1. Select "Tech Alarm..." from the Operations menu.
2. An "Alarm Parameters" box will appear and you should select Tech Alarm "On" and "OK".



3. Verify that the "Technical Monitoring" box is highlighted in the "Acquisition Operations Selected" box on the main screen.
4. Select "Tech Monitoring thresholds" from the settings menu to set low and high thresholds for artifact, impedance and battery levels. Setting a threshold to zero means that that threshold will not trigger the Tech Alarm.

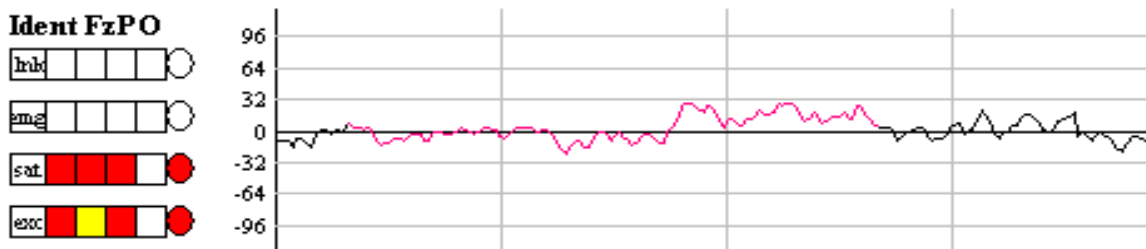


5. Select the Tech Monitoring Channel Setting from the Channel Setting Acquisition box on the main screen.



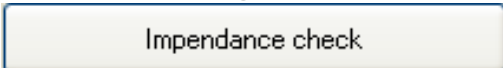
6. Once enabled, you can click on the tech alarm icon to view a five-minute history of artifact levels. Each box is equivalent to one minute of data and is colored as follows:

Colorless = optimal data
 Yellow = Marginal threshold is met
 Orange = Poor threshold is met
 Red = Bad threshold is met

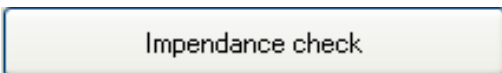


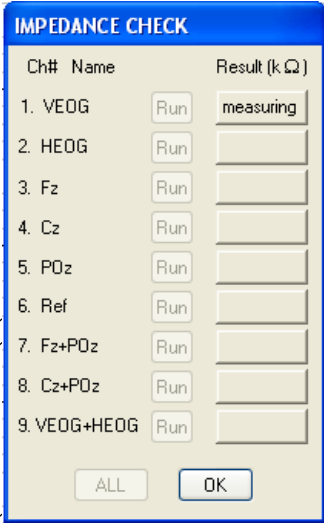
D. Impedance Monitoring



Click on  on the main screen, then click “All” to run impedance on all channels or perform impedance on individual channels by selecting “Run”. If the Tech Alarm is turned On, audio and visual notifications will be presented if an impedance level exceeds the Tech Alarm threshold.

If a sensor fails the impedance test, add conductive cream or remove hair below the sensor or abrade the scalp.

Select  again to retest.



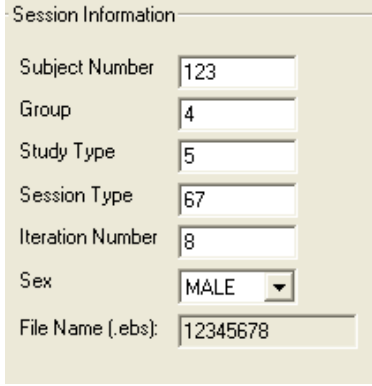
Ch#	Name	Run	Result (k Ω)
1.	VEOG	Run	measuring
2.	HEOG	Run	
3.	Fz	Run	
4.	Cz	Run	
5.	POz	Run	
6.	Ref	Run	
7.	Fz+POz	Run	
8.	Cz+POz	Run	
9.	VEOG+HEOG	Run	

ALL OK

E. Selecting File Name

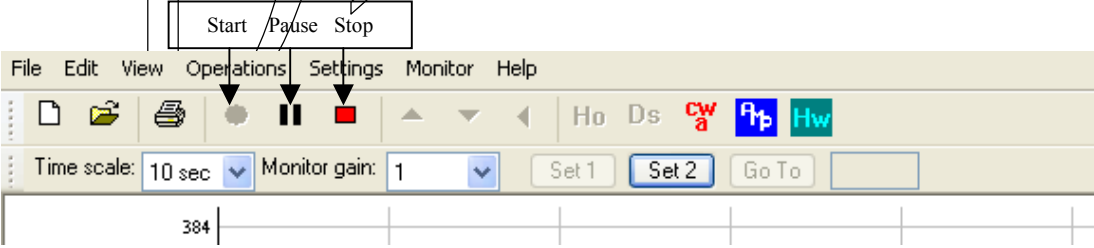
The Sensor Headset software assigns an eight-digit file name using information inputted in Session Information. All session information fields default to zero.

- Subject Number: three digits - zeros will be automatically inserted if less than three digits are inputted.
- Group: one digit - intended for use with counter-balancing protocols.
- Study Type: one digit - for subjects repeatedly tested under different conditions.
- Session Type: two digits - must assign 11 (Eyes Open), 12 (Eyes Closed) and 23 (3-choice Psychomotor Vigilance Task) for the baseline conditions.
- Iteration Number: one digit - ideal for use when two or more sessions with the same session type are recorded on the same day.



