EEGer4 Study Manager

EEGer 4.3.0 (and later) supports a double-blind study mode with the Study Manager feature. In this mode, selected clients are fed prerecorded data from files rather than using the client live signal data. All other actions and controls are the same as using live data and the technician controlling the feedback cannot differentiate between live and simulated data.

How this works is summarized here:

1. The manager for the study selects previously-recorded (by EEGer) raw data files (or parts of files) using the password-protected Study Manager interface. These files are specified for the three EEGer classes (SMR, EXP, AT). A pool of 10 to 20 files needs to be selected so data "repeat" is minimized.
2. The manager designates already-existing clients as "simulated data subjects".
3. When a simulated study client session is started (BEGIN SESSION), the next (preordered or randomly-preordered-at-client-assignment to sham status) prerecorded file is selected as the "input".
4. ***EEGer monitors the actual live data during the session.***
    a. If the amplifier is not operating correctly, the file signal is set to zero.
    b. If the live data from each channel is less than the threshold (currently set at TBD), the corresponding file channel signal is set to zero (as if the electrode is unconnected or has fallen off).
    c. If the live data from the channel is greater than the live threshold, the **file** signal value is multiplied by a value determined by computing how much the live signal exceeds its average value, triggering an artifact condition. The live signal is never seen.
5. The actual live data is recorded in a hidden client file.
6. The data from the session (from the prerecorded file) is saved as though it was a live session (both raw and summary data).

    There is no visible indication before, during, or after a session that the study subject IS a study subject (except that the "results" may differ from actual live feedback).

Caveats:

1. An experienced clinician may be able to recognize that the feedback doesn't seem to be having a "normal" affect on brain activity. However, the goal of the study logic was to "fool" a technician and not a clinician.

2. The artifact adjustments made by the technician will not exactly match the live data characteristics so the seeming-artifact file data waveshapes may not exactly match what a live artifact waveshape would be. However, the short-term averages should correspond and correctly drive the artifact controls (which inhibit rewards).

3. It is the study manager's job to select "suitable" playback files for the pool of files. This must be done BEFORE any clients are selected as "study subjects" (the randomly-ordered file list is predefined at selection time). If including 2-channel training for any of the study subjects, it is recommended that ONLY 2-channel recordings be used for control data.

4. **A study subject has ALL three protocol classes in simulated state. You cannot have live data in one class and simulated data in another.** Be observant in case the simulated feedback leaves a client in a "bad" state.

5. An experienced computer user could browse around and find the "hidden" client storage folders but would only be able to correlate a client "ID" by further browsing inside some files.

Access to the study logic is password controlled (so you can't accidentally set this state on someone).

Several general guidelines should be followed in selecting sham data to use.
1. Ensure that the sham data is representative of the clients to be used for the study.
2. Examine the sham files and remove artifacts and data loss (using the editshan tool).
3. Make sure the pool of sham data is large enough. This may be 10 to 20 samples or a large date-oriented set of data.
4. Keep records of what you do since the sham files are anonymous after editing.

Troubleshooting

If an electrode falls off, the data may drop to zero or have very large non-eeg excursions. Impedance readings reflect the actual connected amplifier so you should check those values. Typically, the (sham) data set should be relatively constant but artifacts from the live amplifier inputs may (and should) make the data invalid.

Support for controlled studies is available in EEGer version 4.3.0 or later. These instructions provide directions to activate and utilize the Study Manager in EEGer.

For Study Manager to function in EEGer, the following items must be valid:
1. A valid EEGer license for Study Manager must be installed.
2. EEGer 4.3.0 or later must be installed.

- **Install the EEGer Keyblock File from CD/USB:**
  1. Insert the ***EEGer Keyblock File CD*** or USB in your CD/DVD drive.
  2. If the contents of the CD/USB are displayed automatically, close the window. You must load the key using EEGer.
  3. Start the EEGer program. From the **Files** menu, select **Read EEGer Keyblock Files.**
  4. Select the CD/DVD/USB drive for the ***Look In*** field.
  5. The updated keyfile is displayed on the Open dialog. Click the filename to select/highlight and click **Open**.

- **Install the EEGer Keyblock File from emailed file:**

  1. Download the ***EEGer Keyblock File*** .
  2. You must load the key using EEGer.
  3. Start the EEGer program. From the **Files** menu, select **Read EEGer Keyblock Files.**
  4. Select the location where the downloaded keyblock file in the ***Look In*** field.
  5. The updated keyfile is displayed on the Open dialog. Click the filename to select/highlight and click **Open**.

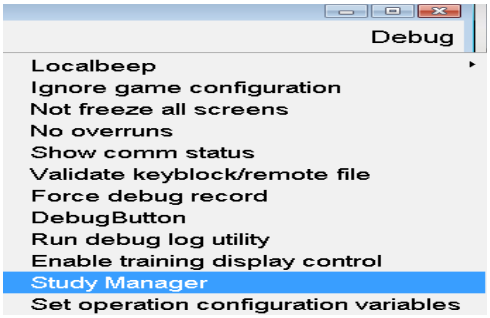
Before continuing, the study data needs to be exmined and cleaned up. Please refer to the 'editsham' instructions later in this document.

