WAVi Scan

Instructions for Use

Version 1.1.0

Revision: 1.1.0

Issuance Date: 04/10/2023

BE SURE TO READ THIS ENTIRE MANUAL BEFORE USING THE WAVi SCAN SYSTEM.

Intended Use:

WAVi Scan is intended for the acquisition, display, and storage of electrical activity of a patient's brain including electroencephalograph (EEG) and event-related potentials (ERP) obtained by placing two or more electrodes on the head to aid in diagnosis. The WAVi Scan system is a Class II device intended for use only by trained healthcare professionals in clinical and/or research settings. Not for consumer sale or use. The WAVi Scan labeling and instructions for use are consistent with FDA regulation requirements listed in section 801.

Contraindications:

There are no known contraindications to the use of this device. This device is non-sterile and does not require sterilization prior to use.

Cautionary Statements:

- For use only with compatible FDA-cleared EEG headsets according to manufacturer guidelines.
- The WAVI EEG System's software includes electronic versions of standardized clinical assessment tools related to psychiatry and neuropsychological evaluation which are provided for convenience and are to be used in accordance with the assessment tools' specific instructions. These tools do not interact with any other of the EEG system's hardware and software measures and are stand alone.
- This system is not designed, and should never be used, for any type of electric stimulation.
- This system is not intended to replace professional clinical evaluation.
- The software, EPU, and other applied parts cannot be serviced or maintained while in use with the patient.
- Patient information stored on the system computer must be safeguarded in accordance with appropriate clinical standards.

No adverse reactions or medical complications related to the use of this device have been reported.

No known hazards due to simultaneous use of other patient-connected medical equipment except as noted below.

WARNING: Not designed for use near high frequency/high voltage surgical equipment.

WARNING: Regulations require that the laptop must only be connected to the included type BF charger in order to ensure a supply mains with protective earth.

WARNING: Cellphones and other RF-generating devices should not be operated in close proximity to the WAVi EPU during data acquisition.

WARNING: No protection against ingress of water or particulate matter. Do not use in a wet environment. Such use may result in equipment failure.

WARNING: No modification of this equipment is allowed. Do not connect any parts not mentioned in this manual.

WARNING: Do not connect any non-system components to laptop while in use with patient.

Contact Information:

www.wavimed.com

support@wavimed.com

Contents

1. System Setup

1.1. List of Parts

At a minimum your WAVi Scan system kit should include the following standard items:

- (1) WAVi Scan Instructions for Use (this document)
- (1) Laptop PC running Microsoft Windows®, preconfigured with WAVi Scan software
- (1) AC power adapter for laptop PC (type BF)
- (1) WAVi Electronic Processing Unit (EPU)
- (1) USB Mini-B cable for EPU
- (1) Pair of stereo headphones (with auxiliary 3.5mm stereo cable if needed).
- (1) USB mouse
- (1) Bag or case for transport and storage

If any of the above items are missing from your kit, please contact WAVi customer support for assistance. Any additional equipment and/or consumable supplies which may be bundled with your kit are outside the scope of this document. Please consult the relevant manufacturer and/or supplier directions for how to set up and use any such items.

1.2. Computer Setup

Place the laptop PC and all standard accessories on a table. Plug the mouse into any available USB port on the laptop, and position the mouse on the side of the participant's preferred hand. Ensure that there is enough space for both the test administrator and the participant to comfortably operate the laptop. **Do not place the laptop on an uneven or unstable surface, as doing so may introduce artifacts during recording and can interfere with the participant's ability to properly complete all tests.**

If you are using the laptop in battery mode, make sure it is sufficiently charged. If you are using mains power, ensure you have easy access to the laptop's AC power connector in case you need to unplug it during a session. Always make sure to use only the approved type BF power adapter provided with your kit.

Next, power on the laptop and sign into the appropriate Windows user account.

After you are signed in, we recommend checking that "Airplane mode" is active. This helps to prevent software updates and other internet disruptions from occurring during a session. Look for an airplane icon in the Windows taskbar (Figure 1-1). If you see a Wi-Fi icon instead of an airplane icon, first click the Wi-Fi icon, then in the popup panel click the "Airplane mode" button to enable it. The computer will remain in Airplane mode until you choose to disable it. Note that this mode blocks the use of wireless accessories such as Bluetooth mice, so if you must use those, you can instead turn off just the Wi-Fi by toggling the "Wi-Fi" button to the left of the "Airplane mode" button.

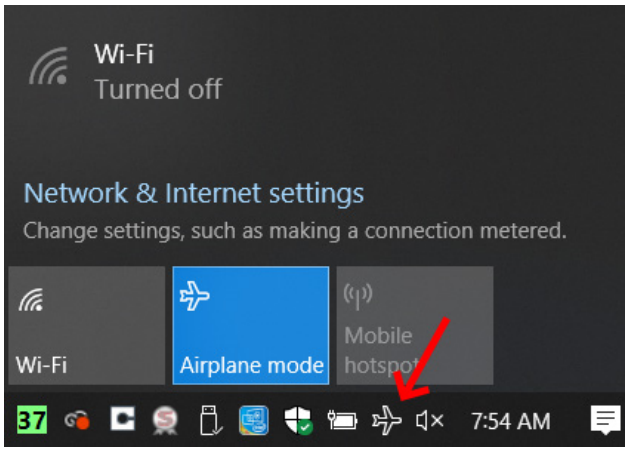

Figure 1-1.

You may now connect the EPU to the laptop using the provided USB Mini-B cable. Allow the EPU time to initialize. If a Windows device setup notification appears, wait for it to disappear before opening the WAVi Scan app.

Prepare a compatible EEG headset, electrodes, and any other relevant supplies as per the manufacturer's instructions, but do not apply these to the participant's head or body yet.

1.3. Starting the Software

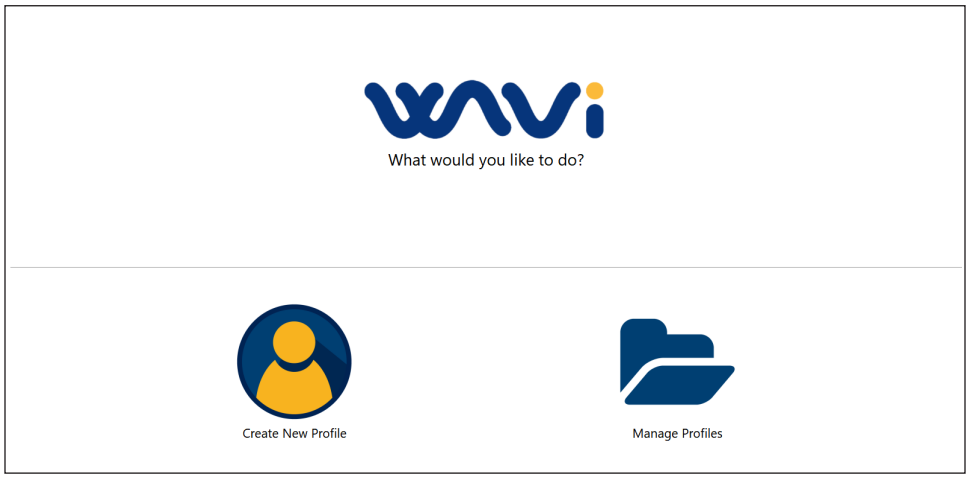

Figure 1-2.

Open the WAVi Scan app by double-clicking its icon on the Windows desktop. Upon app startup you will see a welcome screen as shown in Figure 1-2.

If the participant does not already have a profile, press the **Create New Profile** button and proceed to section 1.3.1. Otherwise, press the **Manage Profiles** button and skip to section 1.3.2.

1.3.1. Creating a New Profile

If you chose to create a new profile for the participant, you may now input their basic details using the interface shown in Figure 1-3. You are not required to fill in all of the fields, but you must provide at least a birthdate. It is also recommended to provide at least a first and last name if possible. Many of these fields are included when generating reports later, so the answers should be as complete and accurate as possible. Next to some fields, you can press blue question mark buttons to see short explanations of how to use those fields.

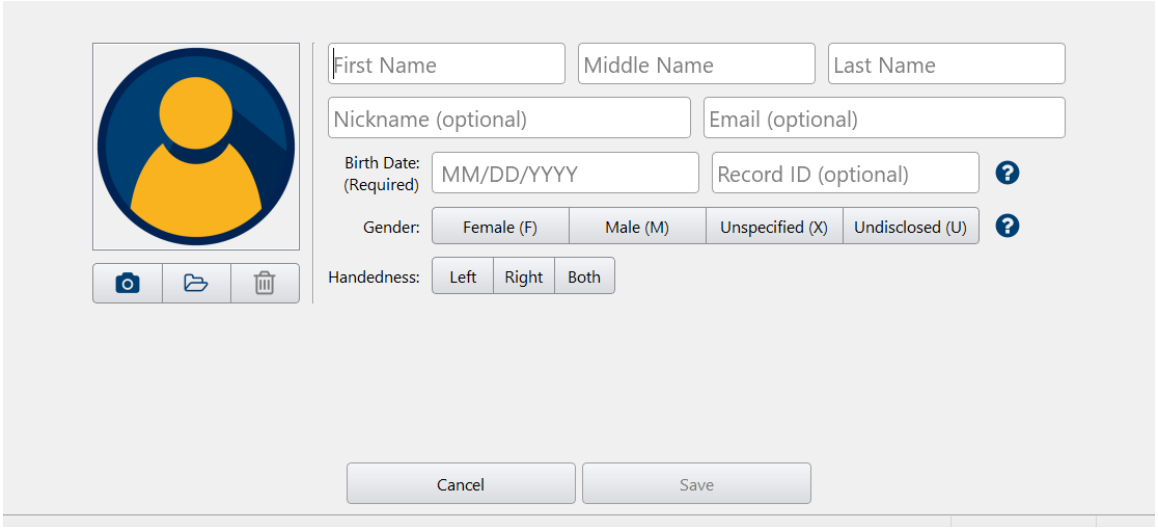

Figure 1-3.

If desired, a photo may be taken using the computer's built-in camera, or you can press the folder button to browse for an existing photo file on the computer. For more details, see section 11.5.

When you have finished editing the basic details for the new profile, press the **Save** button.

At this point, a one-time popup message will ask if you want to add a consent form (Figure 1-4). This step is optional and does not need to be completed immediately. However, it must eventually be completed if you intend to share the participant's data with WAVi for anonymized research purposes. For this example, do this now by pressing the **Yes** button.

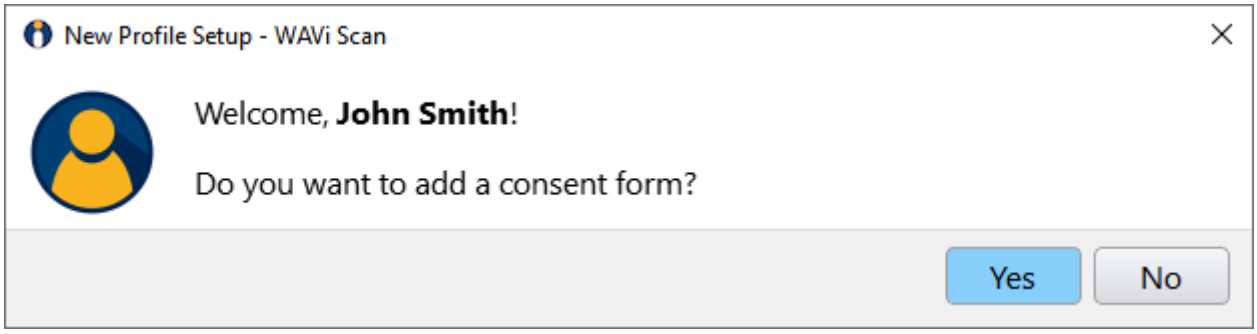

Figure 1-4.

Select "WAVi IRB Consent Form" in the subsequent dialog window (Figure 1-5), then press **OK**.

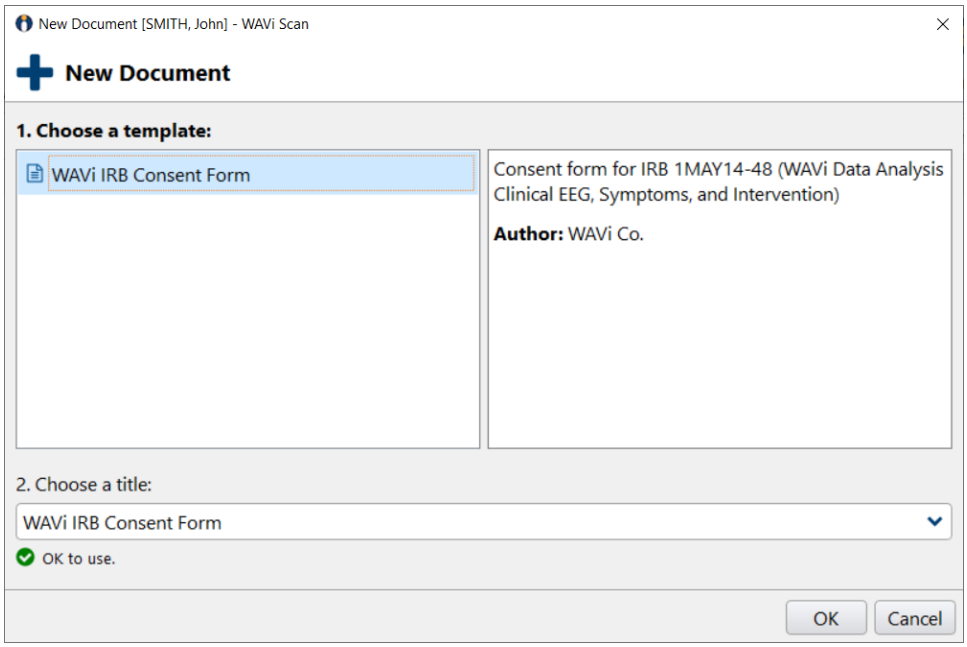

Figure 1-5.

Instruct the participant and/or their guardian to read and complete the consent form (Figure 1-6), using the touch screen to sign where needed. When finished, press **Exit Form** in the upper right corner of the window. The completed form will be automatically saved to the new participant profile.

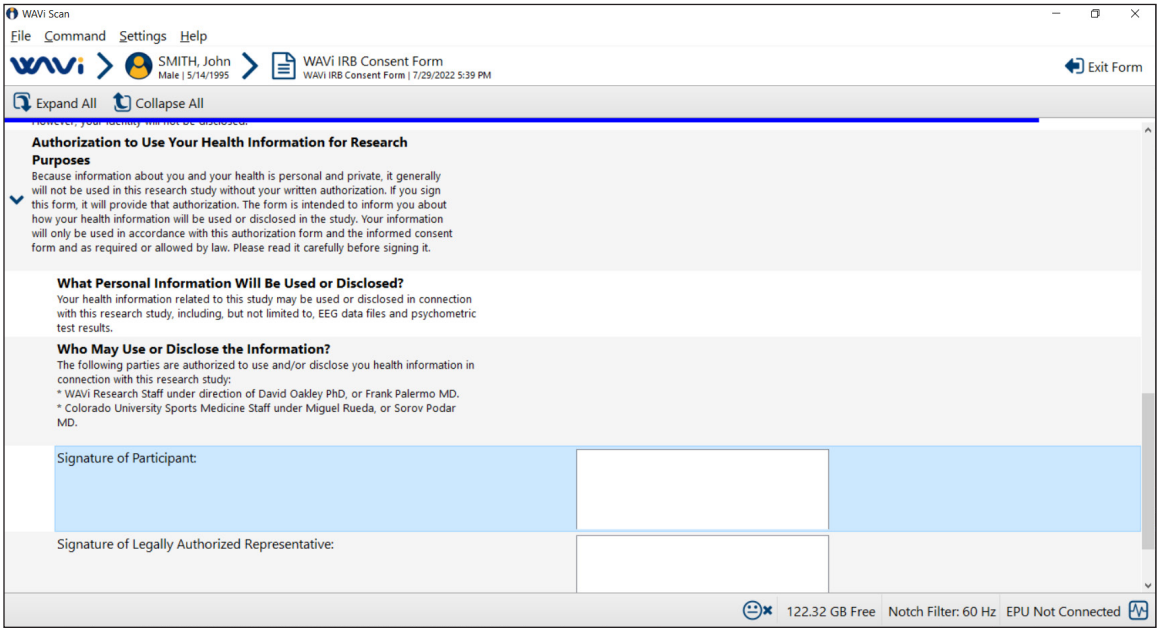

Figure 1-6.

1.3.2. Opening an Existing Profile

If the participant already has a profile in the system, it will appear in the list of "All Profiles" as shown in Figure 1-7. Double-click on the participant's name in the list to open their profile. (Note: if there are many profiles, you may need to scroll in the list or use the search box to find the correct one.)

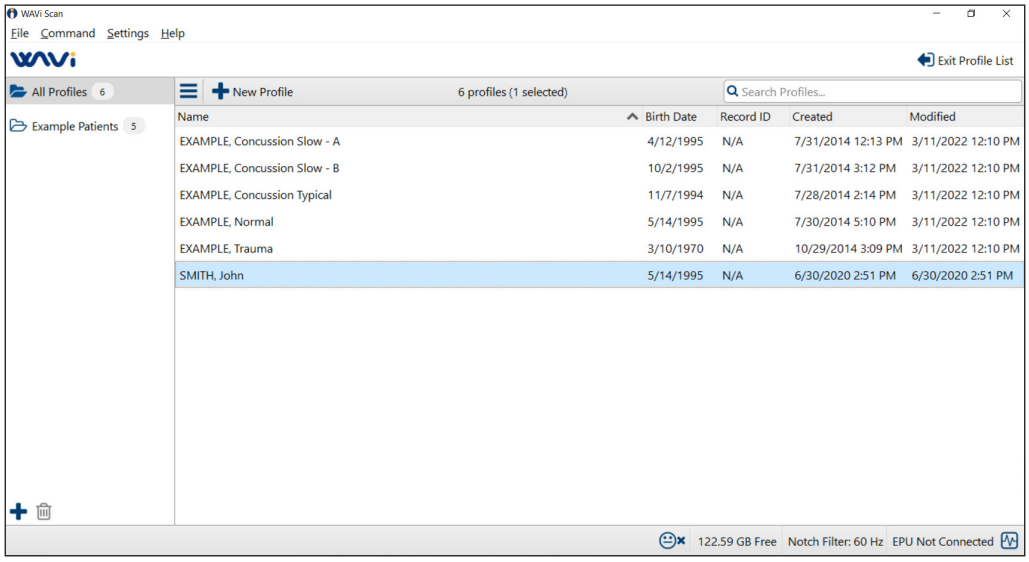

Figure 1-7.