Session Information	
Subject Number	123
Group	4
Study Type	5
Session Type	67
Iteration Number	8
Sex	MALE
File Name (.ebs):	12345678

F. Viewing Signals during Acquisition



Start / Pause / Stop

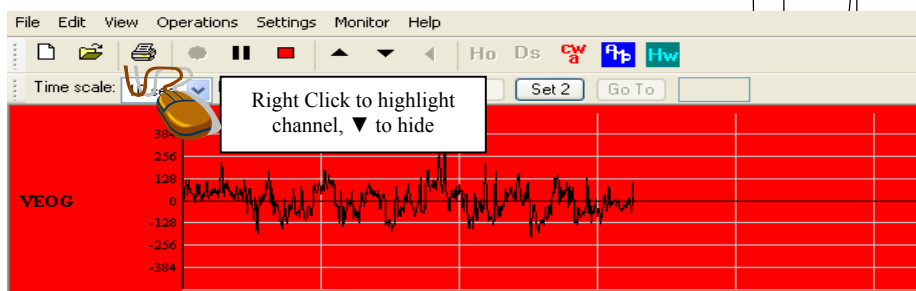
File Edit View Operations Settings Monitor Help

Time scale: 10 sec Monitor gain: 1 Set 1 Set 2 Go To

384

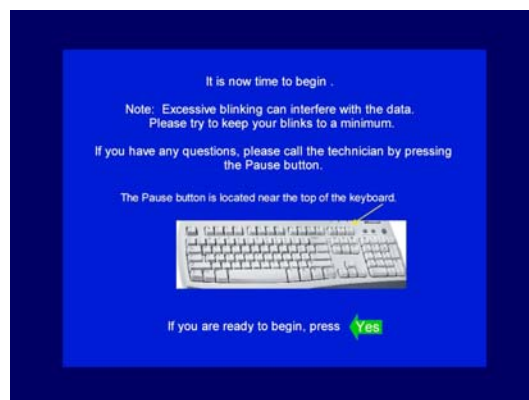
- Adjust the time scale to select the number of epochs to be presented to the screen.
- The monitor gain increases the resolution of the signal in proportion to the peak-peak settings established in the Channel Map.

- To change the number of horizontal lines in each channel for recognition of the microvolt level of the signal, select Settings, Presentation Color Settings, and Signal Panes. Major presents two lines above and below the zero line (see example below). Minor presents four lines above and below the zero line.
- Use the Start, Pause and Stop buttons for recording.
- Select Set 1, Set 2 to present the channels assigned to the respective sets in the Channel Map.
- Channels can be selectively hidden so that the remaining channels appear larger on the screen. If you wish to hide a channel left click (in the general area of the channel) to highlight the channel to be hidden (Left click a second time to un-highlight). To hide the highlighted channel, select the ▼ or right click. Select ▲ to unhide the channel. Select ◀ to present all channels in the set.



G. Acquiring Baseline Data

1. Click on **Acquire Baseline Data** on the mainscreen.
2. Enter a three digit subject number and select the location where the Sensor Headset program is located. You can save this location as a default, that will appear automatically every time you click “Acquire Baseline Data”.
3. Click “OK” and follow the instructions on the screen.



4. The three five-minute baseline tasks are:

3 Choice Vigilance Task (3C-VT) (5 minutes):

- Stimuli consist of 3 shapes: upside triangle, downside triangle, diamond
- Subject presented w/ one shape at a time, in random intervals

- Subject instructed to press 'Yes' to upside triangle, 'No' to other stimuli

Eyes Open (EO) (5 minutes):

- Subject responds to a red circle presented at 2 second intervals (EO), or a tone sounded at 2 sec. intervals (EC).
- If a subject's response time is > 5 seconds, he/she will receive an alarm sound. If the alarm sounds twice, the session is automatically terminated, and will need to be rerun.
- If a subject's response time is >3 seconds, 10 seconds is added to the length of the session, for a maximum task length adjustable by the AMP program.

Eyes Closed (EC) (5 minutes):

- Subject keeps eyes closed and responds to a tone sounded at 2 second intervals.
- If a subject's response time is > 5 seconds, he/she will receive an alarm sound. If the alarm sounds twice, the session is automatically terminated, and will need to be rerun.
- If a subject's response time is >3 seconds, 10 seconds is added to the length of the session, for a maximum task length adjustable by the AMP program.
- To ensure good data quality, it is critical that the subject does not or flutter their eyes during the EC session.

5. After baseline acquisition is finished, the program will return to the main screen and definition files for the subject may be created using the three baseline files.

Chapter 5: Viewing Previously Recorded Data

A. Selecting the Off-line Viewing Mode:

Previously recorded signals can be visually inspected:

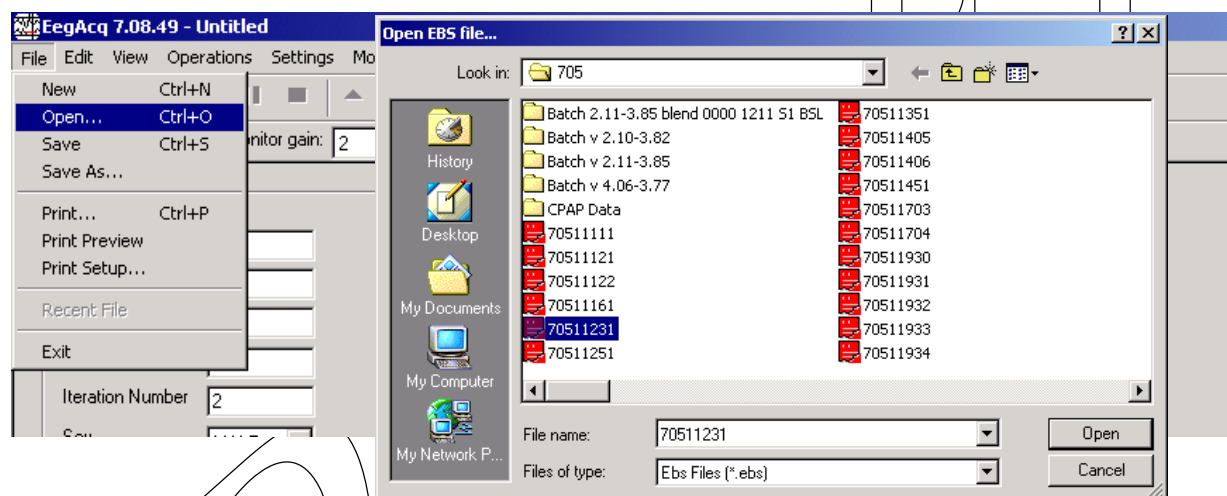
- with or without artifact identified and/or decontaminated,
- with or without brain state classifications.

The presentation of the signals can be made either in:

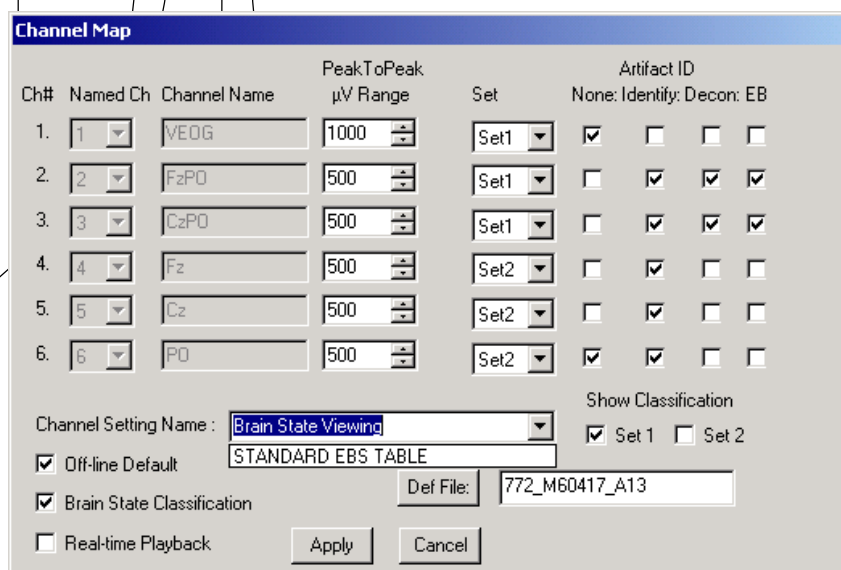
- real-time playback, or
- off-line viewing mode

To open a file for off-line review:

1. Select File and Open.
2. Browse to find the record of interest and press Open.



3. Go to the Channel Settings Name to apply the settings for an existing channel map. Following the instructions provide for data acquisition (see Chapter 4, section B, Selecting Signals to be Presented) to adjust the Channel Map options.



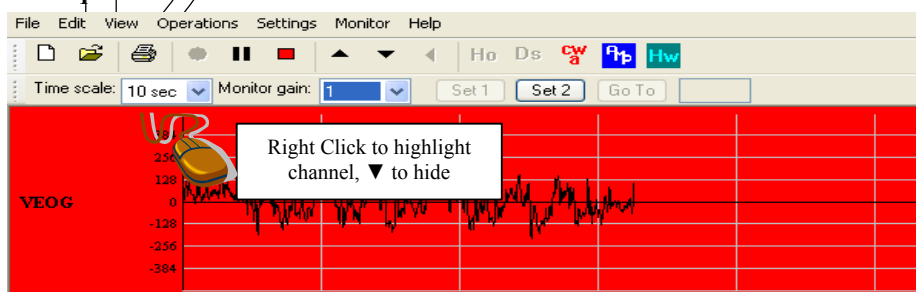
4. When you check Real time playback, the file will retrace as if it were being acquired for the first time and you will be unable to scan throughout the file. When the Real-time Playback box is unchecked, the conventional off line review mode will be presented.
5. Brain State Classification: Classifications will be generated when this box is checked for either of the off line viewing modes.
6. If you check Brain State Classification, you must click on Def File and select a definition file to apply.
7. To save the unique configuration settings, type in a new Channel Setting name and check Off-Line Default. Each time a file is opened for off line viewing, these settings will be presented.
8. Click Apply and the Channel Map screen will disappear.
9. See Chapter 6 below to select the files to be generated before continuing.
10. Press the Start box and the session will processed.
11. When processing has completed, the signals selected with the Channel Map will be presented and the output files will be saved in the designated folder.

B. Off-Line Viewing

- To change the number of horizontal lines in each channel for recognition of the microvolt level of the signal, select Settings, Presentation Color Settings, and Signal Panes. Major presents two lines above and below the zero line (see example below). Minor presents four lines above and below the zero line.
- Use the Start, Pause and Stop buttons for recording.
- Select Set 1, Set 2 to present the channels assigned to the respective sets in the Channel Map.