- **Select Control Data and Set Up Study Clients**

  Use Review/Replay/Spectral to choose recorded EEG sessions from your existing clients to use for the control sample(s). (10 to 20 control files are recommended)

  - **ACCESS THE STUDY MANAGER MENU**

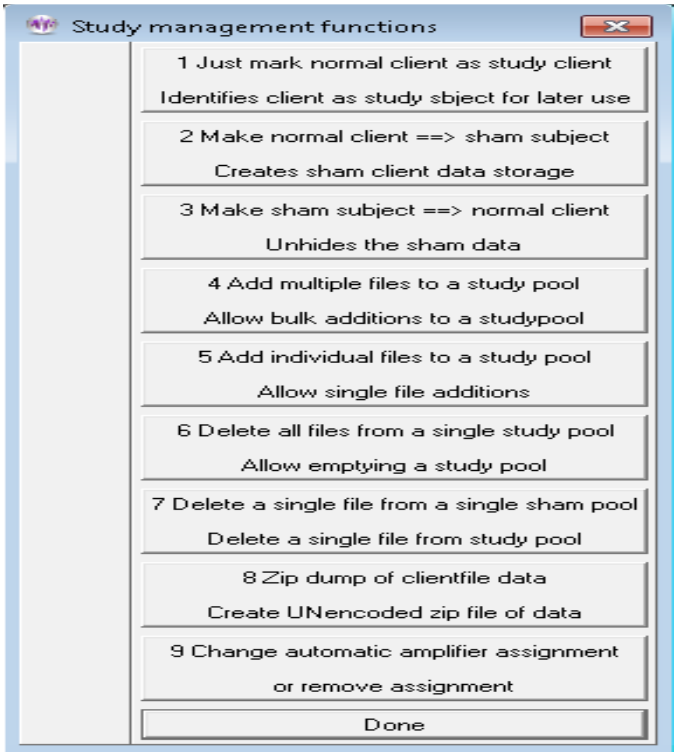
    1. To access the Study Manager from the main EEGer display, press **Ctrl** + **Alt** + **Right-Mouse Button** at the same time and the **Debug** menu becomes visible.



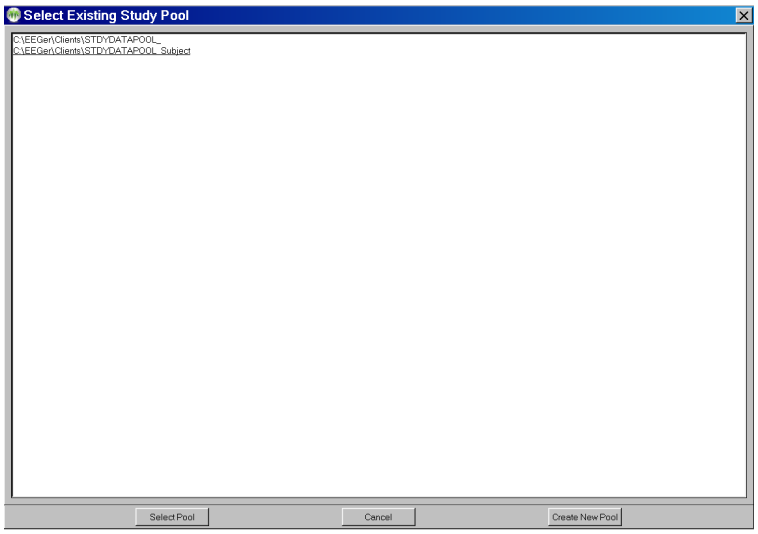
    2. From the **Debug** menu, select **Study Manager**.
    3. Enter the Password provided to access the Study Manager dialog.

  - **SET UP CONTROL SAMPLE FILES**

    1. To set up control data samples, select **Add multiple files to a study pool**.



2. Select the desired sham study pool folder:



If desired, a new study pool can be created. Clicking on "**Create New Pool**" brings up a box where the new pool 'name' can be entered.

3. Select Client IDs that contain the desired samples (double-click or click once to highlight and click OK).

4. Select the desired session(s) from the client's data (Entire or Partial).

5. Repeat steps 3-4 until you have selected the sample set.

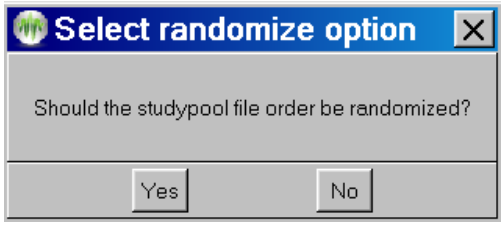
- **SELECT STUDY CLIENTS**

1. Click **Make a normal client ==> study subject**.

2. Select the Client ID to convert to a study subject (double-click the ID or click once to highlight and click OK).

3. Select the desired sham study pool folder.

NOTE: Changing a client to a study subject converts ALL protocol classes for the Client ID to use study control samples.



4. Choose whether to randomize the order that the study pool files are used or leave them in the order specified by their 'name' (sequential within a particular pool).

5. Repeat steps 2-4 to select all study participants.

- **RESTORE CLIENT TO LIVE STATUS**

1. Click **Make sham subject ==> normal client**

2. Select the Client ID to convert (double-click the ID or click once to highlight and click OK).

3. Repeat step 2 for each client.

Note: This makes the live data folders visible again but named with the GUID of the actual client.

- **JUST MARK NORMAL CLIENT AS A STUDY SUBJECT**

Select the normal Client ID to to mark as part of study. Study subjects (normal and sham are treated specially for exports and such but otherwise leaves them alone.

- **DELETE ALL FILES**

1. Click **Delete all files from a single sham pool**
2. Select the desired sham study pool folder.
3. Confirm the deletion.

- **DELETE A SINGLE FILE**

1. **Click Delete a single file from a single sham pool**
2. Select the desired sham study pool folder.
3. Select the filename to be deleted.
4. Repeat step 3 as desired.

Note: Take great care in deleting files that may still be selected by a sham subject.