1.3.3. Viewing the Profile

After either creating a new profile or opening an existing profile, you will see a view like the one shown below in Figure 1-8. This interface allows you to create new sessions, open existing sessions for review, generate reports, and manage other information associated with the current profile. For more details, see section 11.

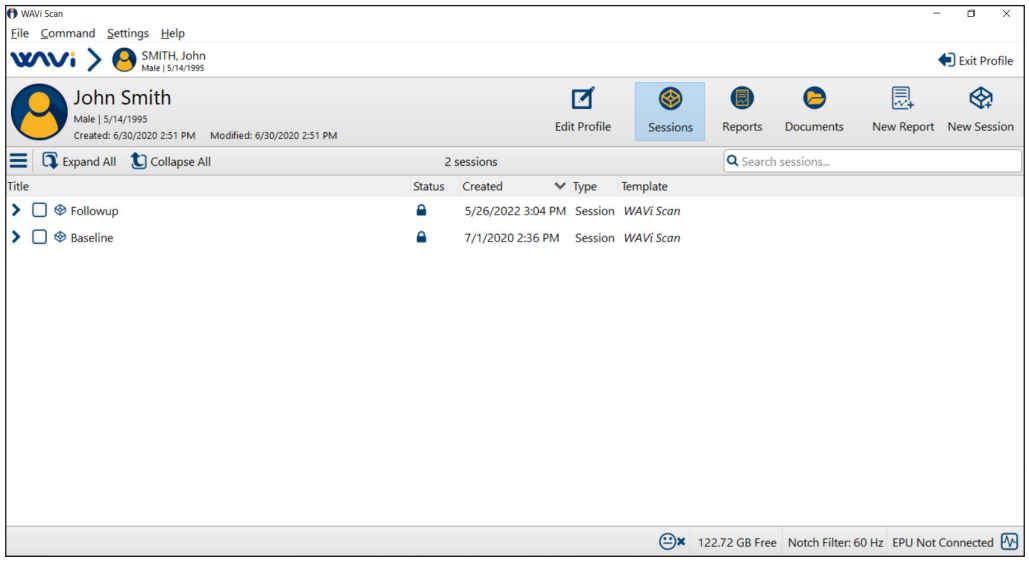

Figure 1-8.

1.4. Participant Preparation

Prepare the participant to wear the EEG headset and electrodes according to the manufacturer's instructions. Recommendations often include removing any bobby pins, barrettes, ponytails, and certain earrings (Figure 1-9). Make sure the participant also turns off their cellphone and any other personal electronic devices to avoid distractions or electrical interference during testing (Figure 1-10). Any wearable electronics such as smartwatches or fitness trackers should be removed from the body and powered off for the duration of the session.

Figure 1-9.

Figure 1-10.

1.5. Headset Preparation

Select a proper headset size for the participant according to the manufacturer's instructions. Sizing often includes measuring with a tape around the head. The headset should fit comfortably and securely. It is important to ensure the headset is positioned correctly on the participant's head, and that all electrode locations are prepared using appropriate contact procedures. Maintaining good ground and ear contacts is critical to obtain clean data during a session.

The WAVi Scan system is designed to acquire up to 19 active EEG channels named according to the International 10-20 EEG naming convention, as well as a ground location (G), and two ear reference channels (A1 and A2). The standard layout is shown in Figure 1-11.

Follow the manufacturer's directions for how to apply the headset and electrodes to the participant, and verify that all relevant parts have been applied correctly before continuing.

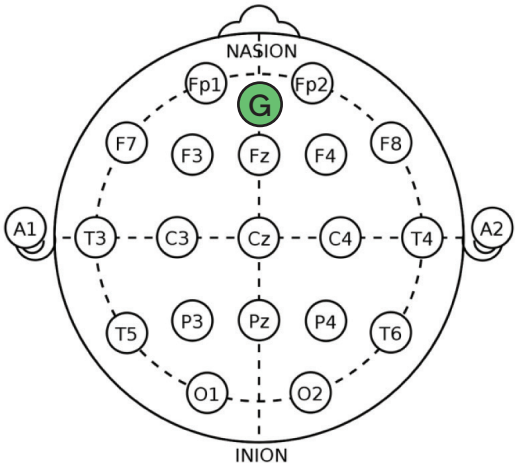

Figure 1-11.

1.6. Headphone Preparation

After the headset and electrodes have been applied, place the stereo headphones over the participant's ears. Take care not to dislocate the headset or any of the electrodes. The headphones can help to further secure the headset in place, but make sure the fit is not too tight. Allow the participant to adjust the headphones to achieve a comfortable fit as needed.

1.7. EPU Preparation

Visually inspect the EPU's 32-pin input connector for any corrosion, debris, or other contaminants. If needed, clean the contacts with an alcohol wipe wrapped around a blunt needle or similar thin tool. Make sure the contacts are completely dry before connecting to the headset.

Securely attach the EPU to the headset's output connector, either directly or via a compatible adapter module as provided by the headset manufacturer. Make sure the connection is not loose or misaligned.

Connect the headphones directly to the EPU's audio port. **Do not connect the headphones to the laptop.**

Make sure the EPU is firmly connected to the laptop via its Mini-B USB cable before proceeding. The connection status is shown by a label in the lower-right corner of the main app window. If you see the words "Not Connected," disconnect the USB cable from the laptop, then re-connect it and wait for the software to detect the EPU again. Make sure the USB cable is fully pushed in at both ends.

If you see an error message saying the EPU could not be initialized, we recommend the following steps:

1. Disconnect EPU from computer.
2. Exit the WAVi Scan software.
3. Reconnect EPU to computer and wait 15 seconds.
4. Restart the WAVi Scan software.

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2. Starting a New Session

2.1. Choosing a Session Template

After you have prepared the participant and all relevant equipment, it is time to start a new session. To begin, press the **New Session** button located in the top-right corner of the profile view (Figure 2-1).

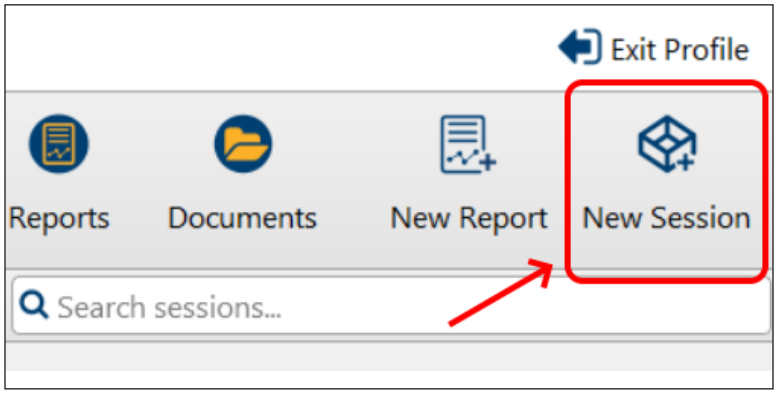


Figure 2-1.

The **New Session** dialog window will appear as shown in Figure 2-2. The system provides a number of session templates which are appropriate for different situations. Each template includes one or more intake forms, an assessment form, and a predefined selection of standard testing protocols. To help you choose, a short description of the currently selected template and its contents are shown in the box on the right side of the dialog. Note that once you are in the session, you may add or subtract any items as needed. Additionally, most reports may later be generated from any session type; see section 8 for more details. Once you have made your template selection, press the **Next** button.

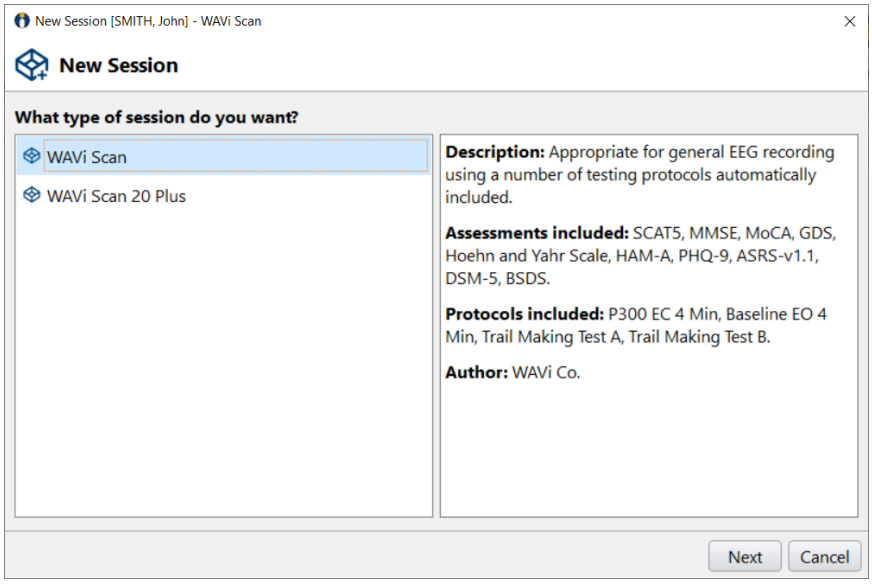


Figure 2-2.

On the next dialog page, enter the required **Reason for Visit** (Figure 2-3). You may choose one of the suggested options from the dropdown menu, or type a custom reason if you wish. This will be used as the title for the new session, so please keep it brief (the maximum is 50 characters). Whatever you specify for this field, make sure it accurately describes the purpose of the session in order to minimize possible confusion later. When ready, press **OK** to continue.

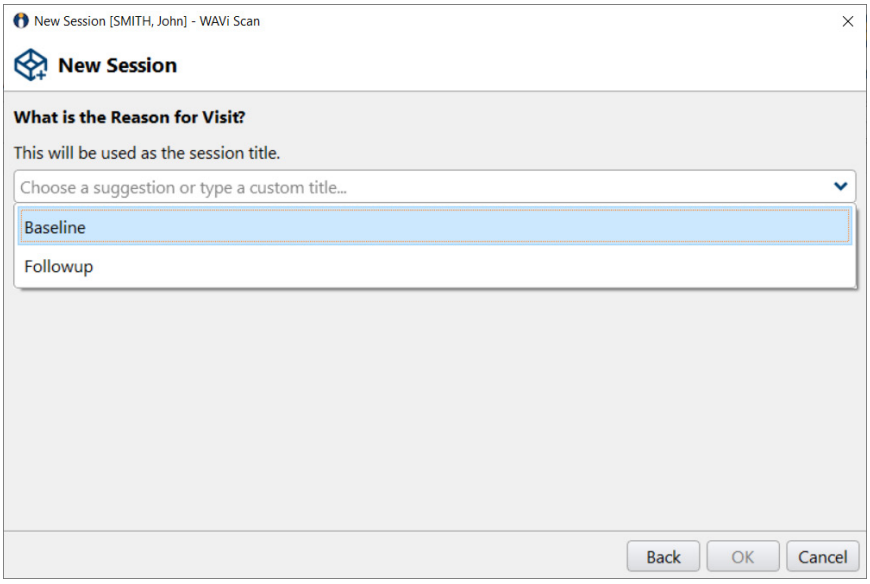


Figure 2-3.

2.2. Session View

After you finish the New Session dialog, the interface will change to the **Session View** (Figure 2-4). This is where you will perform all tasks related to administering and reviewing the session.

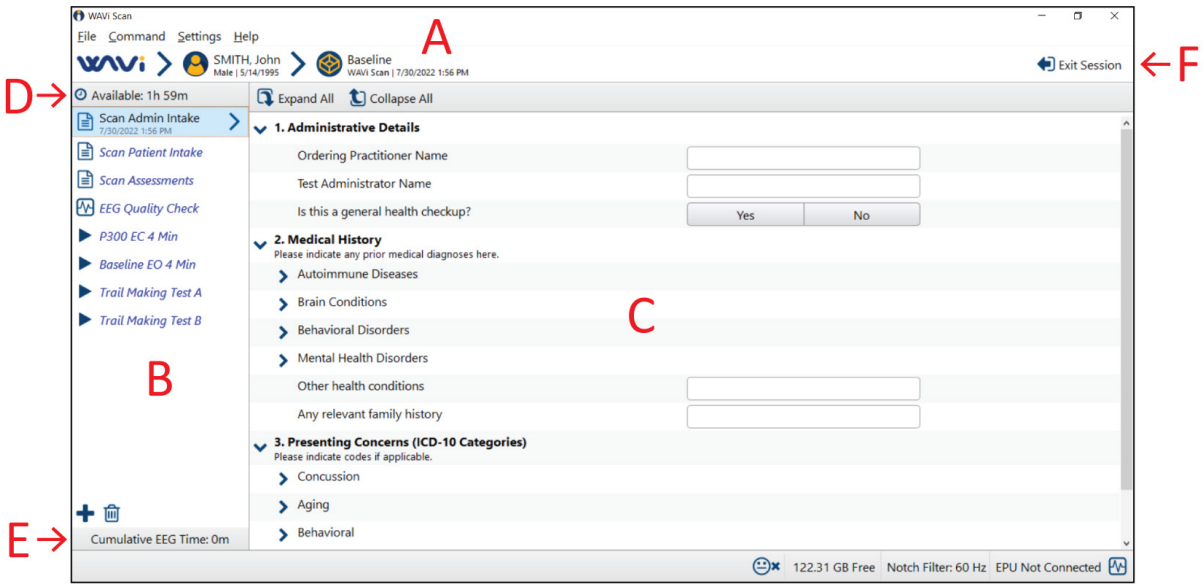


Figure 2-4.

Following is a brief summary of the Session View interface (indicated by red letters in the figure):

A. Session title (Reason for Visit), session template name, and the date and time when the session was created. Some of this information will be included later when generating a report.

B. The "queue": a list of items (forms, protocols, etc.) to be completed in a suggested order. Items which have not been touched yet are shown in a blue italic font, while items which are at least partially completed are shown in a black normal font along with a checkmark symbol. While you are not required to complete every item in the queue, we recommend doing so whenever possible, both for consistency and to maximize the collection of usable data. Items can be added to or removed from the queue if needed by using the Add (plus icon) or Delete (trash icon) buttons at the bottom.

C. Content area: a context-dependent view onto the currently selected queue item.

D. Indicator for time remaining until the current session becomes "locked." This is 2 hours by default. After the time limit is reached, all forms and protocols in the session will become locked and cannot be modified, and you will not be able to add or remove items from the queue. (Note: session lock does not apply to editing protocol comments or manual artifacting.)

E. Indicator for how many total minutes of EEG data have been recorded across all EEG protocols in the current session. This is relevant if you plan to seek insurance reimbursement for performing an EEG. Note that not all protocols involve the acquisition of EEG data, so the Cumulative EEG Time may be less than the total time spent running protocols. It also does not count any time spent doing EEG quality checks, or practicing protocols before officially running them.

F. Button to save changes and exit the session. (Disabled whenever a protocol is running.)

2.3. Intake Forms

Upon entering the new session, the first item in the queue will automatically open by default. Normally this will be an **Intake Form** similar to the one shown in Figure 2-5.

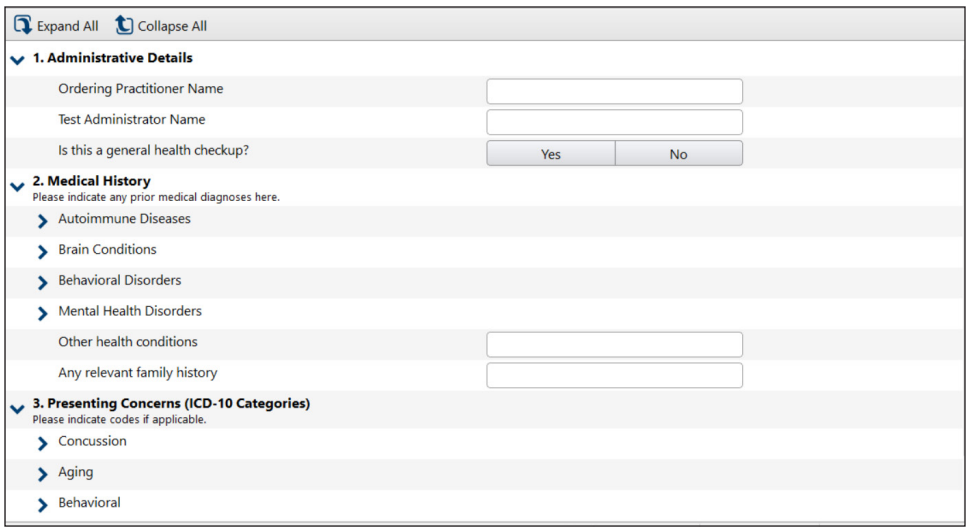


Figure 2-5.

There are currently two different Intake forms available in WAVi Scan:

- **Scan Admin Intake**, to be completed by the test administrator. This contains a variety of fields which may be used to record the participant's medical history and presenting concerns, if any. Relevant ICD-10 codes may also be input here.
- **Scan Patient Intake**, to be completed by the participant (with assistance from the test administrator if necessary). This contains a variety of questions asking the participant about their current physical and mental state.