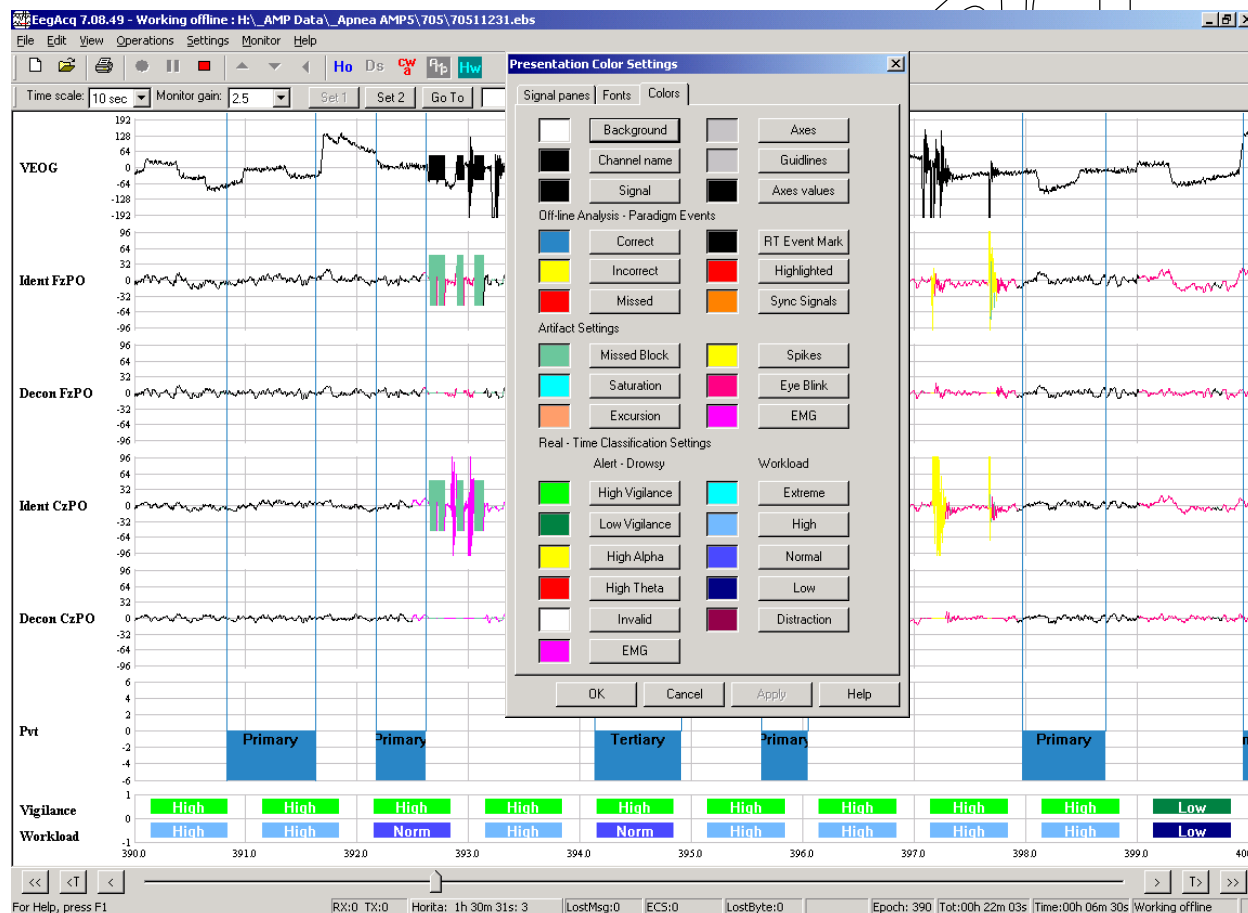


- Channels can be selectively hidden so that the remaining channels appear larger on the screen. If you wish to hide a channel left click (in the general area of the channel) to highlight the channel to be hidden (Left click a second time to un-highlight). To hide the highlighted channel, select the ▼ or right click. Select ▲ to unhide the channel. Select ◀ to present all channels in the set.



A sample screen is presented below, note:

- The artifact colored in the Identify channels that is replaced with zero values in the Decon channels.
- Eye blinks are colored in the same region for both Identify and Decon, must the artifact is removed in the decon.
- The stripes at the bottom of the screen present the brain state and workload levels.
- The stripes and vertical lines identify the start of the PVT stimulus until the user responds.