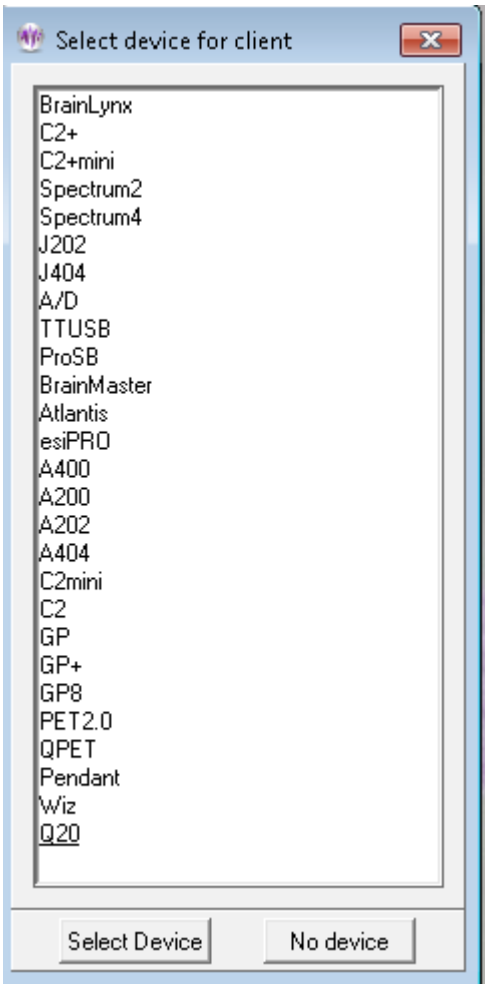
- **ZIP DUMP OF FILE DATA**

1. **Click Zip dump of file data**
2. Select the clients of interest (either live or sham)
3. A Zip-formatted file will be created with all the client data. Ths file will also include any hidden (live) data from sham clients.

CAUTION: this zip file will show sham clients and data!

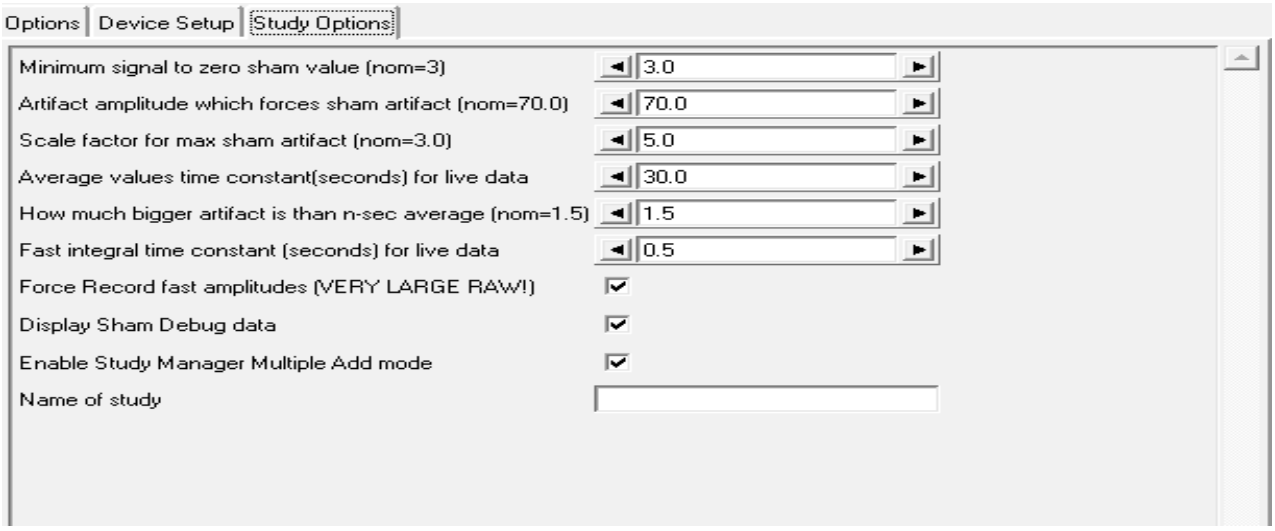
- **CHANGE AMPLIFIER ASSIGNMENT**

1. **Click on Change amplifier assignment**
2. Select a client of interest (live or sham_)
3. Select an amplifier from the available list or specify "No Device"



4. If an amplifier was selected, that amplifier will be selected as the default amplifier in **EEGer** whe the client is next selected

Some options available to the study manager:



The study manager can specify the lowest average voltage for a signal to “be there” (currently 3 microvolts P-P). This is usually dependent on the desired electrode placements (and the expected typical readings there).

The study manager can set an absolute amplitude at which an “artifact” condition will be detected. Default value is 70 microvolts peak.

The study manager can determine the scaling of the sham signal when in full artifact (default is 5 times the sham signal). This makes the artifact look “real”.

The study manager can set the time constant for measuring the average P-P amplitude of the live signal. This is usually 30 seconds (using a moving window).

The study manager can determine the scale factor for NON-max artifacts. The data looks 'real' with a nominal scalar of 1.5 times the live signal average value.

The study manager can specify the fast integral time constant. This controls how fast EEGer tracks the live artifact and how sharp the edges of the artifact are.

The study manager can force recording of trace amplitudes at high speed (256 Hz). This is to allow later analysis of the data. The option can also be user-selected on the Special settings tab.

Warning: This makes the files 5 or 6 times larger than usual and may provide a “clue” that the software is doing something unusual. However, this size differential affects ALL clients so there is no difference in size between live data and sham data recordings.

The study manager can allow display of sham debug data. **NOTE: USE ONLY DURING TESTING**.

The study manager can enable multiple add mode when building sham data pools

The study manager can insert a “name” for the study. Clients marked as study subjects will display the name of the study. **WARNING: if a study name is entered, make sure that ALL normal study clients are marked as 'study sjubjects' or only sham subjects will display the study name <u>BREAKING THE BLIND!</u>**

The editsham tool

This tool allows viewing/editing of EEGer eeg data files to allow selection of valid sham data samples. Although originally written for the ICAN study, it also works for other studies. The current version (1.5) has only beeen tested for single channel files.