Items on each Intake form are organized into a tree structure with nested levels, which can be expanded or collapsed using the arrow buttons in the left-most column. It is not necessary to answer every question, and in most cases you will want to use only portions of the form. However, it is very important to collect accurate information here so that the context and conditions of the session can be known for later review and analysis. Some of this data will also be pulled into reports.

2.4. Assessments Form

The next item in the queue is the **Scan Assessments** form. This contains a variety of optional public-domain questionnaires organized into several broad categories. These are intended for convenience only, and are to be used in accordance with the assessment tools' specific instructions for use. Not all of these are relevant to every session, so just use the sections which you think are most appropriate. Answers from the assessments form can be optionally included on some reports. For more information on the available assessments and their scoring, please refer to section 10.

2.5. Checking Contact Quality

The next step in the setup process is to check the contact quality of the headset and electrodes. **This is extremely important to obtain good data quality, and should never be skipped.**

First, verify that the bottom right corner of the main app window shows the message "EPU Ready" (Figure 2-6). If it does not, re-check that the USB cable between the EPU and the laptop is firmly plugged in at both ends.

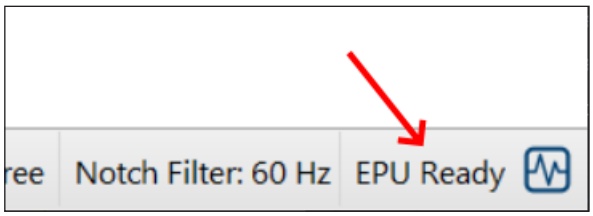


Figure 2-6.

Select the **EEG Quality Check** item from the queue. By default, this brings up the **Contact** view (Figure 2-7) which measures the contact quality at each electrode location. The system will first check the contact of the ground location and both ears. A green circle indicates good connection, yellow is acceptable, and red is unacceptable.

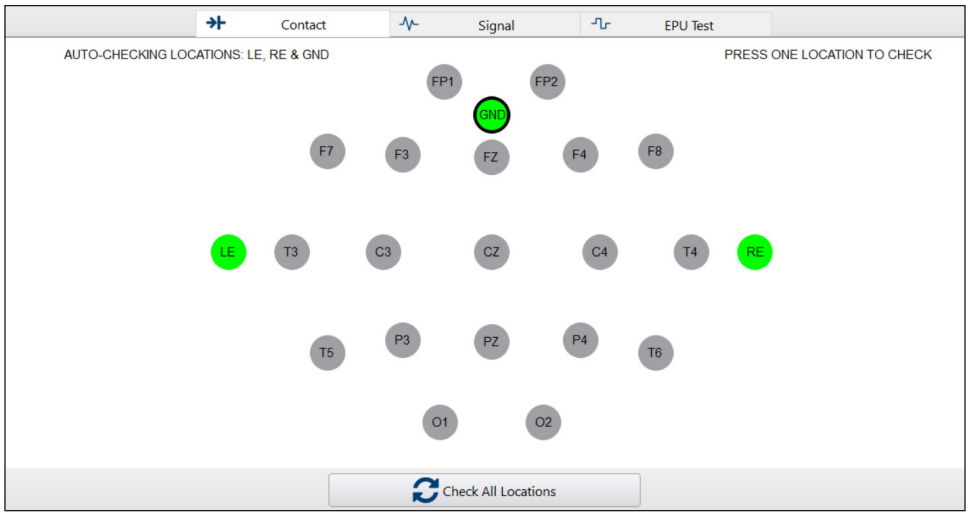


Figure 2-7.

Visually inspect the headset and ensure that all electrodes are making proper contact with the participant's scalp. Make any adjustments as needed according to the headset manufacturer's recommendations.

It is important to strive for green connections at the ground and both ear locations. However, yellow should suffice in situations where green is not attainable. If a better connection is needed, follow the headset manufacturer's recommendations for contact improvement techniques.

Once the ground and both ears show good or acceptable contact, press the **Check All Locations** button located under the electrode diagram. The system will begin to automatically measure the contact quality at all electrode locations, in groups of two or three at a time (Figure 2-8).

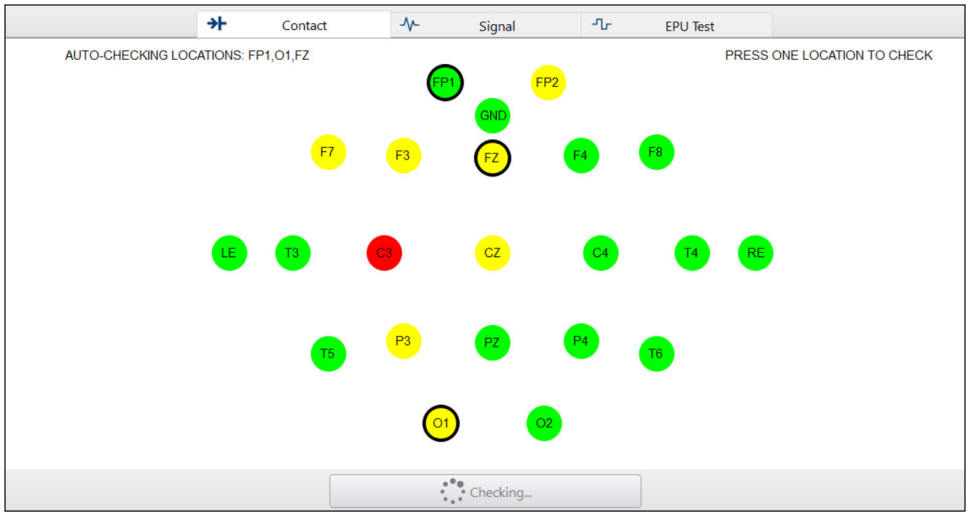


Figure 2-8.

The locations currently being measured are marked with bold outlines. It takes several seconds to get an accurate measurement for each group. Again, the colors indicate good (green), acceptable (yellow), or unacceptable (red) contact quality.

Figure 2-9.

Figure 2-10.

After the system has finished automatically checking the contact quality at all locations, you can perform contact improvement techniques where needed while monitoring the screen for immediate feedback. Use the mouse or touch screen to select a particular electrode location where better contact is desired (Figure 2-9). This will provide real-time feedback of the contact quality at just that location. Repeat contact improvement techniques until all locations show good or acceptable contact. Techniques often include:

1. Moving hair: use your finger or blunt needle syringe to move hair until the electrode is making direct contact with the scalp (Figure 2-10).
2. Exfoliate the scalp directly underneath any problematic electrode locations.
3. Filling gaps: use a blunt needle syringe with electro-conductive cream to fill small gaps between electrodes and the scalp.

For more troubleshooting tips, see section 13.

2.6. Checking Signal Quality

In addition to checking the contact quality, you ***must also*** check the signal quality to ensure that you are acquiring clean data. Many users tend to rush through this step or skip it altogether, but that is a mistake because the signals can still be noisy even if the contact looks OK. Take your time here, and you will get better data quality.

With the same EEG Quality Check queue item selected as before, press the **Signal** tab at the top of the screen to inspect incoming raw EEG waves (Figure 2-11).

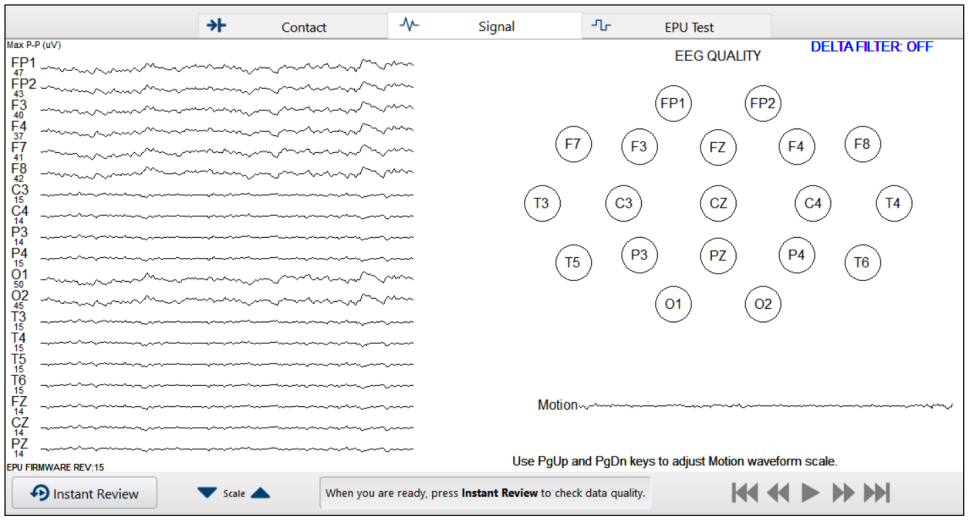


Figure 2-11.

Instruct the participant to close their eyes, relax their jaw, and remain as still as possible. Observe the raw waves for about one minute while looking for acceptable signal quality on all channels. If you see obvious drifting or noisy EEG waves (Figure 2-12), repeat contact improvement techniques until better signals are achieved (Figure 2-13). It is important to remain calm and confident when striving for improved signal quality.

Unacceptable

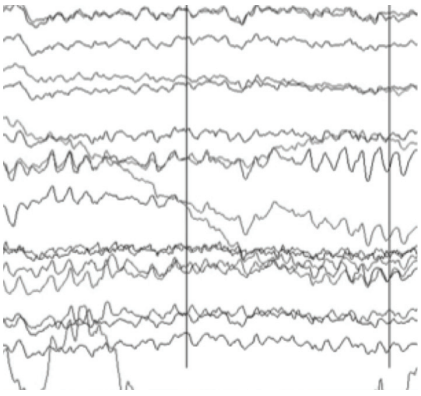


Figure 2-12.

Acceptable

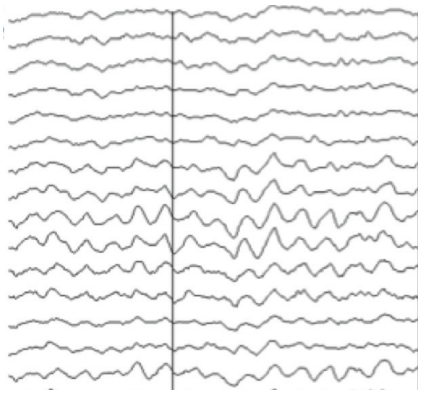


Figure 2-13.

Once the live waves look acceptable, press the **Instant Review** button (Figure 2-14). The system will automatically capture about 15 seconds of sample data, indicated by a progress bar (Figure 2-15).

Figure 2-14.

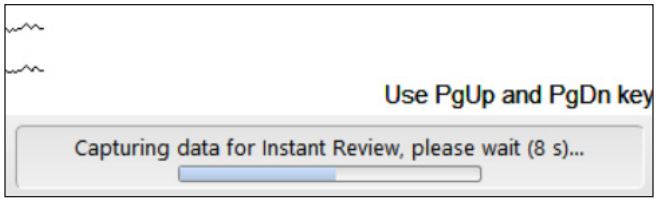


Figure 2-15.

The purpose of the Instant Review mode is to allow you to proactively identify possible artifacts in the EEG, and take corrective actions to improve the signal quality before running any protocols. Artifacts can be caused by many things, such as head and body movement, muscle tension, poor scalp-electrode contact, and various other environmental factors. These issues are revealed most clearly in Instant Review, so using this tool now can help you to avoid larger problems later.

After the progress bar has completely filled up, the segment of EEG data just acquired will be automatically replayed, with any artifacts and problematic electrodes highlighted (Figure 2-16).

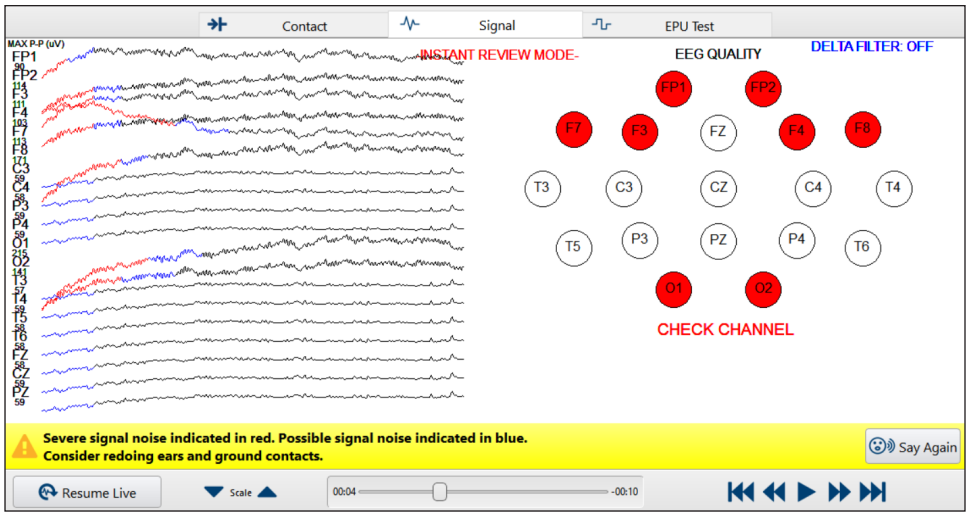


Figure 2-16.

The EEG waves are colored differently depending on the presence and severity of artifact:

- **Black lines** indicate acceptable data, which may also sometimes contain negligible amounts of artifact. Black sections are usable for computing all metrics.
- **Blue lines** indicate possible artifacts, which are still acceptable for computing evoked potentials such as the P300. These sections are included when computing evoked potential metrics, but not other background EEG metrics.
- **Red lines** indicate severe artifacts, which are excluded from all metric computations.

If any red lines are present, a yellow warning bar will show a short description of the issue and one or more suggested actions you can take to improve the signal quality. Additionally, if the Voice Alerts feature is enabled, and 25% or more of the acquired EEG segment is contaminated by artifact, a voice alert will audibly summarize the issue and suggest corrective actions.

When you first enter the Instant Review display, the acquired EEG segment is automatically replayed once to provide a quick overview. However, it is often helpful to stop and examine the waves more closely to identify potential problems. The bar located under the wave display has several controls for this purpose (Figure 2-17). You can manually scroll through the data by pressing and dragging the time slider knob to a specific position in time. Alternatively, you can use the playback buttons on the right side to step forward or backward, jump to the beginning or end, and start/stop automatic playback. If needed, you can also adjust the vertical scale factor of the waves by using the up/down Scale buttons on the left side of the control bar.

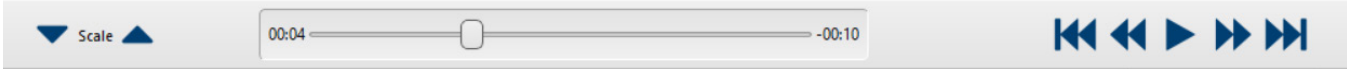


Figure 2-17.

If any of the EEG waves appear to be wandering or noisy (Figure 2-18), follow the headset manufacturer's recommendations for improving contact quality at the specific electrode locations which are problematic.

In general, brief isolated sections of blue or red lines are not cause for concern. However, any persistent or repeating patterns of blue or red lines may indicate a problem, and should not be ignored.

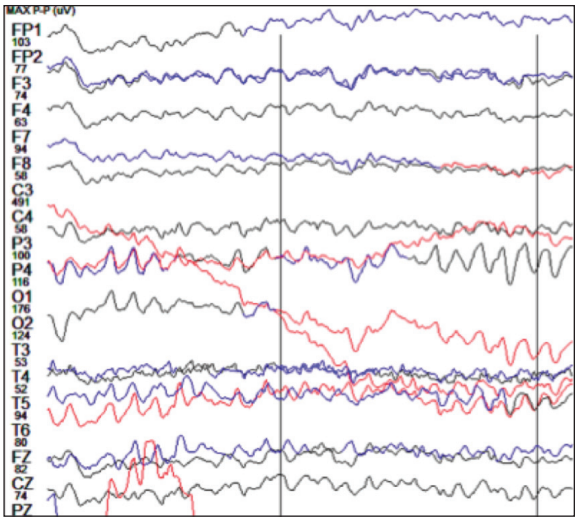


Figure 2-18.

After taking appropriate corrective actions, press the **Resume Live** button at the left end of the control bar (Figure 2-19). This will switch the display back to showing live waves.

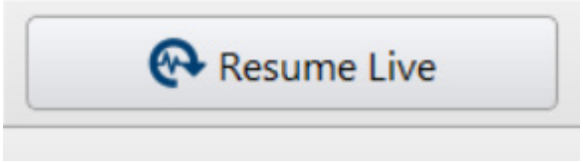


Figure 2-19.

Note that the brief EEG segment captured during Instant Review is not saved, and cannot be viewed again after leaving the Instant Review mode. It also does not count toward the Cumulative EEG Time shown at the bottom of the queue. However, you can and should repeat the Instant Review process using contact improvement techniques until the signal quality is improved.

When you are satisfied with the signal quality in general, inform the participant of the equipment's sensitivity to motion. Instruct them first to move, then blink their eyes, and finally clench their jaw to demonstrate how each of these actions affects the EEG (see examples in Figure 2-20 and Figure 2-21). Note that blue and red artifact coloring is only shown in the Instant Review mode. It is important for the participant to remain calm and relaxed during the actual tests, so doing these things now can help the participant to release tension and be more comfortable.