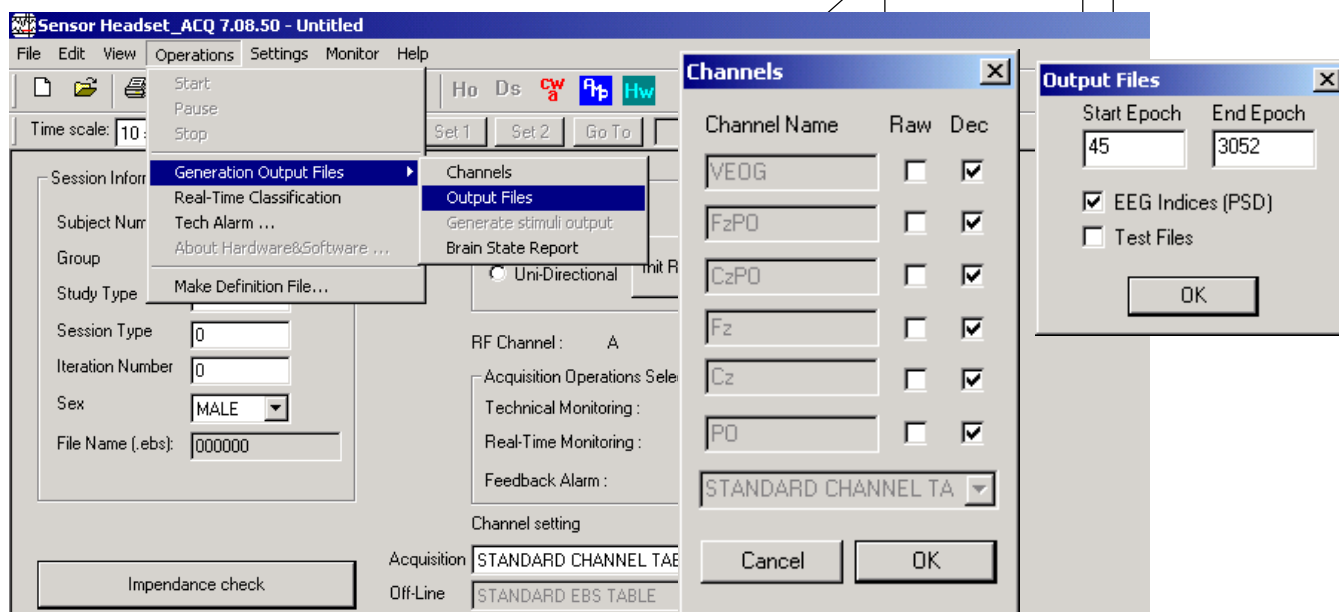


Chapter 6: Generating Output files

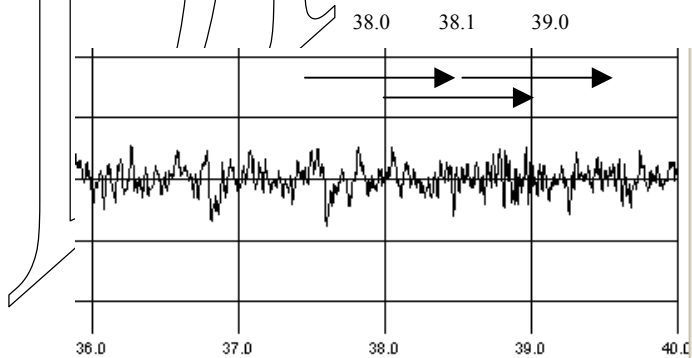
A. EEG Indices (PSD) by Epoch or Overlay

The Sensor Headset software provides the capability to generate output files that can be used for data analysis purposes. Output files include EEG Indices (i.e., power spectral density (PSD) calculations) for each one Hz bin from 1 to 40 Hz and Artifact that was detected.

The “Epoch” option utilizes a 50% overlapping window, which averages PSD calculations from three 256 data point overlays from 0.5-secs prior to and 0.5-secs after the epoch of interest. For the “Overlay” option PSD and Artifact data are reported for each 256 data point window.



To compute the PSD for Epoch 38 in the example below, the values obtained from overlays 38.0, 38.1, and 39.0 are averaged. Alternatively, the PSD values for each overlay can be generated.



Using the Channels option, PSD results can be generated with raw data (Raw) or after Decontamination (Dec). If decontaminated output results are selected, the PSD in the range from

1 to 9 Hz will be labeled Dc instead of Hz, reflecting the impact that the eye blink decontamination routine has on these frequencies.

The output file (generated individually for each channel) includes columns identifying epochs determined to have saturation (Sat), excessive muscle artifact (EMG), insufficient data (Inv) (as a result of inserting zero values replace the data points affected by amplifier saturation, spikes or excursions that result from saturation), or eye blinks. For saturation and invalid data, 0 indicates acceptable and 1 indicates the epoch should not be analyzed. When invalid data is determined, 99999 is inserted in the PSD file. Three levels of EMG are identified, however, level three is generally the only level that should be excluded from analysis. The EEG indices (PSD) are then provided beginning with Hz1 (labeled DC1 for decontaminated data). The PSD of the first two frequencies (Hz1 and Hz2) are affected by the high pass filter and should not be analyzed.

Unique output files will be generated for each channel selected.

Logged:

Raw EEG by epoch:

8-digit file name_FzPO_Lraw_ep.psd

Decontaminated EEG by epoch:

8-digit file name_FzPO_Ldec_ep.psd

Raw EEG by overlay:

8-digit file name_FzPO_Lraw_ov.psd

Decontaminated EEG by overlay:

8-digit file name_FzPO_Ldec_ov.psd

Non-logged:

Raw EEG by epoch:

8-digit file name_FzPO_Nraw_ep.psd

Decontaminated EEG by epoch:

8-digit file name_FzPO_Ndec_ep.psd

Raw EEG by overlay:

8-digit file name_FzPO_Nraw_ov.psd

Decontaminated EEG by overlay:

8-digit file name_FzPO_Ndec_ov.psd

The first 8 columns are formatted as follows:

Sessnum	epnum	Sex	SatFPO	EMGFPO	INVFPO	Eyeblink	Epclass
53411111	37	0	0	0	0	1	0
53411111	38	0	1	0	1	0	0
53411111	39	0	1	3	0	0	0
53411111	40	0	0	0	0	1	0
53411111	41	0	0	0	0	1	0

Note the sequence in the epnum column to designate the overlay when selected:

Sessnum	epnum	Dc1FPO	Dc2FPO	Dc9FPO	Hz10FPO	Hz39FPO	Hz40FPO
53411111	37.0	0.443846	1.002631	-0.034824	0.493816	-0.141100	-0.432520
53411111	37.1	99999	99999	99999	99999	99999	99999
53411111	38.0	99999	99999	99999	99999	99999	99999
53411111	38.1	99999	99999	99999	99999	99999	99999
53411111	39.0	99999	99999	99999	99999	99999	99999
53411111	39.1	0.654632	0.979675	-0.677170	0.668683	0.642560	0.432266
53411111	40.0	0.475813	0.862993	1.066940	0.680225	-0.473269	-0.438904
53411111	40.1	0.775692	0.856615	0.406896	0.590719	-0.371120	-0.711514