There are possible startup options (command line options) that change the default operation of the program. By default, it displays the raw data, the lowpass-filtered moving average data, the theta, beta, and thata-beta ratio data from studypool files.

Options on the command line:

NORAW	Inibit display
NOLP	Inhibit computation/display
NOTBR	Inhibit computation/display
NOTHETA	Inhibit computation/display
NOBETA	Inhibit computation/display
NOTHETASIG	Inhibit computation/display if EVERYTHING was specified
NOBETASIG	Inhibit computation/display if EVERYTHING was specified
EVERYTHING	Enable all the displays (use first, then inhibit as desired)

NOPOOL	Use normal client data instead of studypools Warning: this removes actions from the resulting data file!!!
AUTO	Automatically save each edited file before continuing to another file
NOTICAN	Specify NOT ICAN mode even if study name is ICAN
HELP	Shows the options then quites
ROOT xxxx	Allows selection of client base foler location if not default c:\EEGer\clients or special ICAN dropbox locations.

The default file locations are specified in a data file. The data source/destination paths are defined in a file named

C:\EEGer\Preferences\Settings\smeditsham.ini

This file is created if not already in existance. It usually looks similar to :

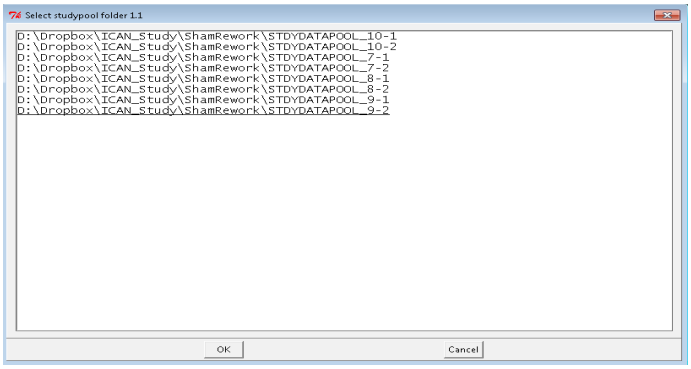
```
[ICAN]
in=dropbox\ICAN\SHAMDATA
out=dropbox\ICAN\SHAMEDIT
backup=0

[default]
in=
out=
backup=1
```

Each project can have its own section specifying where the data is and goes to, The ICAN section says that the root input folder is at the DROPBOX\ICAN\SHAMDATA folder (and usually contains multiple client subfolders). The keyword 'dropbox' makes the program find the linked Dropbox folder. The

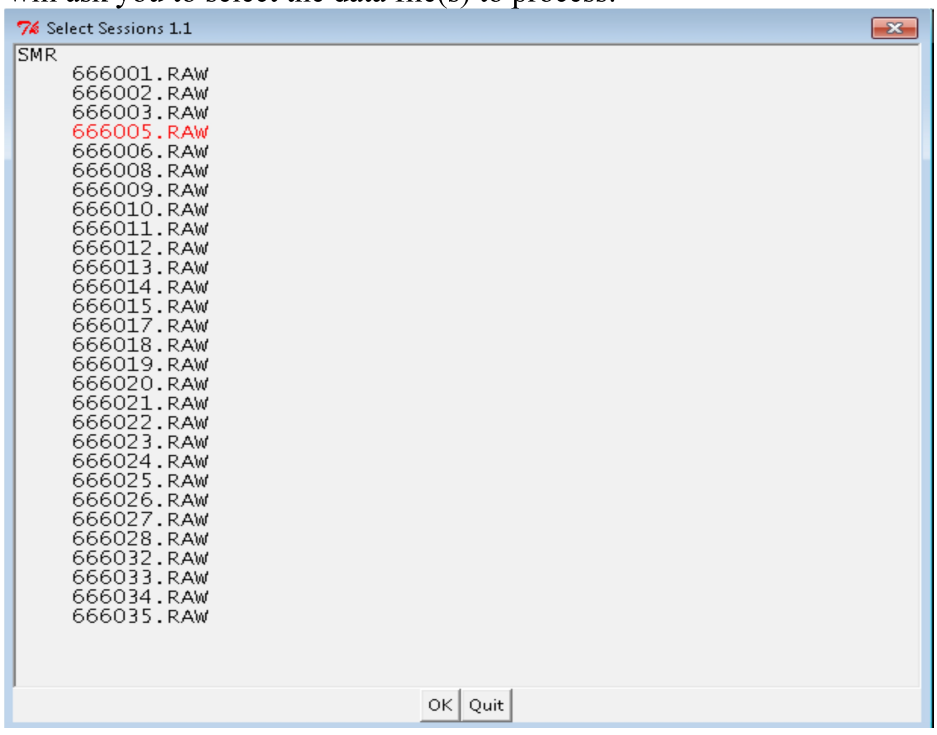
destination is elsewhere (and will then also contain subfolders s the data is processed). The default section doesn't specify places so the default input root folder will be wherever EEGer folder is specified. Since the output folder is the same, a folder will be created below the client-protocol folder (named BACK) where the original file will be backed up.

Start the program. The first ICAN screen will be this:



For ICAN, notice the studypool paths point to a Dropbox folder although there other options. Select a path and click on OK (or just double-click a path).