Eye Blinks

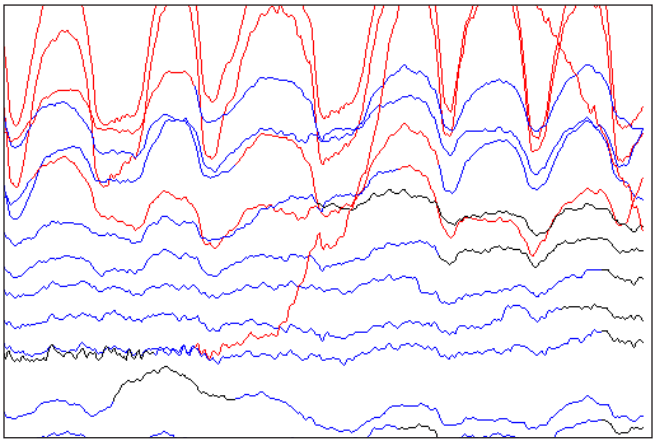


Figure 2-20.

Significant Movement

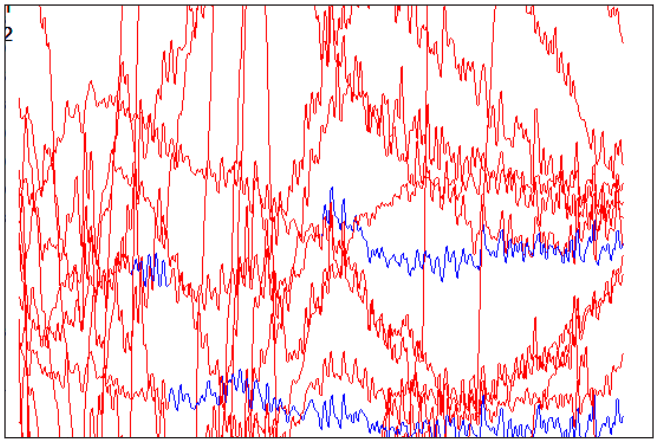


Figure 2-21.

If any of the EEG traces have shifted significantly up or down, or have disappeared off the screen entirely, wait for those traces to return to their normal positions before starting any protocols.

As you work through checking the Contact and Signal quality, please remember that the goal is to aim for improvement, not perfection. Everyone can achieve better data quality with enough time, practice, and patience.

3. Running Protocols

3.1. EEG Protocols

The WAVi Scan software includes several different protocols for acquiring EEG data. Some of these include audio and/or visual stimuli to generate evoked potentials, while others are intended for collecting EEG only during resting states. All EEG protocols contribute to the "Cumulative EEG Time" shown at the bottom of the session queue.

3.1.1. P300 EC 4 Min

Description: A 4-minute protocol to acquire eyes closed EEG with an audio oddball stimulus.

Required accessories: Headphones. | **Optional accessories:** USB mouse.

Directions: Make sure the room is quiet and any bright lights are turned down. Ensure that the participant is sitting upright in a comfortable position and can keep both feet firmly planted on the floor or on a low stool, as dangling feet can cause movement artifact in the EEG. Instruct the participant to either rest their preferred hand on the mouse, or over the spacebar key on the laptop keyboard. Either method may be used for input, so the participant can choose the one which is most comfortable. If using the mouse, it may be positioned either on the table top or on the participant's leg. The position of the mouse does not matter as long as the participant is able to comfortably click the buttons.

Inform the participant that two different audio tones will be presented during the test: a "common" low tone, and a "rare" high tone. One of these tones will be presented once every second, in a random order. The participant must be able to clearly hear both tones in order to perform this test. If they cannot hear the tones, check that the headphones are securely plugged into the EPU (not the laptop) and are comfortably positioned over the participant's ears.

Practice tones will be presented before the actual test is started. Instruct the participant to close their eyes, relax, and press the mouse (or press the spacebar) whenever they hear the high tone. Either the left or right mouse button may be used. Responses are indicated by green vertical lines on the raw wave display. It is important to confirm that responses are being detected by the software. If necessary, have the participant adjust how they are holding the mouse, and make sure they are pressing the mouse buttons with appropriate force.

Synchronized eyeblinks (referred to as "Sync Blinks") can occur if the participant blinks forcefully while responding to rare tones. This results in a disproportionately high voltage seen in the frontal and surrounding locations. To reduce the likelihood of Sync Blinks or jaw clenching, ask the participant to first tightly squeeze their eyes shut for a few seconds, then clench and relax their jaw immediately prior to beginning the test. **Note: Try to limit the amount of instructional commands while explaining the P300 test, as over-explanation may stress the participant and decrease their cognitive resources.**

Once the participant has practiced and completely understands how the P300 test works, press the green **Start** button to begin recording (Figure 3-1).

Figure 3-1.

Note that the mouse cursor is confined inside of the raw wave display during the test. This prevents the participant from accidentally stopping the protocol or closing the app while they are clicking the mouse with their eyes closed. If you need to use the mouse before the test is finished, you can either press the **Unlock Mouse** button (Figure 3-2) using your finger on the touchscreen, or press the 'U' key on the keyboard.

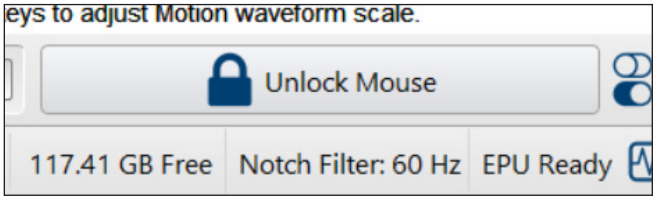


Figure 3-2.

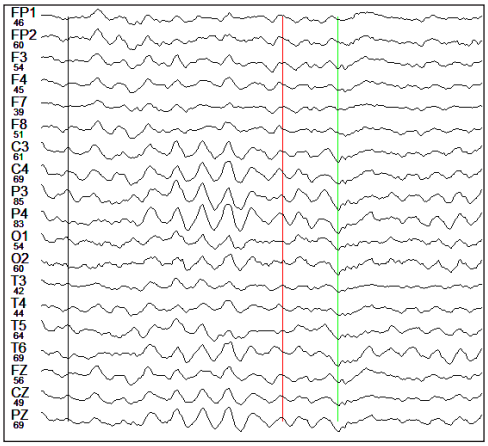


Figure 3-3.

While the P300 test is in progress, vertical lines will appear over the raw wave forms (Figure 3-3). Black vertical lines mark the presentation of the common (low) tones. Red vertical lines mark the presentation of the rare (high) tones. Green vertical lines mark the moments when the participant clicks the mouse or presses the spacebar on the keyboard. It is important to observe the screen and confirm that the participant is responding to the presentation of the high tones.

The signal quality should still be monitored during testing. There may be some intermittent drifting signals due to motion, but for the majority of the test the EEG should appear clean as shown in Figure 3-3.

Realtime quality information is provided by the **EEG Quality** display to the right of the raw waves (Figure 3-4). Red dots indicate excessive artifact in the signal at that location. **Do not attempt to adjust the headset or electrodes during the test**. Instead, observe the raw waves to determine the overall quality of the data. If there are numerous and persistent wandering waves, stop the test and then restart it after contact improvements have been made.

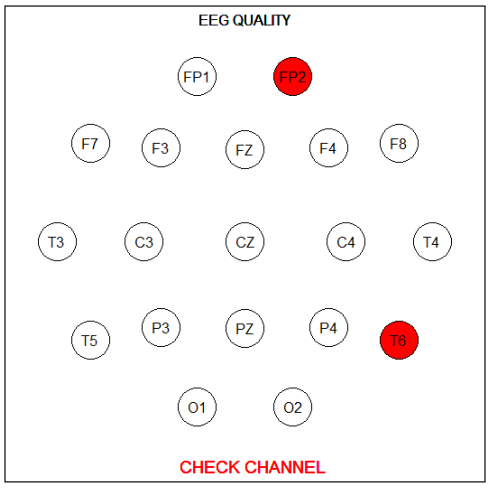


Figure 3-4.

The P300 test is complete when the tones conclude and the raw waves automatically stop recording. If significant artifact was detected during the test, a yellow warning bar will appear at the bottom of the display in review mode (Figure 3-5). In severe cases, an additional warning message may also suggest that the protocol be re-run. For more details on these warning messages, see section 4.2.1.

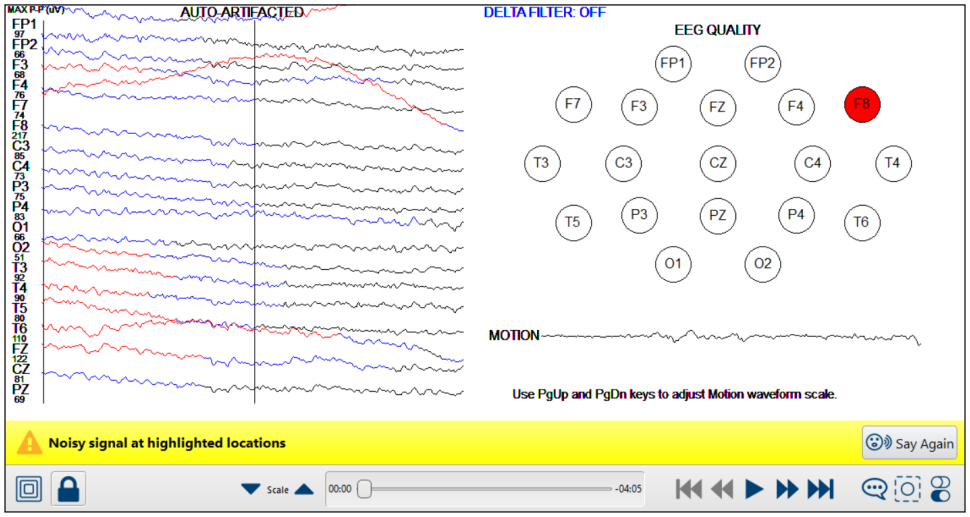


Figure 3-5.

Note: if you decide to run back-to-back P300 protocols, habituation may occur during the second test. This happens when subjects respond less strongly over time to the rare tone, causing the reported P300 voltages to decrease at one or more EEG electrode locations. It is best practice to give the participant a brief break or alternate with a different protocol before choosing to repeat the P300 protocol.

3.1.2. Flanker EO 4 Min

Description: A 4-minute eyes open cognitive challenge involving visual distraction. Eyes open data will be obtained during the Flanker task in order to provide variety and keep the participant focused during longer sessions. The Flanker task generates spectra which compliment those obtained during Baseline Eyes Open protocols.

Required accessories: None. | **Optional accessores:** USB mouse.

Directions: Instruct the participant to either rest their preferred hand on the mouse, or over the left/right arrow keys on the laptop keyboard. Either method may be used for input, so the participant can choose the one which is most comfortable. If using the mouse, it may be positioned either on the table top or on the participant's leg. The position of the mouse does not matter as long as the participant is able to comfortably click the buttons.

An instructional screen will explain how to perform the Flanker task (Figure 3-6). If this is the first time the participant will be doing the Flanker, it is recommended to enter the practice mode by pressing the **Start Practice** button. (Data is not recorded while in the practice mode.)

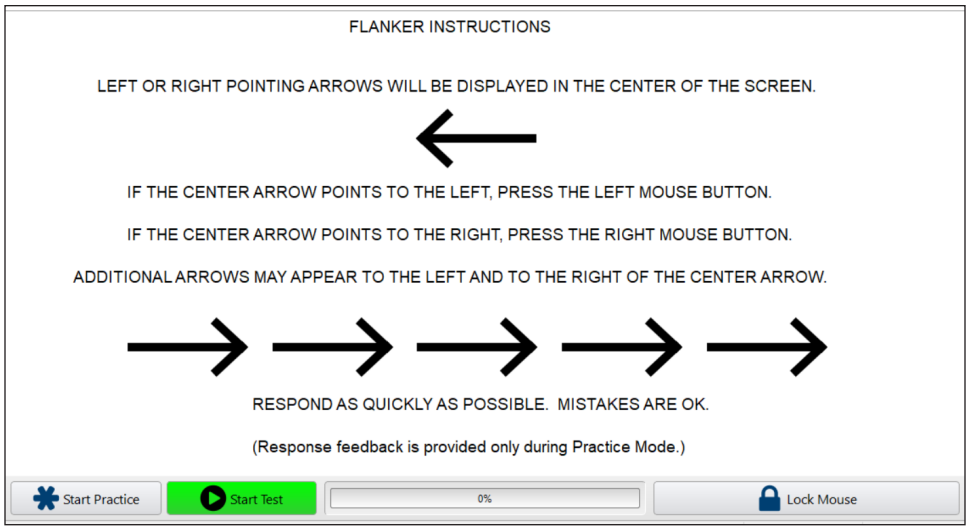


Figure 3-6.

During the Flanker task, a series of arrows will appear in the center of the screen at a rate of approximately once every two seconds. Depending on the direction that the center arrow is pointing, the participant should respond by pressing the corresponding left or right mouse button or arrow key. The participant should respond as quickly as possible. If a mistake is made, reassure the participant by telling them that it is normal to make mistakes and encourage them to continue.

Once the participant has practiced and completely understands how the Flanker task works, press the **End Practice** button to return to the instruction screen, then press the green **Start** button to begin recording. There are a total of 112 trials in the 4-minute protocol.

Upon completion of the protocol, the Flanker results will be automatically displayed (Figure 3-7). Flanker response waveforms are displayed for each EEG electrode location, while various metrics are listed to the right of the waveforms. This display is for educational purposes only. For more information on Flanker results, see section 10.1.2.

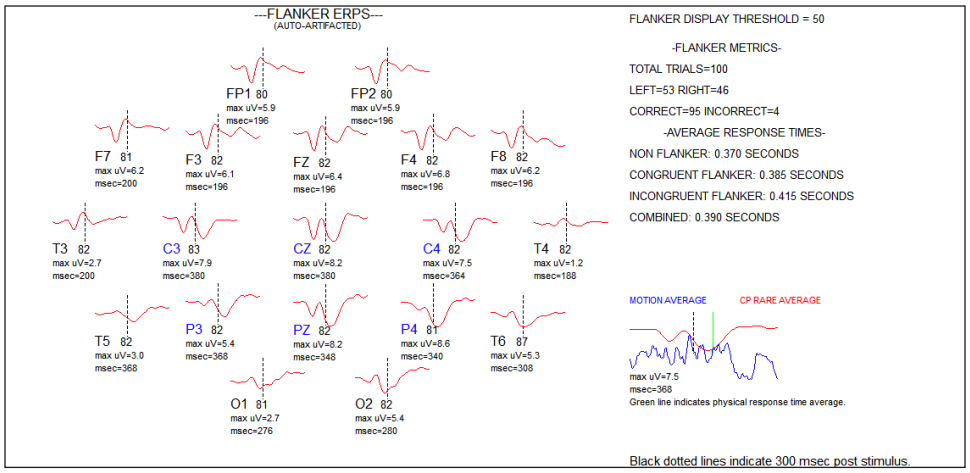


Figure 3-7.

3.1.3. Baseline EC 4 Min (Eyes Closed Resting)

Description: A 4-minute eyes closed protocol with no task or stimulus. This protocol may be used in addition to the P300 EC 4 Min protocol, if eyes closed data acquired during a non-stimulus condition is desired. This is primarily useful where at least 20 minutes of EEG collection is needed. Note: currently all of the Eyes Closed metrics displayed in the review mode, as well as in the reports, are computed from the background P300 EEG data rather than non-P300 eyes closed resting data.

Required accessories: None. | **Optional accessories:** None.

Directions: Make sure the room is quiet and any bright lights are turned down. Ensure that the participant is sitting upright in a comfortable position and can keep both feet firmly planted on the floor or on a low stool, as dangling feet can cause movement artifact in the EEG. Instruct the participant to keep their eyes closed and to remain still for the duration of the protocol.

The interface for this protocol is shown in Figure 3-8 below. When ready, press the green Start button to begin recording. After 4 minutes, the protocol will automatically stop recording and switch into the Raw Wave review mode.

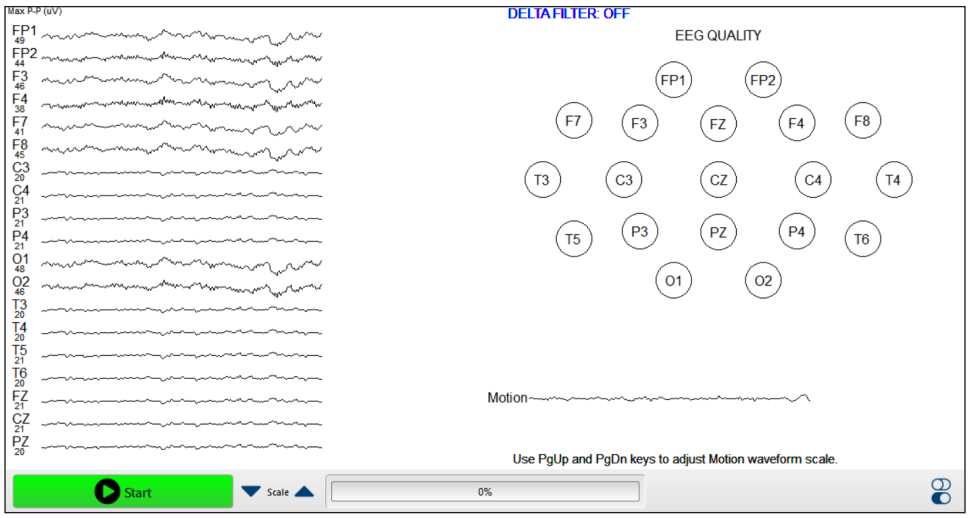


Figure 3-8.

3.1.4. Baseline EO 4 Min (Eyes Open Focused)

Description: A 4-minute eyes open protocol with no task or stimulus. This protocol may be used in addition to the Flanker protocol, if eyes open data acquired during a non-stimulus condition is desired. This is primarily useful where at least 20 minutes of EEG collection is needed.

Required accessories: None. | **Optional accessories:** None.

Directions: Make sure the room is quiet and any bright lights are turned down. Ensure that the participant is sitting upright in a comfortable position and can keep both feet firmly planted on the floor or on a low stool, as dangling feet can cause movement artifact in the EEG. Instruct the participant to keep their eyes open looking straight ahead at the screen, and to remain still for the duration of the protocol.