B. Brain State Classifications

- Files generated for the epoch by epoch classification of brain state are labeled as = 8-digit file name_BrainStateEp.csv)

Epoch	SatFPO	EMGFPO	INVFPO	SatCPO	EMGCPO	INVCPO	BrainState	WorkClass
22	0	9	1	0	5	0	2	
23	0	5	0	0	5	0	2	
24	0	0	0	0	0	0	8	0.1
25	0	0	0	0	0	0	7	0.5
26	0	0	0	0	0	0	7	0.5
27	0	0	0	0	0	0	7	0.5
28	0	0	0	0	0	0	3	0.7
29	0	0	0	0	0	0	3	0.7

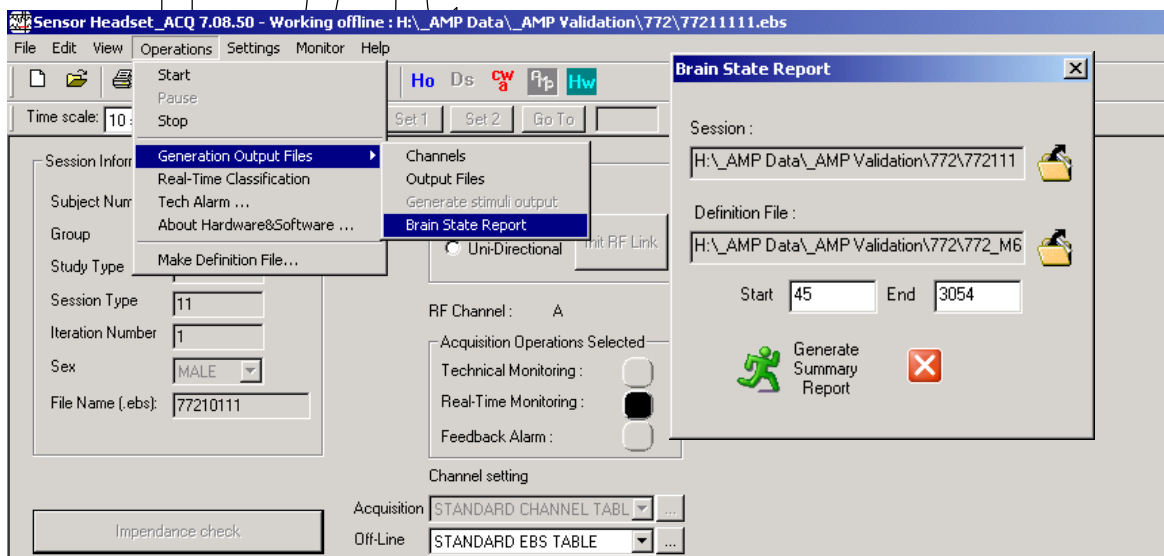
- The brain state numbers correspond to the following classes:

1 = Excessive EMG
 2 = Invalid, insufficient data due to decontamination
 3 = High vigilance
 5 = sleep onset
 7 = low vigilance
 8 = relaxed wakefulness

- The workload numbers correspond to the following levels:

0.1 = Distracted
 0.3 = Low Workload
 0.5 = Normal Workload
 0.7 = High Workload
 0.9 = Extreme Workload

C. Brain State Summary Report



DRAFT

Sensor Headset Model 603-B Specifications

System Specifications - for Head and Host Units	
RF Band	2.4 to 2.48 GHz (ISM band)
Antenna	On-board
Transmission Mode	Bi-Directional
Data Transmission Range	~ 30 feet, line of sight
Average Data Loss	< 0.1%
Transmission Power	~ 1 mW
Power Supply	2 x AAA 900 mAH NiMH batteries
Operating Time	7.0 hours between charges
Power Consumption	~ 80 mA @ 2.5 V
Battery Charger	External, interface via Charging Jack
User Control	ON/OFF
Indicator LEDs	Green = in sync with head unit Red = device on but not in sync with Head Unit
Number of channels	Six: 3 x bi-polar and 3 x uni-polar
Sampling Rate	256 samples/second
Dynamic range	+ 1,000 μ V, sufficient for either EEG or EOG
Resolution	16 bit
Bandpass characteristics	0.5 Hz and 65Hz (at 3dB attenuation) obtained digitally with Sigma-Delta A/D converter
Noise	~ 2 μ V peak to peak
On-line impedance monitoring	Initiated by host computer using bi-directional link
Connector Interface	12-pin/Hi-Rose connector for Sensor Headset
Head Unit Dimensions	5" long x 2.25" wide x 1" deep
Head Unit Weight	4.0 ounces with batteries
Case Material	ABS
Host Unit	Class 2 USB/Blue Tooth Dongle
Software	
Compatibility	Personal computer with Pentium/MMX 450 MHz or higher processor (or equivalent) with Windows Operating System
Estimated File Size per Minute	~ 30 KB/Min/channel
Recharging Batteries on Head Unit	
Provided by USB port on host workstation	350 mA @ 5 Volts
Recharging Cable	10" cable terminated a USB A connector and a HiRose connector on each end
Sensor Headset and accessories	
Headset and Sensor Strip	Medium = Nasium to Inion ~36 cm. From Inion: POz = 7.2 cm, Cz = 18 cm and Fz = 25.2 cm
Sensors	Silver-Silver Chloride coated ABS
Electrode Cream	Highly conductive, electrolytes and preservatives in non-ionic, hypo-allergic base, buffered to skin pH
EEG Sensor pry tool	2" long