The next screen will ask you to select the data file(s) to process:

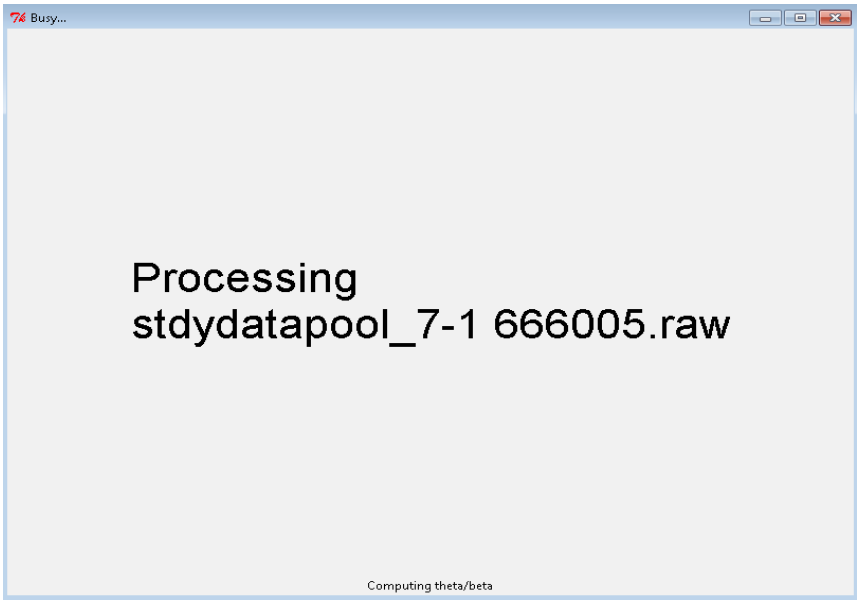


Selecting individual files is by clicking on them to make them RED. Clicking on the protocol class will change all of thes either RED or not RED

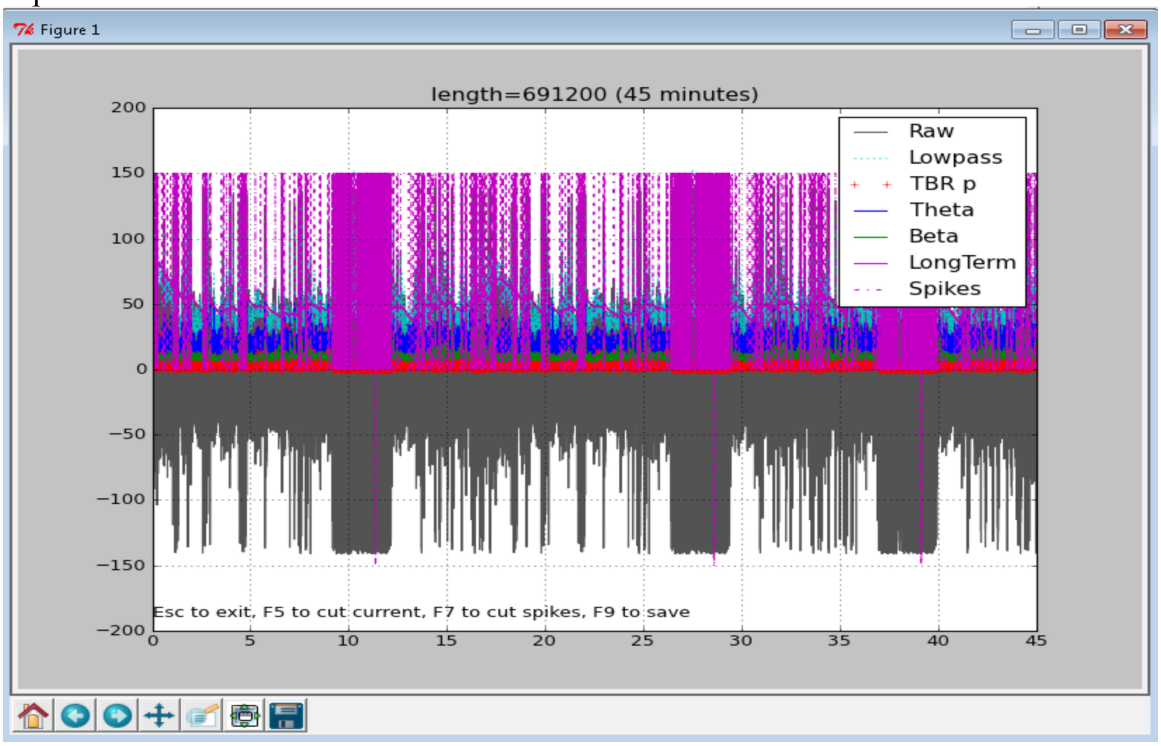
When ready, click on OK.

The program will then begin processing for all the selected sessions.

Processing will then begin with a busy screen:



A typical plot looks like this:



The legend on the top right shows the color/line style of each data plot. The horizontal scale is minutes. You can adjust all this using the following plot controls:

This is the home button and returns the image to its initial condition.

These are the left and right history buttons to move between various images (such as after zooming or scrolling).

This is the scroll button which moves the display to various data locations. Clicking on this leaves you in scroll mode.

This is the zoom button. This will allow the selection box data (drag with mouse) to fill the display