By default, the interface displays a countdown timer instead of raw waves (Figure 3-9). This is intended to give the participant something to look at while minimizing eye movement, and also to help reduce anxiety by providing a clear sense of how much time is left in the protocol. The quality head is still displayed in order to alert the test administrator when there are problems with signal quality. However, you can use the buttons on the right side of the control bar to switch between the timer and raw wave display modes at any time.

When ready, press the green Start button to begin recording. After 4 minutes the protocol will automatically stop recording and switch into the Raw Wave review mode.

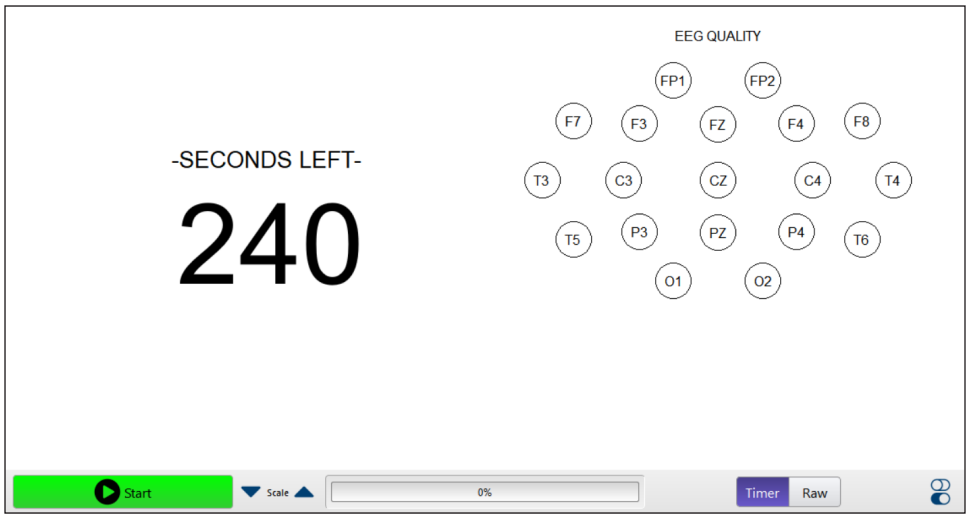


Figure 3-9.

3.2. Non-EEG Protocols

In addition to the various EEG protocols previously described, the system also includes electronic versions of standardized clinical assessment tools related to psychiatry and neuropsychological evaluation, which are provided for convenience and are to be used in accordance with the assessment tools' specific instructions. These tools do not interact with any other of the EEG system's hardware or software measures and are stand alone. As these protocols do not involve the acquisition of EEG data, they do not contribute to the "Cumulative EEG Time" shown at the bottom of the queue.

3.2.1. Trail Making Test A

Description: A cognitive challenge where the participant must connect randomly placed dots with sequential numbers (1, 2, 3, etc.) in the correct order.

Required accessories: None. | **Optional accessories:** USB mouse.

Directions: This test is best performed using the touch screen, but if that is not possible, the USB mouse may be used instead. Upon activating the protocol from the queue, you will see a practice screen with a random pattern of dots (Figure 3-10).

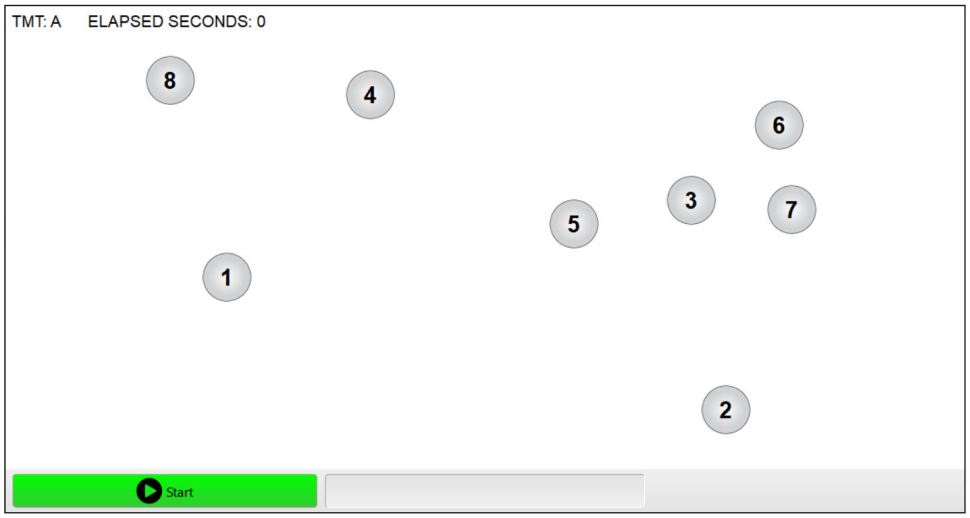


Figure 3-10.

Instruct the participant to select the dots in numerical order as quickly as possible. If using the touch screen, one or both hands may be used. Note: the software may not register a selection unless the participant presses the pad of their finger directly on the correct number.

When a correct selection is made, a gray line will be drawn to connect the dots, forming a trail. If a selection is not registered, this may indicate that the participant has not correctly selected the next number in the sequence. To fix their mistake, instruct the participant to press the last correctly selected number and proceed with the test. If no action is taken, after about 10 seconds the last correctly selected number will be highlighted in green to indicate where the participant should resume.

Once the participant has practiced and completely understands the test, press the green **Start** button to begin recording. The actual test is comprised of the numbers 1-25 arranged randomly around the screen. Note: if a mistake is made, the participant must go back and press the last correctly selected dot before the software will allow them to continue.

Figure 3-11 below shows a completed Trail Making Test A. The time displayed in the top left corner indicates how long it took for the participant to complete the test. (Reference ranges will be included when you generate a report later.) Any errors are indicated by red lines.

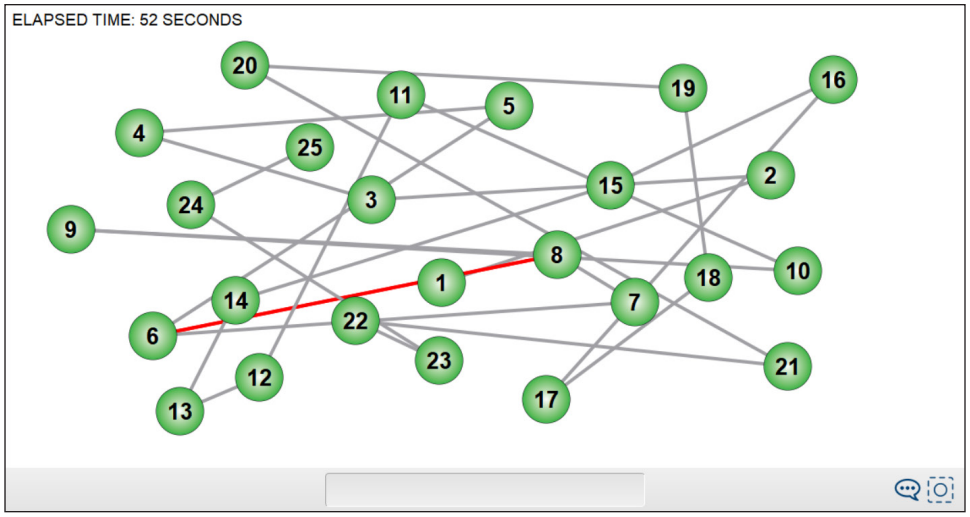


Figure 3-11.

3.2.2. Trail Making Test B

Description: A cognitive challenge where the participant must connect randomly placed dots alternating between numbers and letters (1, A, 2, B, etc.) in the correct order.

Required accessories: None. | **Optional accessories:** USB mouse.

Directions: This test should be performed after Trail Making Test A. It is best performed using the touch screen, but if that is not possible, the USB mouse may be used instead. Upon activating the protocol from the queue, you will see a practice screen with a random pattern of dots (Figure 3-12).

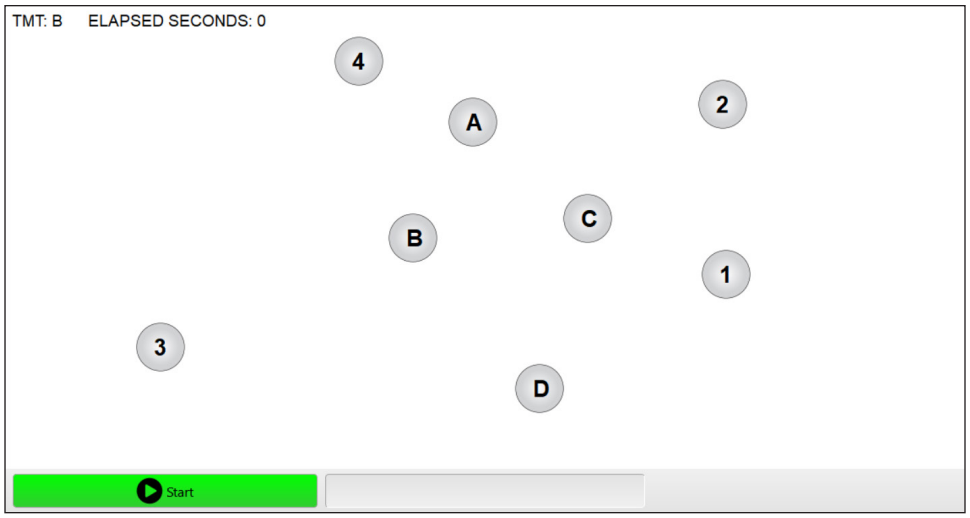


Figure 3-12.

Instruct the participant to alternately select numbers and letters in numerical and alphabetical order (1-A, 2-B, 3-C, etc.) as quickly as possible. It may be helpful if the participant says the numbers and letters aloud. If using the touch screen, one or both hands may be used. Note: the software may not register a selection unless the participant presses the pad of their finger directly on the correct dot.

When a correct selection is made, a gray line will be drawn to connect the dots, forming a trail. If a selection is not registered, this may indicate that the participant has not correctly selected the next number or letter in the sequence. To fix their mistake, instruct the participant to press the last correctly selected dot and proceed with the test. If no action is taken, after about 10 seconds the last correctly selected dot will be highlighted in green to indicate where the participant should resume.

Once the participant has practiced and completely understands the test, press the green **Start** button to begin recording. The actual test is comprised of numbers 1-13 and letters A-L. Make sure that the participant can distinguish the number "1" from the letter "I". Note: if a mistake is made, the participant must go back and press the last correctly selected dot before the software will allow them to continue.

Figure 3-13 below shows a completed Trail Making Test B. The time displayed in the top left corner indicates how long it took for the participant to complete the test. (Reference ranges will be included when you generate a report later.) Any errors are indicated by red lines.

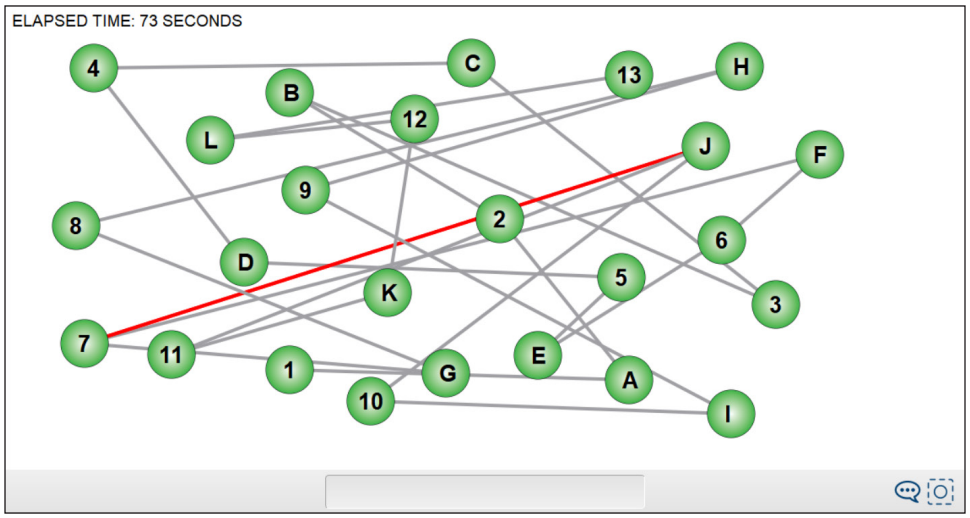


Figure 3-13.

3.3. Adding a New Protocol To a Session

Sometimes you may need to add a new protocol to the session queue for various reasons. This can be done at any time while the session is unlocked. To do this, first press the "plus" icon at the bottom of the queue, then choose **New Protocol...** (Figure 3-14).

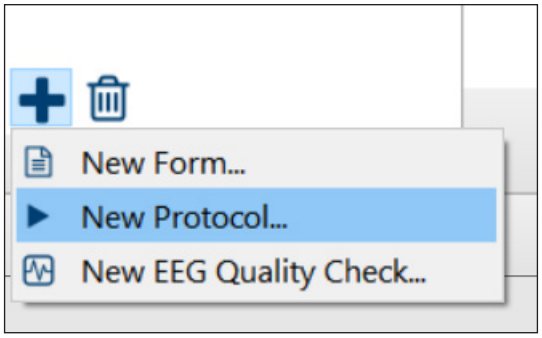


Figure 3-14.

The **Add New Protocol** dialog window will appear as shown in Figure 3-15, with a list of available protocol templates. To help you choose, a short description of the currently selected template is shown in the box on the right side of the dialog.

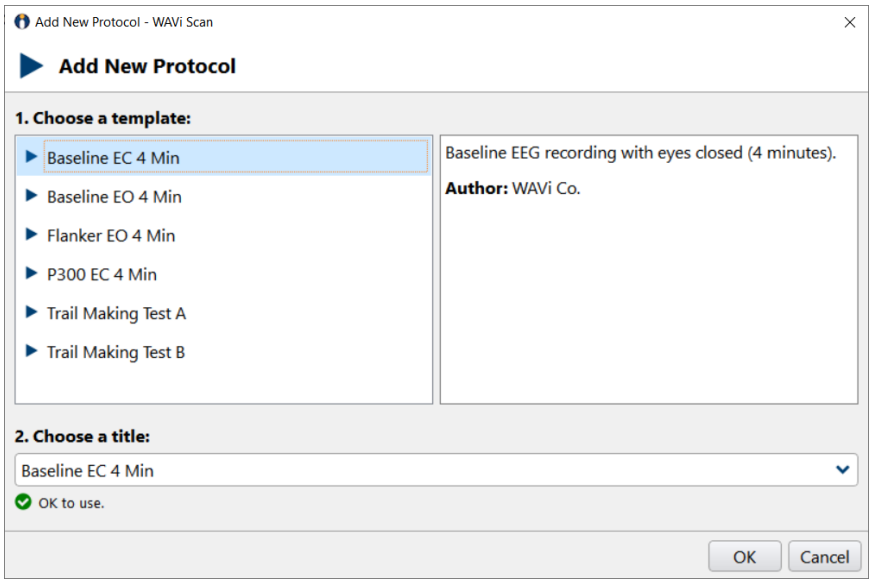


Figure 3-15.

Once you have decided which protocol template to use, you must also choose a title for the new protocol. A sensible default title is automatically generated based on the name of the chosen template, but you can change this if you wish. When you are ready to continue, press **OK** to accept the choices and close the dialog.

The new protocol will be appended to the end of the queue using the title you specified. At this point, a popup message will ask if you want to activate the new protocol right now (Figure 3-16). If you choose **Yes**, the interface will immediately switch away from whatever item you are currently viewing to show the new protocol. If you instead choose **No**, the interface will remain as-is, and you can activate the new protocol later when you are ready to use it by choosing its item in the queue.

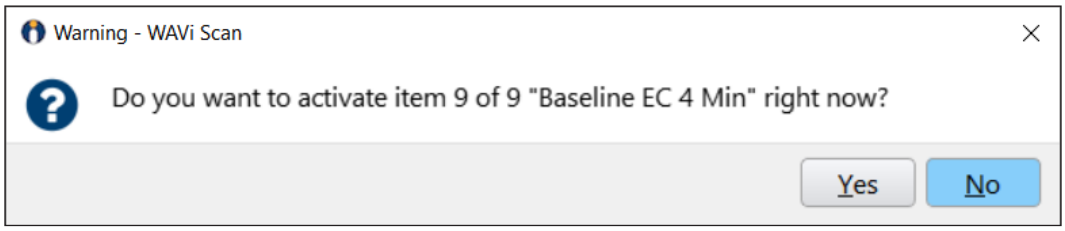


Figure 3-16.

3.4. Deleting a Protocol From a Session

You can delete a protocol from the session queue as long as the session is unlocked. This can be done using one of the following methods (indicated by red letters in Figure 3-17):

A. Right-click on the protocol item in the queue, then choose **Delete** from the popup menu.

B. First activate the protocol by left-clicking its item in the queue, then press the trash can icon at the bottom of the queue.

After choosing the Delete action, a popup message will ask you to confirm your choice (Figure 3-18). Deletion is permanent and cannot be undone, so take care not to delete valid data. If in doubt, do not delete.

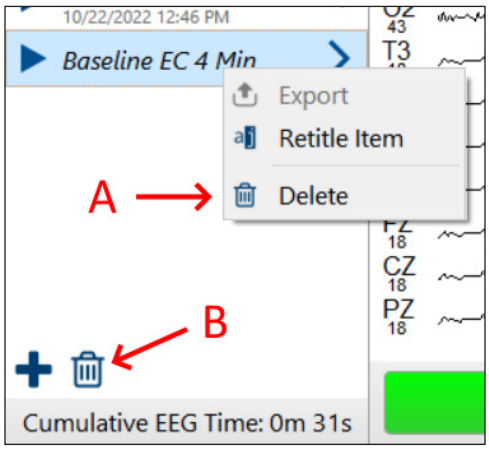


Figure 3-17.