Environmental Conditions:

Environmental Condition	Operation	Transportation	Storage
Temperature	5°C to 40°C 41°F to 104°F	-20°C to 70°C -4°F to 140°F	-20°C to 70°C -4°F to 140°F
Relative Humidity	15% to 95% non-condensing to be compliant with IEC 60601-1, sub-clause 44.5	15% to 95% non-condensing	15% to 95% non-condensing

Preliminary Specifications, subject to change



Compliance

A. FCC

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try and correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: 1) This device may not cause harmful interference, and 2) this device must accept any interference received, including interference that may cause undesirable operation.

Table 201

Guidance and manufacturer's declaration – electromagnetic emissions		
The Model 603-B is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 603-B should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Model 603-B uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	The Model 603-B is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Table 204

Guidance and manufacturer's declaration – electromagnetic immunity			
The Model 603-B is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 603-B should assure that it is used in such an environment.			
Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Model 603-B, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. ^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Model 603-B is used exceeds the applicable RF compliance level above, the Model 603-B should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Model 603-B ^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 206

Recommended separation distances between portable and mobile RF communications equipment and the Model 603-B			
The Model 603-B is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model 603-B can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model 603-B as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 1.2 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

B. General Compliance

Item	Compliant With
Equipment classification	Safety Standards: IEC 60601-1, CSA 601.1 UL 2601-1, EN865, EN/IEC 60601-1-2 2 nd edition
Type of protection	Internally powered by battery
Degree of protection against electrical shock	Type BF – Applied part
Mode of operation	Continuous
Degree of protection against ingress of water/liquids	IEC 60601-1, sub-class 44.6 IPXO
Degree of Safety in presence of flammable mixtures	UL 2601-1, sub-clause 5.5, Not suitable
Applied sensor label to indicate Type BF applied part	IEC 60601-1 Symbol 2 of Table DII of Appendix D
Attention Symbol, consult accompanying documentation	IEC 60601-1 Symbol 9 of Table DI of Appendix D
External case made with non-conductive plastic	IEC 60601-1, sub-clause 16(b)
Case mechanically strong	IEC 60601-1



CAUTION: Changes or modifications not expressly approved by Advanced Brain Monitoring, Inc. could void the user's authority to operate the equipment.

Software License Agreement

Copyright © 2003 Advanced Brain Monitoring, Inc. All rights reserved.

IMPORTANT – READ CAREFULLY THE FOLLOWING SOFTWARE LICENSE AGREEMENT (“LICENSE”) BEFORE BREAKING THE SEAL ON THE SOFTWARE PACKAGE CONTAINING THE CD. BREAKING THE SEAL CONSTITUTES YOUR ACCEPTANCE OF THE TERMS AND CONDITIONS OF THIS LICENSE WITH RESPECT TO THE USE AND POSSESSION OF THE SOFTWARE CONTAINED THEREIN.

IF YOU DO NOT WISH TO BE BOUND BY THE TERMS AND CONDITIONS OF THIS LICENSE, PROMPTLY RETURN THE PACKAGE WITH THE SEAL INTACT ALONG WITH THE SENSOR HEADSET PRODUCT TO WHICH IT APPLIES.

ADVANCED BRAIN MONITORING, INC. retains full ownership rights to the software program (“Program”) and documentation and upon payment of the purchase price of the Sensor Headset product grants to the Purchaser a nonexclusive license subject to the following conditions:

This Program may be used with the Sensor Headset product to which it applies. The Purchaser may install the Program on only one computer, make one copy in machine readable form solely for backup purposes, provided that you reproduce all proprietary notices on the copy; and physically transfer the Program from one computer to another provide that the Program is used only on one computer at a time. The Purchaser may not copy, distribute, rent, lease, sublicense, transfer or use the Program except as allowed herein. In Addition, the Purchaser may not alter, modify, decompile, translate, disassemble the Program; or use it to create a derivative work.

Purchaser’s right to use this Program automatically terminates upon failure to comply with any provision of this License or upon your destruction of all copies of the Program and documentation.

If Purchaser purchases an upgrade version of the Program, either separately or with a Sensor Headset product purchase, it constitutes a single product with the Program that you upgraded.

This License is deemed made, accepted and delivered in the State of California and shall be construed, interpreted and governing by the laws of the State of California, without regard or effect given to its or any other jurisdiction’s conflicts of law jurisprudence.

Software Limited Warranty

ADVANCED BRAIN MONITORING, INC. warrants for a period of 90 days from the date of delivery to the Purchaser that the Program diskette will be free from defects in material and workmanship under normal use. In the event Purchaser within the warranty period notifies ADVANCED BRAIN MONITORING, INC. of defects in material or workmanship, ADVANCED BRAIN MONITORING, INC. exclusive remedy will be to replace the defective diskette.

ADVANCED BRAIN MONITORING, INC. SPECIFICALLY DISCLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO DEFECTS IN THE DISKETTE AND THE PROGRAM. IN NO EVENT SHALL ADVANCED BRAIN MONITORING, INC. BE LIABLE FOR ANY LOST PROFIT OR ANY OTHER COMMERCIAL DAMAGE, INCLUDING, BUT NOT LIMITED TO, SPECIAL, INCIDENTAL, CONSEQUENTIAL OR OTHER DAMAGES EVEN IF ADVANCED BRAIN MONITORING, INC. HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

Some states/jurisdictions do not allow limitations on the duration of the implied warranty, so the above limitation may not apply to you.