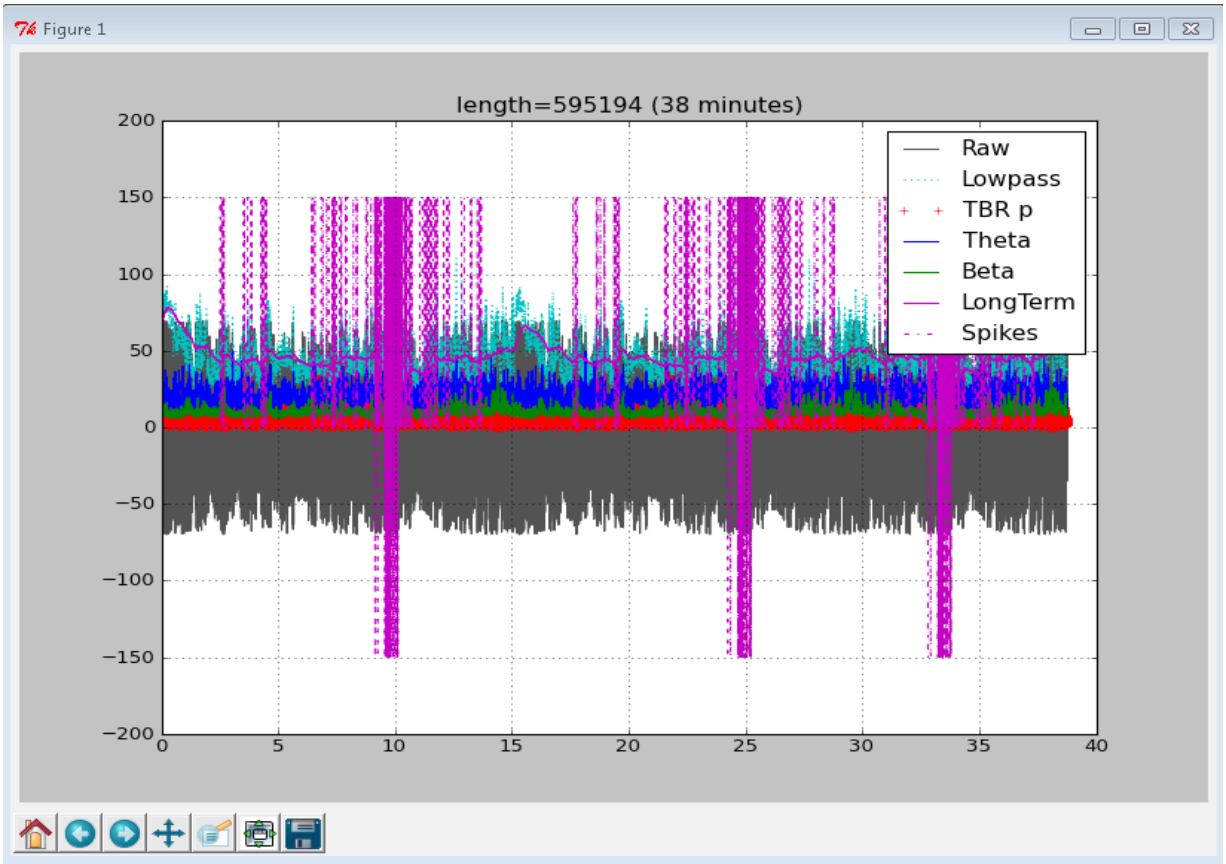
window. This mode stays active until another button is selected.

This is the save button (to allow saving the current image).

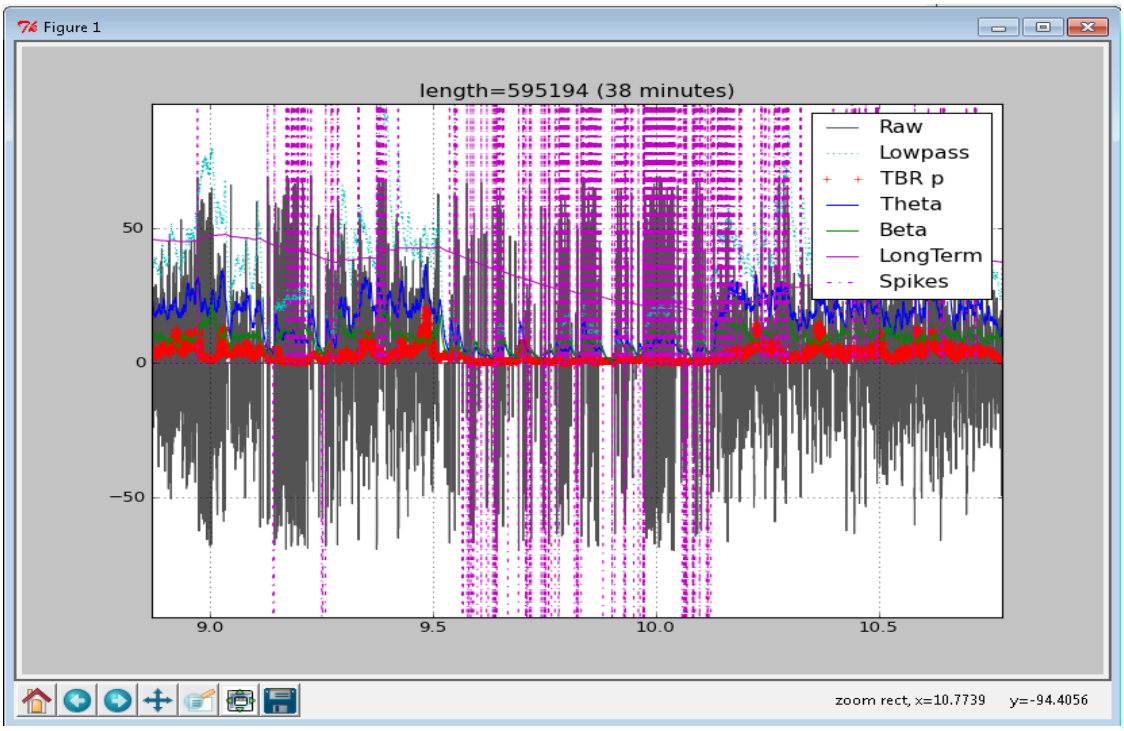
You can also resize the display window by dragging the window border.

Notice the legend at the bottom of the screen. Use Esc to quit without saving. F5 CUTS out the current (hopefully ZOOMed in region) and then redisplays the graph. F7 attempts to cut out the spikes (and zero points) and then redisplays the graph. F9 saves the current data set . The very first time a file is edited, the original is renamed to (name)OLD before saving the data file. At the top of the graph is displayed a legend showing how many minutes of data are contained in the current data set. Not shown is F1 which brings up this help note.