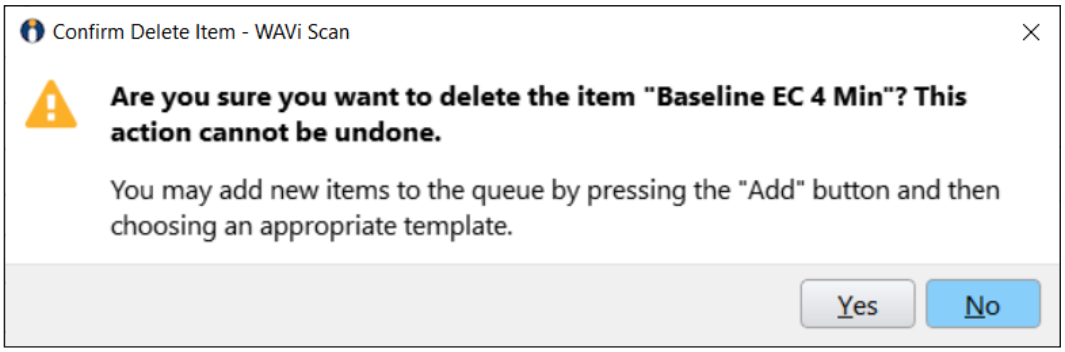


Figure 3-18.

4. Reviewing EEG Protocols

After you have finished recording an EEG protocol, you should take a moment to review the data and verify its quality before proceeding to other tasks. Do not assume that EEG data will be clean just because the contact or signal quality looked good beforehand—sometimes problems can arise during a recording, and some of them may not be noticed when they occur. The different review modes also display information about the participant's performance on various metrics, so you should be at least somewhat familiar with these modes before attempting to generate or interpret WAVi reports.

4.1. Selecting the Display Mode

EEG data can be reviewed using a number of different display modes which are described in the following subsections. These are selected using the **Display Mode** button at the left end of the control bar (Figure 4-1). You can press this button anytime to see a popup menu of available modes and switch between them. You can also switch modes by using the indicated keyboard shortcuts. The available modes shown in the menu will vary depending on the current protocol type.

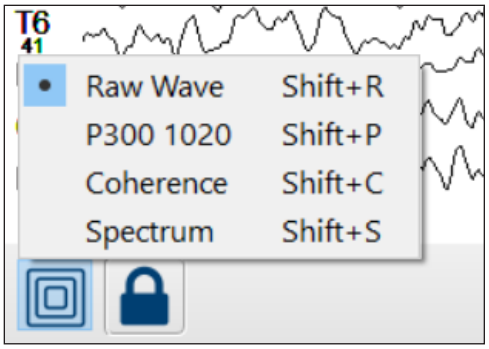


Figure 4-1.

4.2. Raw Wave

The Raw Wave display mode (Figure 4-2) shows the microvolt activity of all active EEG channels across the length of the file, in epochs spanning 500 contiguous samples (equal to 2 seconds at the default WAVi EPU sample rate of 250 Hz). The EEG quality for the current epoch is shown to the right of the waves, along with a motion indicator showing the average amplitude of head movements.

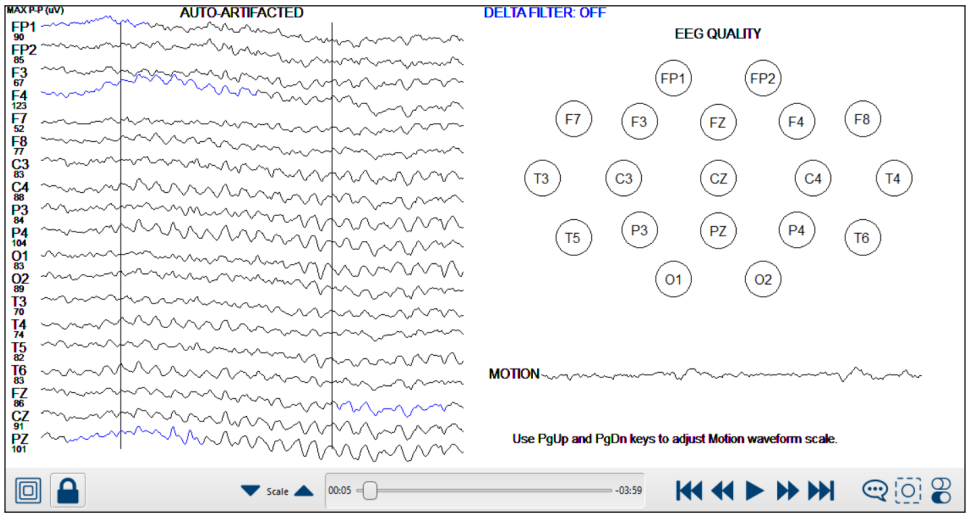


Figure 4-2.

Figure 4-3 shows the control bar for the Raw Wave display mode. The functions of each control (marked by red letters in the figure) are described below.

Figure 4-3.

A. Button to show the Display Mode menu.

B. Button to enter/exit the Manual Artifacting mode. (See section 6 for details.)

C. Wave scale controls: these can be used to adjust the vertical scale of the EEG waves if they are too small or too large to view clearly. (Note: the motion waveform scale is controlled separately via the Page Up/Page Down keyboard keys).

D. Time slider: this shows your current position in the file. The value on the left (Time Elapsed) corresponds to the approximate time of the first visible sample in the current epoch. The value on the right (Time Remaining) corresponds to the difference between the approximate time of the last visible sample in the current epoch and the end of the file. (Both of these values are rounded to the nearest second.) You can press and drag the slider to quickly scan through the data and jump to a specific point in time.

E. Playback controls: from left to right, these buttons allow you to jump to the beginning of the file; step backward one increment; start/stop automatic playback; step forward one increment; and jump to the end of the file. The increment size, which also determines the speed of automatic playback, can be changed through the display options menu (see item H below).

F. Button to show/hide the Comments panel. (See section 5 for details.)

G. Button to take a screenshot of the current display.

H. Display Options menu: pressing this button shows a popup menu with additional options for the Raw Wave display (Figure 4-4). Each of these options is described on the next page.

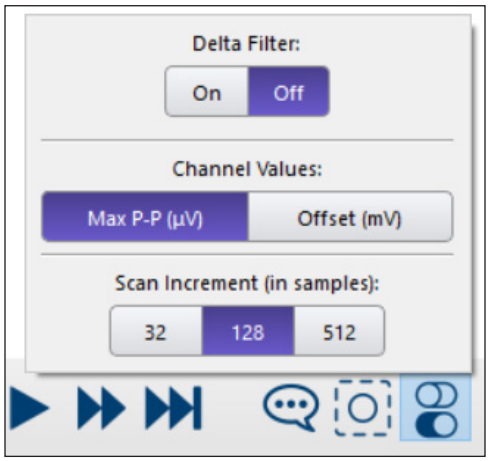


Figure 4-4.

The following items can be changed through the Display Options popup menu:

- **Delta Filter**: This option applies extra filtering in the Delta frequency band (1.0-4.0 Hz). Sometimes filtering out lower frequencies in the Delta range, which are often due to artifact, can make it easier to see higher frequencies of interest. This may be preferable to scaling down the waves themselves, which could make higher frequencies more difficult to see. However, the Delta Filter can also obscure real artifacts and give viewers a false impression that the data is cleaner than it actually is. For this reason the Delta Filter is turned "Off" by default, and should only be used when absolutely necessary. This option has no effect on automatic artifacting or computed metrics.
- **Channel Values**: This option sets what is shown underneath each channel name on the left side of the wave display. The default is to show the maximum peak-to-peak microvolt value of that channel within the current epoch. Alternatively, you can choose to show the DC offset in millivolts with respect to the ear references, which can be useful for troubleshooting. The offsets may be very large in cases with poor active or reference electrode contact. If all of the offsets are large, this may indicate a problem with the ear references. If only a few electrode offsets are large, this may indicate contact problems with those specific electrodes.
- **Scan Increment (in samples)**: This option sets the number of samples by which to increment the currently displayed epoch when moving forward or backward in the file using the playback controls. Larger increments will cause the waves to scroll faster, which can be useful to quickly get an overall sense of the data quality. Smaller increments will cause the waves to scroll slower, which can be useful for a more detailed review.

4.2.1. Raw Wave Warning Messages

If the system detects any problems which could affect the reliability of computed metrics, a yellow warning bar will appear below the raw wave display (Figure 4-5).

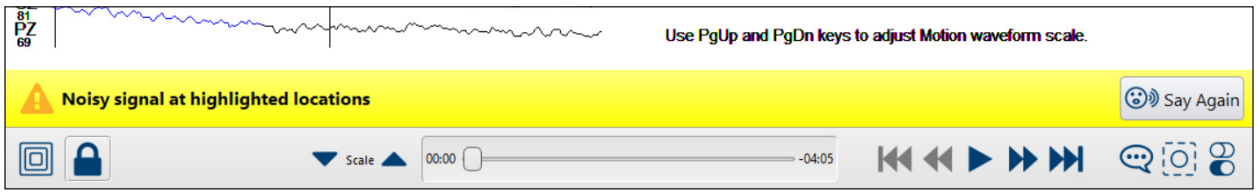


Figure 4-5.

While the session is unlocked, this bar will show both a short description of the issue and one or more suggested actions you can take to improve data quality before running another protocol. If the Voice Alert feature is enabled, the system will also audibly summarize the issue and suggest corrective actions. Voice alerts automatically play only once, when the protocol is initially opened for review. You can manually repeat a voice alert anytime by pressing the **Say Again** button on the right end of the warning bar.

After the session becomes locked, the warning bar will just show the issue description without any suggested actions. Voice alerts will not be automatically played, but they can still be manually played by pressing the Say Again button.

Following is a list of yellow bar warnings that you may see in the Raw Wave display mode.

- **Excess Synchrony**: This warning indicates that two or more EEG channels are too similar and may not be physiologically plausible. Excess Synchrony may be caused by improper electrode connections and/or electrical bridging between electrodes. The suggested corrective actions are to first improve contact using Instant Review, then repeat the protocol.
- **Noisy signal at highlighted locations**: This warning is triggered by significant artifact on one or more channels, indicated by red locations in the EEG Quality map. The suggested corrective actions are to first improve contact using Instant Review, then repeat the protocol.
- **SYNC-BLINKS**: This warning can occur if the participant blinks forcefully while clicking the mouse in response to rare tones during a P300 protocol. Eye muscle movement can cause significant deviations on channels FP1 and FP2. These do not reflect actual EEG activity and may reduce the reliability of reported P300 response voltages at frontal and other locations. The suggested corrective action is to consider repeating the protocol while instructing the participant to hold their eyelids closed with their free hand.
- **Synchronized motion with P300 response**: This warning is triggered by the detection of head movements during the P300, such as forceful nodding while pressing the mouse. This causes artifacts which can affect the reliability of reported P300 metrics. The suggested corrective action is to consider repeating the protocol while instructing the participant to minimize head movement as much as possible.

In addition to yellow bar warnings, you may see warning messages under the EEG Quality display (Figure 4-6), which may include the following:

- **CHECK CHANNEL**: Appears if severe (red) artifact is detected on any channels during the currently displayed epoch.
- **CHECK CHANNEL OFFSET**: This warning is triggered by excessive DC offset on one or more channels, and is usually caused by poor electrode-scalp contact.
- **CHECK EAR CONNECTIONS**: This warning is shown if all locations are red, which may indicate a problem with the ear references. It is also a good idea to check the ground electrode connection in this case.

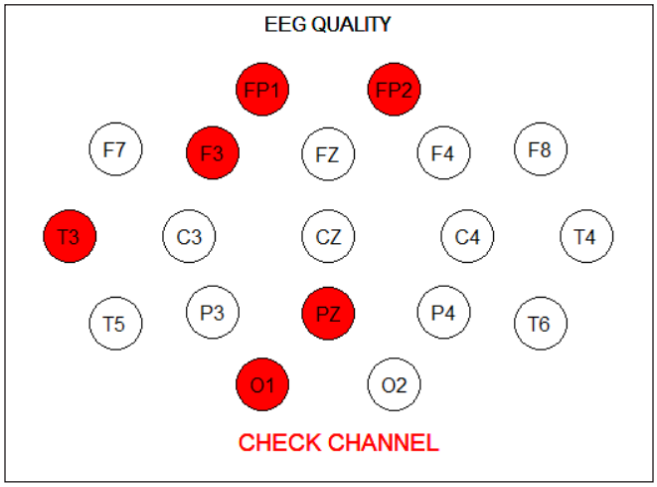


Figure 4-6.

Note that there are many possible sources of artifact, and a protocol may be affected by more than one type of artifact. Therefore the suggested corrective actions mentioned above are intended only as general guidelines, not guaranteed solutions. For more information on general troubleshooting, see section 13.

4.3. Flanker ERP

Figure 4-7 shows the default review display mode for a Flanker protocol. Flanker response waveforms are displayed for each EEG electrode location, while various metrics are listed to the right of the waveforms. This display is for educational purposes only. For more information on Flanker results, see section 10.1.2.

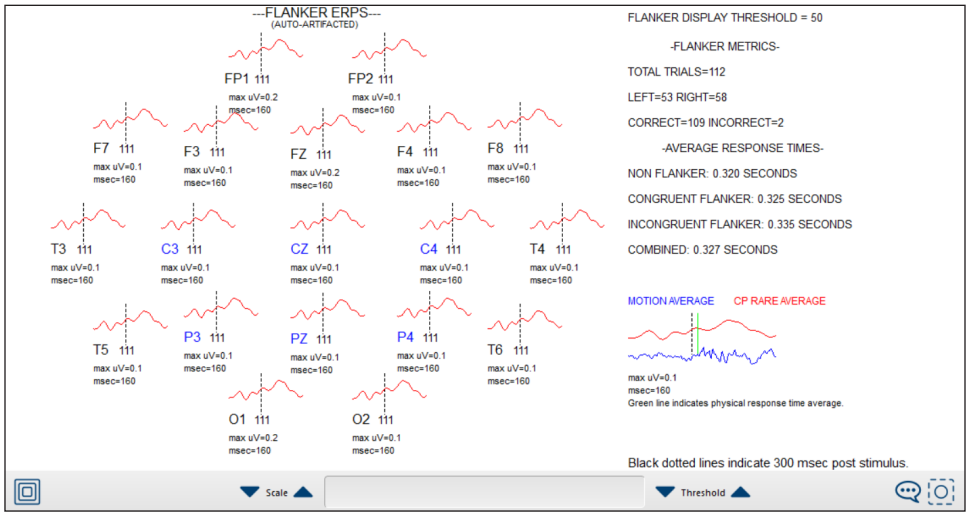


Figure 4-7.

The control bar for the Flanker ERP display mode offers the following adjustments:

- Buttons to scale the response waveforms up/down for better visibility.
- Buttons to adjust the Flanker threshold: this corresponds to the minimum number, or yield, of clean Flanker responses required at a given location in order to display a response waveform. The yield at a given location can be reduced by excessive artifact. If the yield is lower than the current threshold, the display will show "N/A" at that location. The default threshold is 50 responses (out of 112 in a typical 4-minute Flanker protocol).

4.4. P300 1020

If you are reviewing a P300 protocol, this mode summarizes the P300 responses and various related metrics in one consolidated display (Figure 4-8).

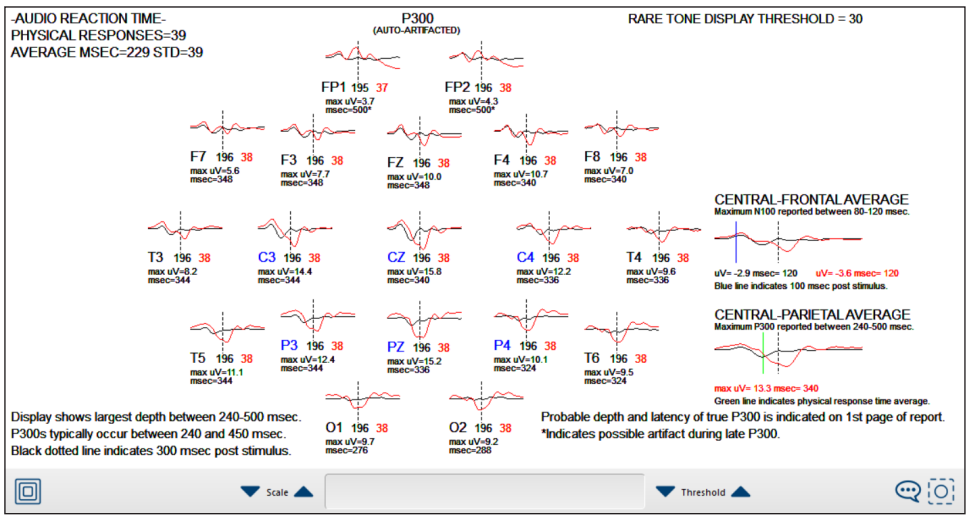


Figure 4-8.

This display includes graphs of the average responses to the P300 audio stimulus at each location in the standard 10-20 EEG layout, along with graphs for Central-Parietal P300 average and Central-Frontal N100 average. Waveforms are plotted as voltage (positive down) versus time after stimulus. The negative (upward) peak near 100 ms is the N100, and the positive (downward) peak for the rare tone near 300 ms (dashed lines) is the P300. At each location the number of accepted rare tones (out of 40) are shown, below which are displayed the P300 depth (μV) and latency (msec) at that location.

The control bar for the P300 1020 display mode offers the following adjustments:

- Buttons to scale the response waveforms up/down for better visibility.
- Buttons to adjust the Rare Tone Display Threshold: this corresponds to the minimum number, or yield, of clean responses to the rare audio tone at a given location required to display a response waveform. The yield at a given location can be reduced by excessive artifact. If the yield is lower than the current threshold, the display will show "N/A" at that location. The default threshold is 30 responses (out of 40 rare tones in a typical 4-minute P300 protocol).