To return Program diskette to ADVANCED BRAIN MONITORING, INC. under a warranty claim, the Purchaser must first contact ADVANCED BRAIN MONITORING, INC.'S Customer Support at (866) 677-2737 and receive a Return Merchandise Authorization (RMA) number. Purchaser must place the RMA number on the outside of the package containing the diskettes being returned and ship the package to ADVANCED BRAIN MONITORING, INC.'s facility, freight prepaid. Any return diskette received by ADVANCED BRAIN MONITORING, INC. without a RMA number shall be sent back to the Purchaser.

Product Limited Warranty

ADVANCED BRAIN MONITORING, INC. warrants the Sensor Headset products are to be free from defects in material and workmanship under normal use and service for a period of 90 days from the date of delivery. The obligation of ADVANCED BRAIN MONITORING, INC. under this warranty is limited to repair, re-work or replacement at ADVANCED BRAIN MONITORING, INC.'s option, of any Sensor Headset product which within the 90 days from date of delivery is examined by ADVANCED BRAIN MONITORING, INC. and discloses to ADVANCED BRAIN MONITORING, INC.'s satisfaction to have been defective.

For this warranty to be available to Purchaser, within 14 days of purchase ADVANCED BRAIN MONITORING, INC. must have received a completed warranty card.

ADVANCED BRAIN MONITORING, INC. will not be responsible for, and the warranty shall not apply to, any damage caused by the following: natural disasters, war, civil disturbances, abuse, misuse, negligence, usage of incorrect electrical supply voltage, usage not in accordance with the operation instructions manual, or normal wear and tear.

This warranty shall not apply to any Sensor Headset product which as been repaired, services, disassembled or modified by any party other than ADVANCED BRAIN MONITORING, INC. or the warranty card has been tampered with. No warranty claim will be allowed for Sensor Headset products damaged by improper use, operation or handling after deliver of the Sensor Headset product. Purchaser must file all claims resulting from damage in transit with the carrier or carrier's agent. Expenses incurred in connection with claims for which ADVANCED BRAIN MONITORING, INC. is not liable may be charged to the Purchaser.

Upon submission of a warranty claim, Purchaser is deemed to have waived any and all other claims against ADVANCED BRAIN MONITORING, INC.. ADVANCED BRAIN MONITORING, INC. shall in no event be liable to Purchaser or to the Purchaser's customers for any incidental or consequential damages, loss of use or other commercial loss, however occasioned.

ADVANCED BRAIN MONITORING, INC. MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR PARTICULAR PURCHASE OR PERFORMANCE CHARACTERISTICS, EXCEPT TO THE EXTENT SET FORTH HEREIN.

Returns

To return a Sensor Headset product to ADVANCED BRAIN MONITORING, INC. under a warranty claim, the Purchaser must first contact ADVANCED BRAIN MONITORING, INC.'S Customer Support at (866) 677-2737 and receive a Return Merchandise Authorization (RMA) number. Purchaser must place the RMA number on the outside of the package containing the Sensor Headset product being returned and ship the package to ADVANCED BRAIN MONITORING, INC.'s facility, freight prepaid. Any returned a Sensor Headset product received by ADVANCED BRAIN MONITORING, INC. without a RMA number shall be sent back to the Purchaser.



Service

The solid-state circuitry within the Model 603-B requires no periodic maintenance or calibration other than battery replacement. ABM does not recommend field repair of the Model 603-B. The circuit boards in the Model 603-B are multi-layer boards using traces 0.01" wide. Due to the very small trace size, extreme care must be used when replacing components to prevent permanent non-repairable damage to the circuit board. Most components are surface-mounted and require special hot air jet soldering and desoldering equipment. After any repairs are made, the Model 603-B must be tested to ensure correct operation.

All repair work on the Model 603-B should be done by trained ABM personnel. All non-warranty work shall be done according to ABM standard rates and charges in effect at the time of delivery to ABM. All repairs include a complete retest of the Model 603-B using factory software and/or test fixtures.

Customer Support

If you have any questions regarding this product, please first refer to this User's Manual. To obtain warranty service, you must call ADVANCED BRAIN MONITORING, INC. and speak with a Customer Service Representative. Be prepared to provide: 1) your name, address and telephone number, 2) the Sensor Headset model and serial numbers, and 3) an explanation of the problem.

Telephone: (760) 720-0099 or Toll-Free (866) 677-2737
9 AM to 5:30 PM Pacific Time
Monday – Friday

Fax: (760) 720-0094

Email: Support@B-Alert.com

Web: <http://www.B-Alert.com>

Mailing Address: 2850 Pio Pico Drive, Suite A
Carlsbad, CA 92008

Warranty Information

(Retain this information for your records)

ADVANCED BRAIN MONITORING, INC. thanks you for your recent product purchase. For your benefit, we recommend that you record the pertinent details below. This information will be needed to submit a warranty claim or obtain service.

Sensor Headset Model Number: _____

Serial Number: _____

Date of Purchase: _____

Trademark Acknowledgements

B-Alert is a registered trademark, and Sensor Headset and Wi-Med are trademarks of Advanced Brain Monitoring, Inc., Carlsbad, CA.

Synapse® is a registered trademark of Med-Tek/Synapse®, Arcadia, CA.

Windows is a trademark of Microsoft Corporation.

All other products or brand names are trademarks or registered trademarks of their respective companies.