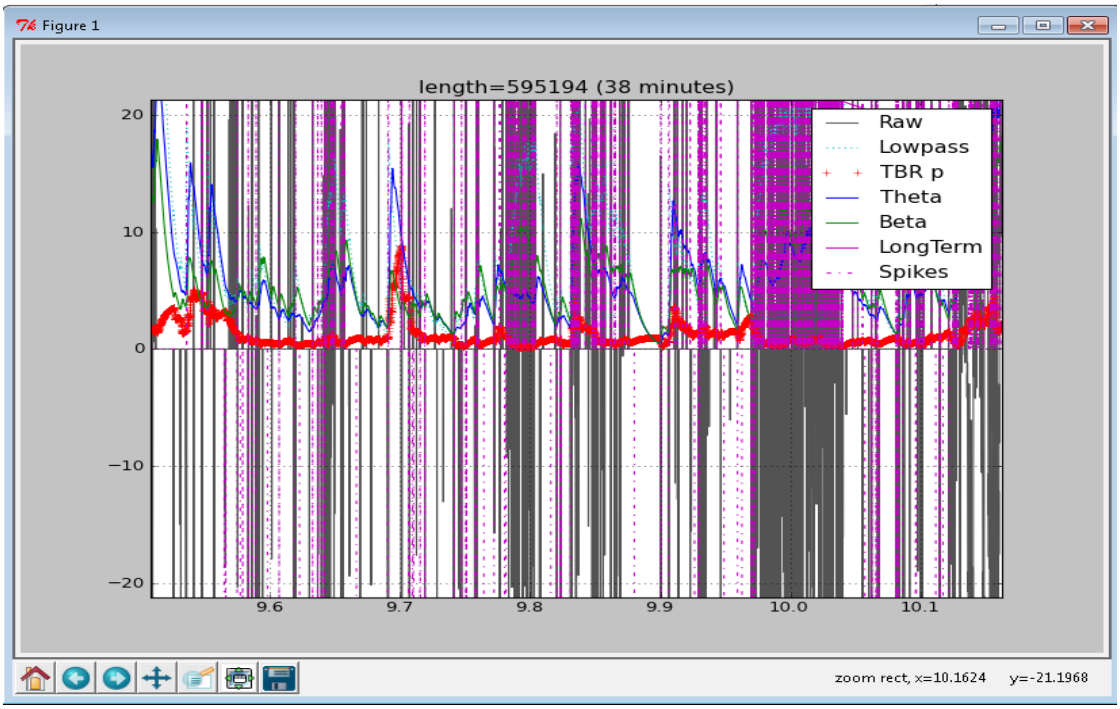
Using F7 on the above sample brings up this graph:



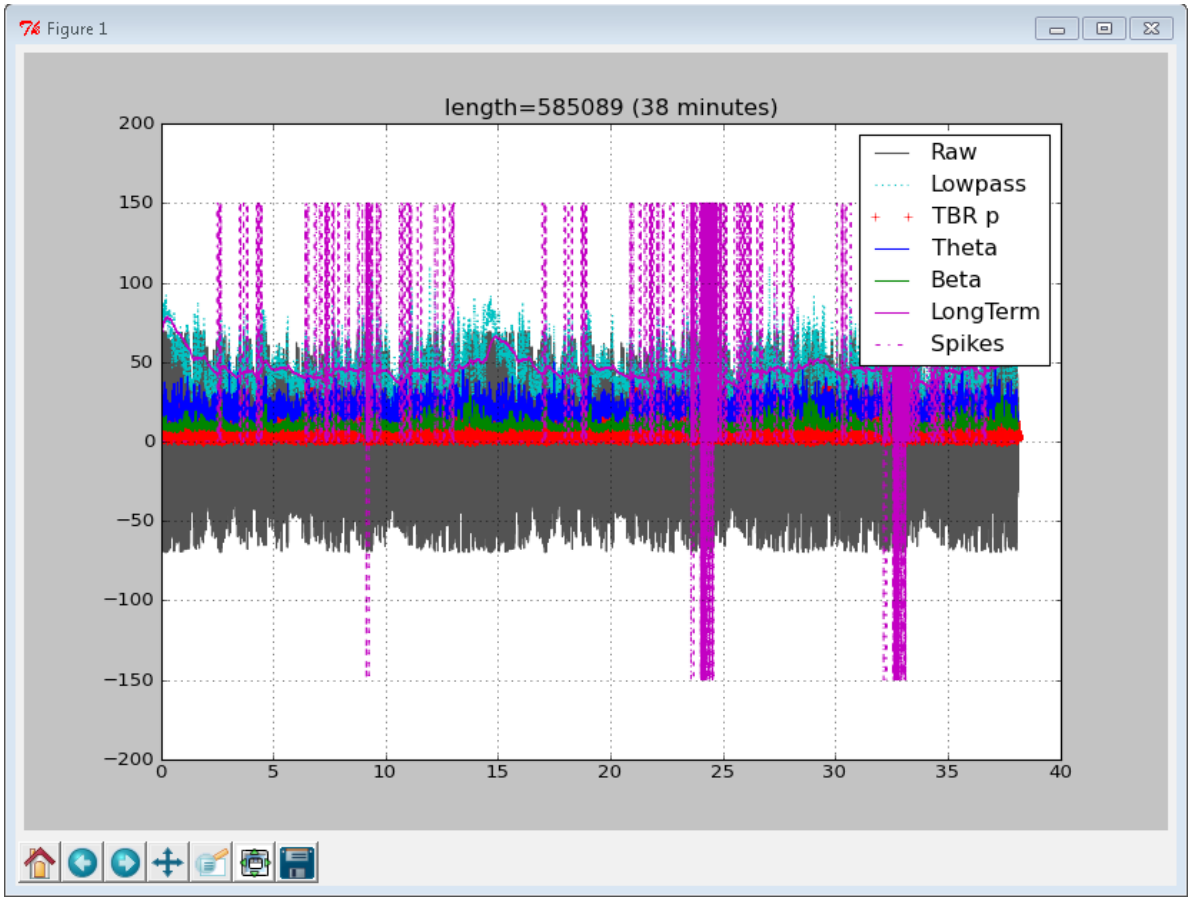
Not everything is handled automatically. Notice the loss of data at about 10 minutes. Zooming in here (click in the zoom button and mark the region) gives this display:



I didn't get the zoom region closely enough marked so I will just zoom in again and get this:



Then cut this with F5 and get:



Note the zero point at 10 minutes has gone. Repeat the process until satisified and then press F9.

You can then repeat this for all selected data files.

For ICAN, the files are just replaced with the edited files. Otherwise, the original files are renamed to (filename)old (but only the FIRST time) and the edited files replace the old files. When happy, all the ()old files can be manually deleted although they do NOT affect operations.

The ExportStudy tool

A problem exists when blinded users need to transmit data for UNblinded observers to analyze the data. The ExportStudy tool resolves this issue. This tool exports selected clients/files in a special encrypted format. Sham subject data is exported with both the sham records AND the live recording of the same session. Normal (non-sham) subject data is exported using the live date and a scrambled copy of the same live data. Because there are similarly-sized files exported for live/sham subjects, it is very difficult to determine live/sham status. These files are generated in the EEGer Export folder with a file extension type of ".sece.zip".

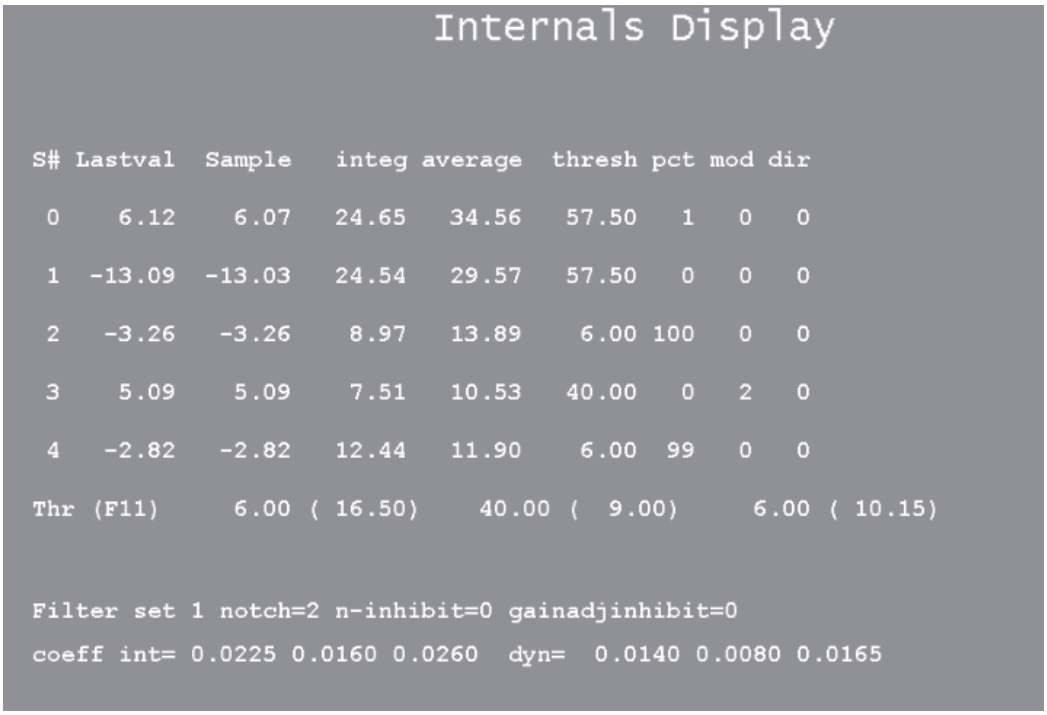
There is a corresponding "ImportStudy" tool that retrieves the true live data and sham data into the correct locations. There is a code required to import the data from the specially encoded file. The tool is available by request from EEG Software LLC.

Internal V&V procedures

There are several undocumented test processes that can be used to verify and tune the EEGer Study Manager logic. **Do NOT leave these options enabled or the study blind may be broken.**

The principal method is a special display mode where the sham data is displayed on trace A and the live channel A data is displayed on trace B. This allows visual verification of how well the settings are adjusted for passing artifact data from the live data to the prerecorded sham data.

A first option must be set to enable display of sham data values. This is done on the Debug options page where the "Display sham debug data" checkbox must be set. This value persists until disabled. Setting this option causes the live data values to additionally be displayed on the (mostly undocumented) "Internals Display" (reached by Ctrl-Alt-F1). This display normally shows data in real time for the displayed traces:



If the "Display sham debug data" option is selected AND this is a shamified client, there will be two additional traces displayed after the ones shown which are the live channel A and live channel B values. They are merely numbered as the two next traces (the above display is for the 2-channel 5-trace display layout) so they would be 5 and 6 in this case.

The extra special case involves having both the "Display sham debug data" flag set AND an EEGer command line option set at startup (value is INTERNALCHEAT). This is normally added to the startup shortcut on the desktop and removed after testing.

In this mode, the A trace displays normally but the B trace shows the live A channel data. The label will be 'B=A n.n' where the n.n value is the dynamically-changing multiplier value used to impose the artifact onto the prerecorded data.