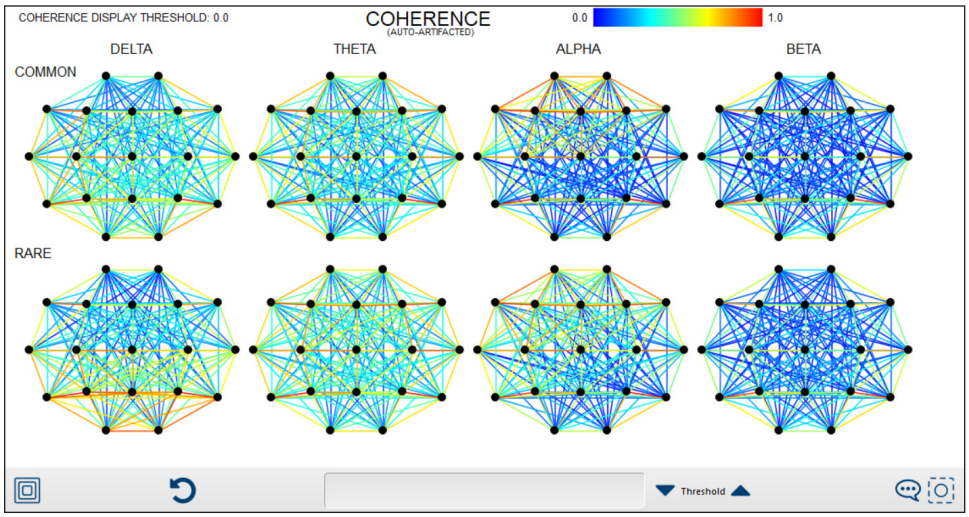
If the upper left corner shows the message "MISSING PHYSICAL RESPONSES," this means that the participant failed to press the mouse in response to 15 or more presentations of the rare tone.

If Sync Blinks are detected, this fact will be noted by explanatory text in the upper right corner.

If the participant's maximum EEG response to the rare P300 audio tones occurs later than 500 ms following the stimulus, this is considered a "late" response, which appears as a dip near the right edge of the P300 waveform for a given location. However this "late" response may also be due to artifact or other physiological factors and is therefore marked with an asterisk (*).

4.5. Coherence

The Coherence display mode provides information about the functional connectivity between different cortical regions. Coherence in each frequency band is represented using colored lines between pairs of EEG electrodes in a topographic format (Figure 4-9). The definitions for each frequency band are shown in the table on the right. Note that due to its susceptibility to artifact, the Delta band is not included here unless you have enabled it in the System Settings; see section 12.2 for details.



Band	Frequency
Delta	1.0–4.0 Hz
Theta	4.5–7.5 Hz
Alpha	8.0–13.0 Hz
Beta	15.0–35.0 Hz

Figure 4-9.

If you are reviewing a P300 protocol, the Coherence display will include two rows of graphs as shown in Figure 4-9, with the top row graphing coherence during the common tones, and the bottom row graphing coherence during the rare tones. For all other protocol types, only one row of graphs is displayed.

Coherence values range from 0.0 (no coherence) to 1.0 (total coherence). To reduce visual complexity, the Coherence Display Threshold (indicated in the top left corner) can be adjusted between 0.0 and 1.0 using the threshold buttons in the control bar. You can also touch any electrode location on the graphs to see the coherence between just that location and all other locations. To view all coherence pairs again, press the **Reset Coherence Display** button (circular arrow icon).

One or more warning messages may be displayed under the graphs. This happens if the system detects data quality issues which could affect the reliability of the coherence computations, such as low yield due to artifact, or the effect of Sync Blinks on frontal coherence.

Excess Synchrony between pairs of locations due to improper electrode connections and/or electrical bridging between electrodes may inflate the displayed coherence values in one or more frequency bands. Therefore, it is important to always check the Raw Wave display mode for Excess Synchrony warnings if numerous unreasonably high coherence values are displayed.

4.6. Spectrum

The Spectrum display mode provides a magnitude spectrum (magnitude versus frequency) for each electrode location, displayed in a topographic format (Figure 4-10). The number displayed below the x-axis to the right of each location name indicates the frequency in Hz with the highest magnitude, or peak frequency, within the Alpha range of 8–13.0 Hz.

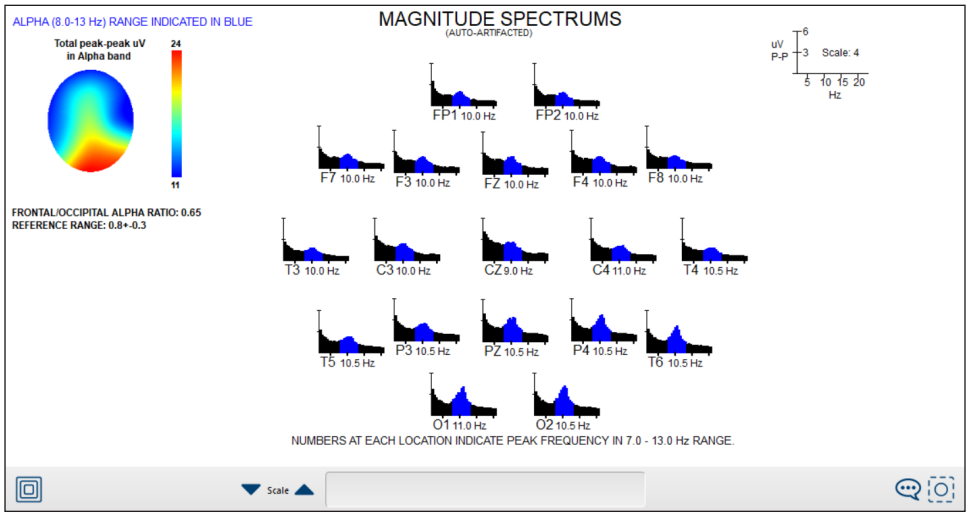


Figure 4-10.

The vertical scale of the spectrum graphs can be adjusted using the Scale buttons in the control bar. The current scale and values of the vertical tick marks are indicated by the legend in the top-right corner.

The topo in the upper left corner shows an interpolated color map of the peak frequencies in the Alpha band. This display complements the frequency graphs by providing a more intuitive visual overview of Alpha magnitude across the head. The ratio of frontal to occipital Alpha is also displayed under the topo.

If the peak frequency inside of the Alpha range is smaller than the peak frequency outside of the Alpha range at a given location, the Alpha peak value for that location will be marked with three asterisks (***) to indicate that it should be considered a questionable value. This often occurs with a flat, low amplitude spectrum.

5. Protocol Comments

After recording a protocol, you can optionally enter text comments associated with that protocol. Comments may be used to provide relevant information about the context of a recording, environmental factors, and noteworthy events or problems which occurred. This is helpful for future review, especially if you intend to share the data with other clinicians or neurologists. Comments may be edited at any time after a protocol has been recorded, regardless of whether the session is locked; however, it is recommended to enter comments as soon as possible following a recording. You are encouraged to use the comment tools whenever it is practical and appropriate to do so. Protocol comments can be automatically included when generating reports; see section 9.14 for more details.

5.1. Showing/Hiding the Comment Panel

Press the speech bubble icon located on the right side of the control bar to toggle visibility of the comment panel. When there are no comments the icon looks empty (Figure 5-1 left), otherwise it looks filled in (Figure 5-1 right).

Figure 5-1.

5.2. Raw Wave Comments (for EEG protocols only)

If a protocol involves EEG recording, you can make short text comments directly on the Raw Wave display. This is useful to explain features of interest in the data. You can create as many raw wave comments as you like. Figure 5-2 shows an example with several raw wave comments.

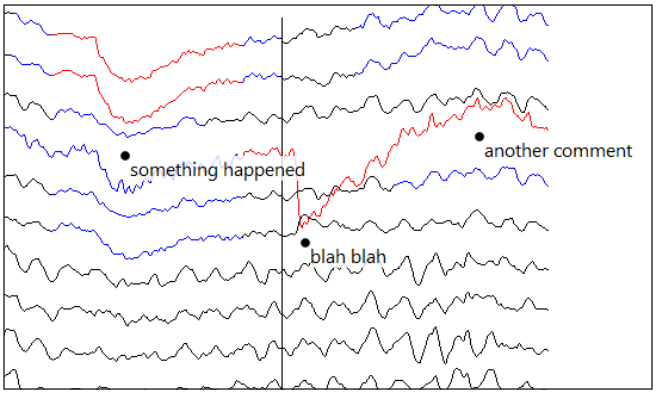


Figure 5-2.

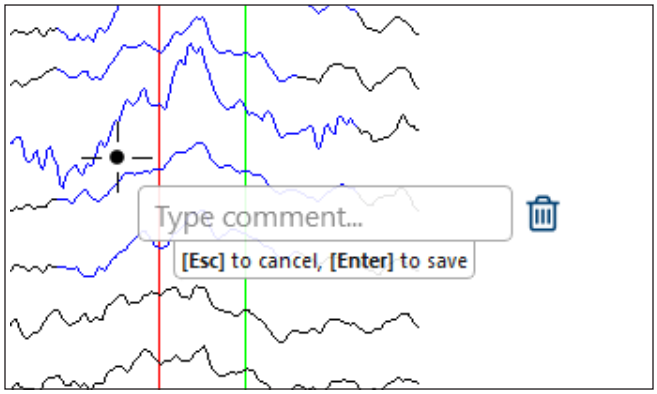


Figure 5-3.

To make a new raw wave comment, right-click anywhere over the raw waves. A floating comment editor will appear, with a marker icon indicating the exact point you clicked (Figure 5-3). Type your comment (up to 50 characters long), then press the Enter key to save it. To cancel changes without saving, press the Escape key. Note: all other interface controls are temporarily disabled while the comment editor is visible.

A raw wave comment can be moved by dragging its marker while in the editing mode. To do this, press and hold the left mouse button over the marker, then drag the marker to a new location and release the mouse. You can move the comment anywhere on the current raw wave display.

By default, a raw wave comment has a solid black dot marker, but this can be changed to one of several other styles if you wish. To change the marker style, right-click the marker while in the editing mode. A popup bar will appear showing several style choices (Figure 5-4). Left-click on the desired marker style to apply it.

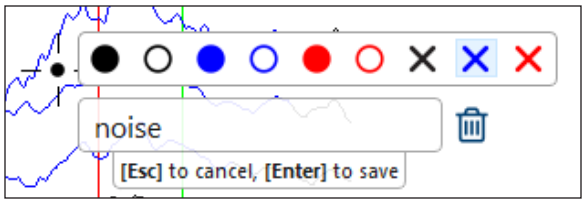


Figure 5-4.

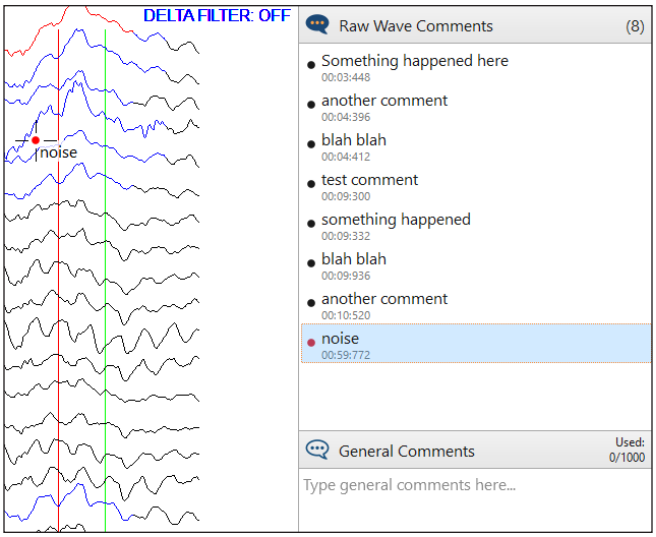


Figure 5-5.

All raw wave comments for the current protocol are listed in a panel to the right of the raw wave display (Figure 5-5). These are displayed in chronological order from top to bottom, with the time position of each comment indicated to millisecond precision. You can jump directly to any comment simply by clicking on its entry in the list. This is useful if a file has a lot of comments, and allows you to quickly find comments which may be positioned far apart in the file. When you hover the mouse over a comment marker in the raw wave display, its corresponding entry in the comment list is simultaneously highlighted, and vice versa.

You can edit any existing raw wave comment by right-clicking its marker icon to bring up the comment editor. To delete a raw wave comment, press the trash can icon to the right of the editor's text box.

5.3. General Comments (for any protocol)

All types of protocols can have general comments. These can be much longer than raw wave comments, and are associated with the whole protocol, not a specific position in time. General comments may be viewed and edited from any display mode. To edit general comments, first show the comment panel, then enter your comments in the box under the heading "General Comments" (Figure 5-6).

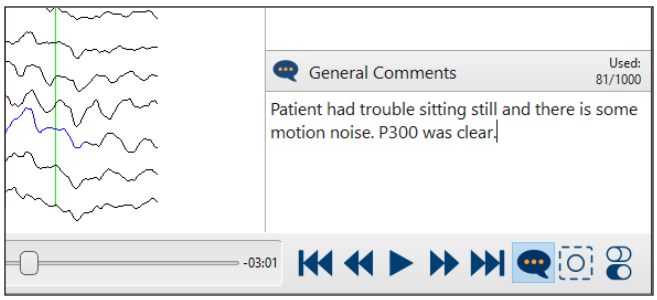


Figure 5-6.

Note: general comments are not a substitute for filling out the session intake and assessment forms. Comments should only relate to the current protocol being reviewed.

6. Manual Artifacting

WAVi EEG data is automatically artifacted by default. While not perfect, automatic artifacting is usually sufficient for computing qEEG metrics. Manual artifacting done by qualified EEG technicians may in some cases improve data yield, however the results may be inconsistent due to variations in training and artifacting style. Experiments at WAVi have demonstrated that automated artifacting is superior to manual artifacting in many cases, especially for statistical analysis, since all EEG files are artifacted using consistent rules. For these reasons WAVi does not recommend manual artifacting in normal practice. However, tools are provided for users who want to do manual artifacting for the purpose of comparing the results of manual and automatic artifacting methods.

6.1. Entering the Manual Artifacting Mode

Manual Artifacting is only available for EEG protocols, and can only be used while in the Raw Wave display mode. Press the **Unlock Artifact Tools** button at the left end of the control bar (Figure 6-1) to enter the Manual Artifacting mode. The icon will change to an open lock.

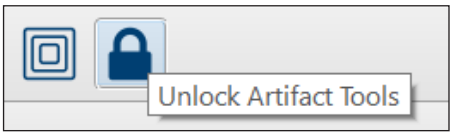


Figure 6-1.

Figure 6-2 shows an example of the interface in Manual Artifacting mode. All normal EEG review and comment functions are still available, but are now joined by additional controls for manual artifacting.

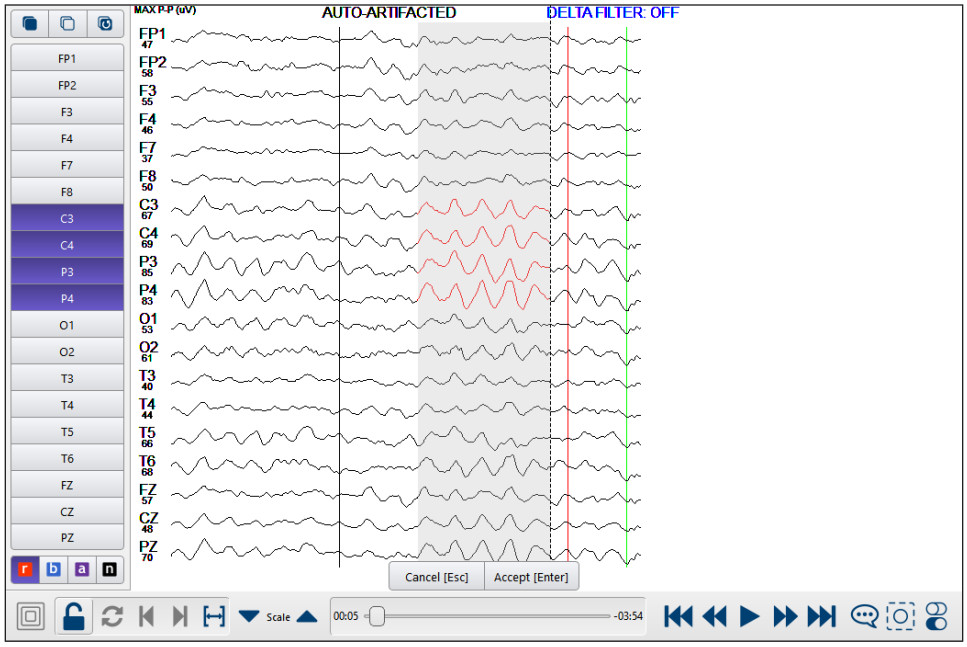


Figure 6-2.

Manual artifacting involves three basic steps which may be performed in any order: selecting channels, selecting the artifact color mode, and selecting a span of raw data to modify. Each of these steps and the tools to perform them are described in the following subsections.

6.2. Selecting Channels

The panel to the left of the raw wave display contains checkable buttons corresponding to each of the standard 19 EEG channels. Any channel can be added to or removed from the active channel selection by repeatedly pressing its button. In the example shown at right in Figure 6-3, only channel C4 is active, while the rest are not. This means that the next manual artifacting operation will only apply to channel C4.

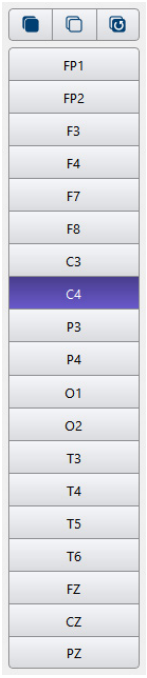


Figure 6-3.

The three small buttons at the top allow you to quickly toggle the active channel selection in some useful ways. From left to right, these are: select all, select none, and invert the current selection. Using these actions can be much faster than checking and unchecking many channel buttons one by one.

The active channel selection can be changed at any time, regardless of whether you have already begun a data span selection. By carefully adjusting the channel selection, you can precisely control the manual artifacting process.

6.3. Selecting the Artifact Color Mode

Below the channel selection buttons are the artifact color mode buttons (Figure 6-4). Only one of these can be active at a time. From left to right these correspond to: Red Artifact, Blue Artifact, Auto Artifact (a combination of Red, Blue, and No or Minimal Artifact), and No or Minimal Artifact (black). These buttons control how the raw waves within a data span selection will be colored.

Figure 6-4.

As previously discussed, the WAVi artifact color levels indicate how segments of data will either be included or excluded for analysis and reporting:

- **Black lines** indicate acceptable data, which may also sometimes contain negligible amounts of artifact. Black sections are usable for computing all metrics.
- **Blue lines** indicate possible artifacts, which are still acceptable for computing evoked potentials such as the P300. These sections are included when computing evoked potential metrics, but not other background EEG metrics.
- **Red lines** indicate severe artifacts, which are excluded from all metric computations.

When using the Auto Artifact color mode (purple button), the software will apply automatic artifacting within the current data span selection exactly as it would by default. When using the No or Minimal Artifact color mode (black button), you can erase any artifact designations within the current data span selection.

6.4. Selecting a Span of Raw Data

Before any artifacting changes can be applied, you must first select a span of raw data. This is done by left-clicking anywhere over the raw waves and then continuing to hold down the left mouse button while dragging to the left or right from your starting position. Release the mouse button to end the selection. The selected span of raw data is shown in light gray (Figure 6-5).

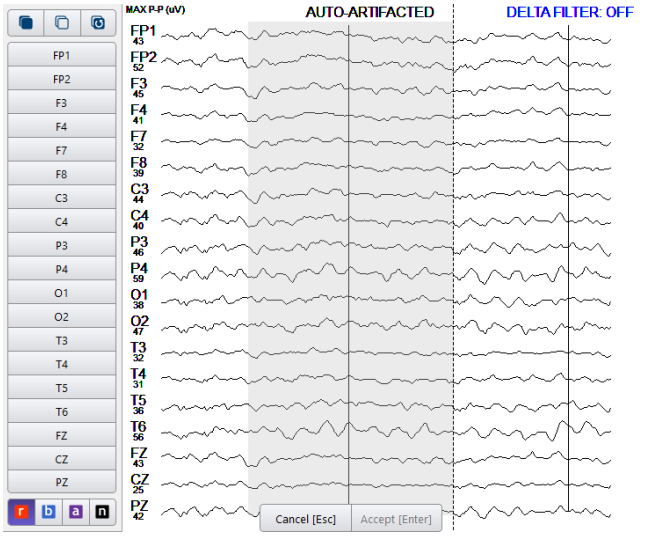


Figure 6-5.

To adjust the size of the selection, move the mouse cursor toward the side you want to adjust. The cursor changes to an open hand, and a solid black vertical line is shown aligned with the edge of the selection (Figure 6-6). This is a "handle" for adjusting the selection. Grab the handle by pressing and holding the left mouse button, then drag the handle to a new position (Figure 6-7). You can even drag one handle across the other, in which case the start and end positions will be swapped. Release the mouse to end the adjustment.

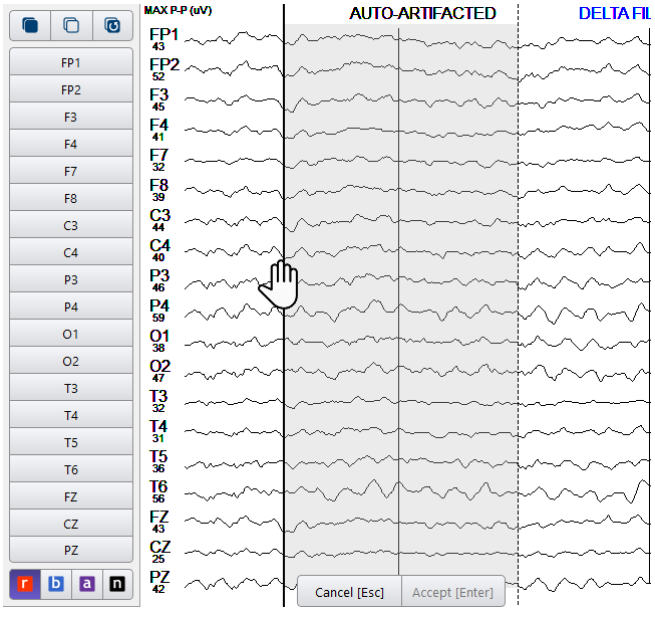


Figure 6-6.

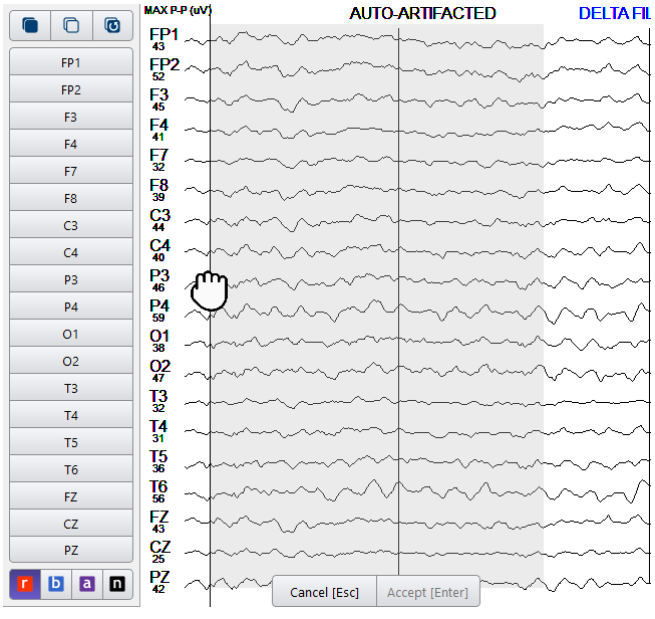


Figure 6-7.

If you drag a handle off the edge of the raw wave display, the view will automatically scroll to keep the cursor visible. This allows you to make selections spanning multiple epochs. A span can range from as little as 3 samples up to the entire file. If a span exceeds the width of the view, arrow buttons are shown which allow you to quickly jump to the start or end of the selection (Figure 6-8).

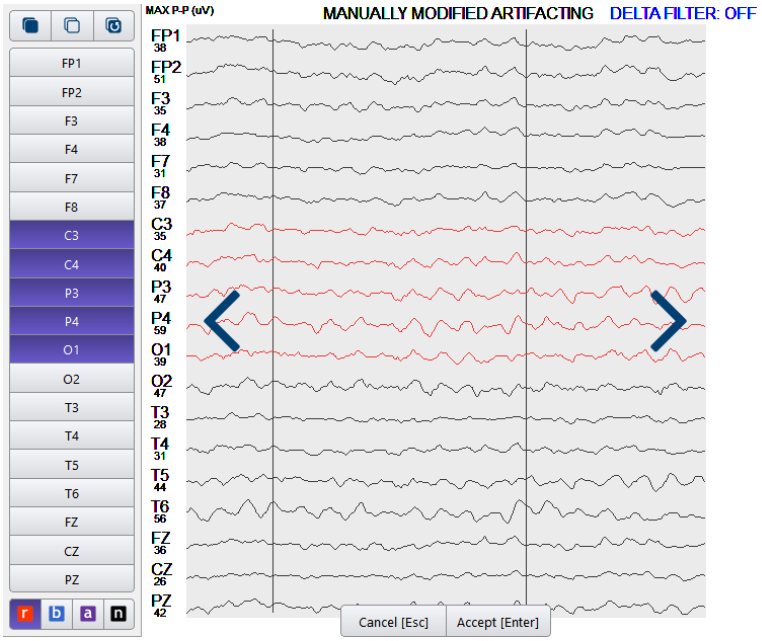


Figure 6-8.

6.5. Accepting/Canceling a Selection

Once a span selection is adjusted to your liking, and at least one channel is active (see section 6.2), you can press the Accept button (or the Enter key) to apply the current artifact color mode to the active channel(s) within the selected data span (Figure 6-9). To cancel the selection without modifying the artifacting, press the Cancel button (or the Escape key), or left-click anywhere outside of the selection.

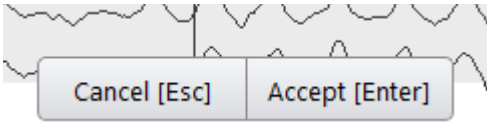


Figure 6-9.

Remember: you can change both the active channels and the artifact color mode at any time. A preview of how the waves will be colored inside the selection is updated in real time, so you can see exactly what will be applied once you accept the selection.

6.6. Other Manual Artifacting Functions

Several additional buttons for common manual artifacting tasks are located to the right of the button for toggling the manual artifacting mode (Figure 6-10). Each of these functions is described below.

Figure 6-10.

If you wish to discard all manual modifications and revert to automatic artifacting for the entire file, you can press the **Revert to Auto Artifact** button (Figure 6-11). This function will erase all manual artifacting for the current file, and replace it with automatic artifacting. A warning is shown first asking you to confirm your choice.

Figure 6-11.

To quickly find spans of data which are already marked as artifact, you can use the **Step to Previous Artifact** and **Step to Next Artifact** buttons (Figure 6-12). These functions can be much faster than visually hunting for artifact spans. They operate in relation to the marker cursor, indicated by a dotted vertical line. When you left-click within the raw wave display or drag to define a span selection, the marker cursor position is updated to match the last mouse position.

Figure 6-12.

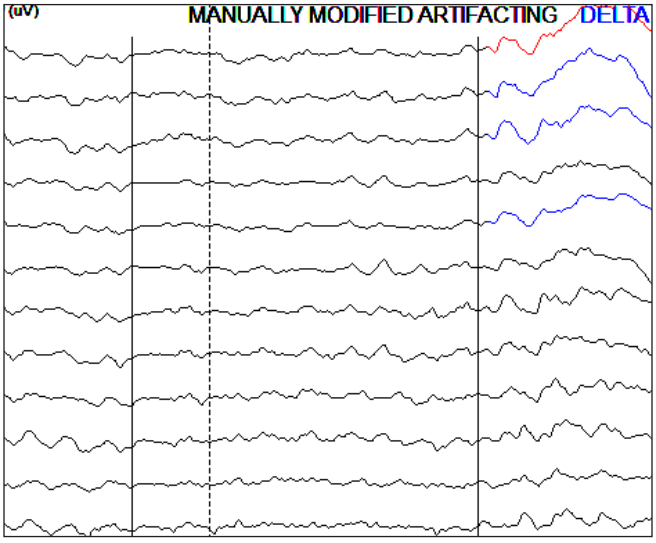


Figure 6-13.

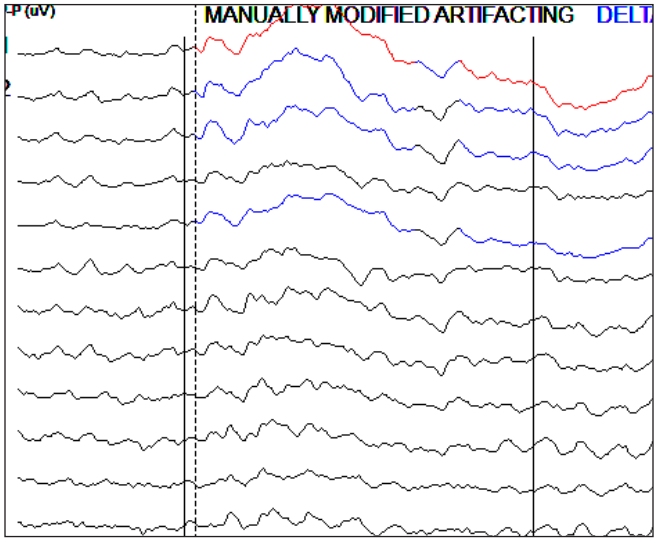


Figure 6-14.

When you then press one of the step buttons, the system will search for artifacts either before or after the marker cursor's position. For example, given the initial marker cursor position shown in Figure 6-13, pressing the Step to Next Artifact button causes the marker to be moved forward to the position shown in Figure 6-14, which in this case coincides with the start of red and blue artifact across several channels. The display also automatically scrolls so that more of the artifact span is visible.

If no marker cursor is visible, the step functions instead operate in relation to the edges of the current data window. The step functions identify changes in artifact color across any channel, which may be useful in situations such as the example above where multiple channels are marked with different artifact colors within a narrow range of time. Note that the step functions only help with navigation, and cannot identify artifacts which are not already marked.

Sometimes you may wish to apply manual artifacting to one or more channels across the entire length of the file, for example if a channel was broken and did not acquire any usable data. While you could start a regular span selection and then manually drag the ends until they coincide with the beginning and end of the file, that approach is both cumbersome and time consuming. Instead, simply press the **Select Entire File** button (Figure 6-15) to automatically create a new selection spanning the entire file from beginning to end.

Figure 6-15.

6.7. Exiting the Manual Artifacting Mode

When you are finished using the manual artifacting tools, press the **Lock Artifact Tools** button at the left end of the control bar (Figure 6-16) to exit the Manual Artifacting mode. The icon will revert back to a closed lock. All changes are automatically saved.

Figure 6-16.

6.8. Checking the Artifact Status of a Protocol

As mentioned at the beginning of this section, all EEG data is automatically artifacted by default. This is indicated by the label "AUTO-ARTIFACTED" at the top of the protocol view. A protocol will retain this default status until any manual modifications are made, at which point the label changes to say "MANUALLY MODIFIED ARTIFACTING." If you subsequently discard all manual modifications by reverting to automatic artifacting for the entire file, the artifact status will also revert to "AUTO-ARTIFACTED." The appearance of the status label varies depending on the current display mode; the figures below show a comparison in the raw wave mode of the same data artifacted two ways.

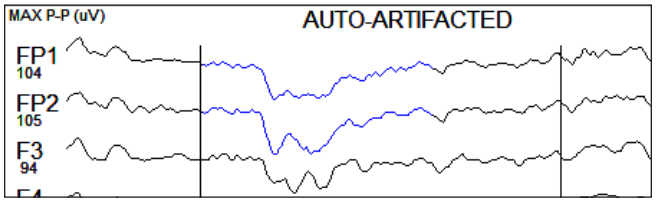


Figure 6-17.

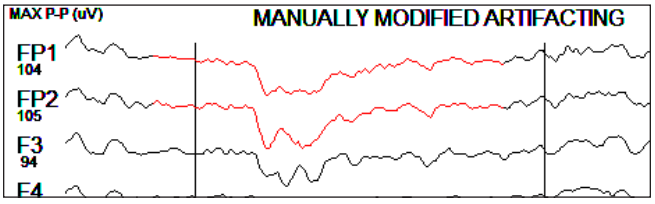


Figure 6-18.

Metrics derived from protocols with manually modified artifacting are always indicated as such on reports. This is important because manually modified artifacting can affect the data yield and accuracy of qEEG metrics.

7. Exporting Protocol Data

Although the WAVi system is designed for stand-alone use, protocol data can be optionally exported on demand for further review and/or analysis using external 3rd-party software. This feature is intended for advanced users who are conducting research, as well as clinicians who need to share data to neurologists or other specialists using industry-standard formats. For normal scenarios where it is not necessary to export data outside of the WAVi system, this section may be skipped. Otherwise, please read on to learn about the protocol export wizard and how to use its options correctly.

7.1. Acceptable Protocol Types

Currently you can only export protocols which contain EEG. Non-EEG protocols, such as the Trail Making tests, cannot be exported at this time.

7.2. Preparing to Export

A protocol may be exported any time after it has stopped recording, regardless of whether the parent session is locked. Before you can start, however, the protocol must first be opened for review. If it is not already active, press the protocol's queue item to activate it so that you can see and review its data. (The review display mode does not matter.) For this example we will use a typical P300 eyes closed protocol opened in the Raw Wave display mode (Figure 7-1).

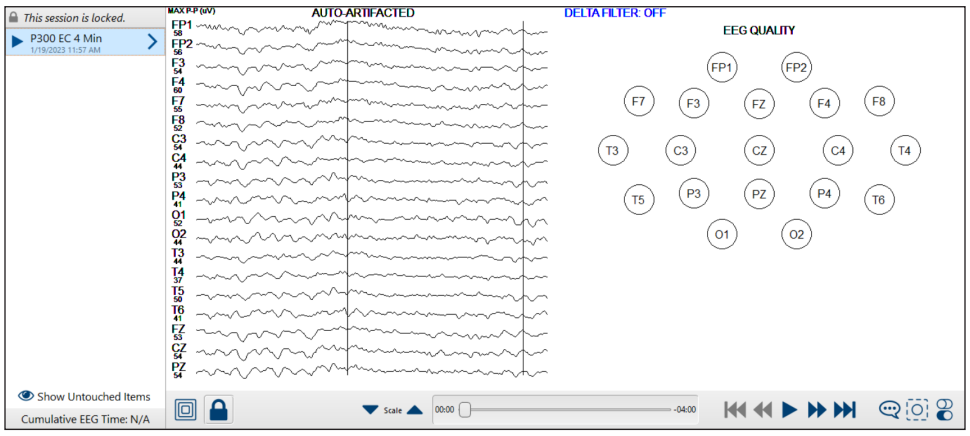


Figure 7-1.

When the protocol data is loaded and visible in the review display, right-click on the associated queue item and choose **Export** from the popup menu (Figure 7-2).

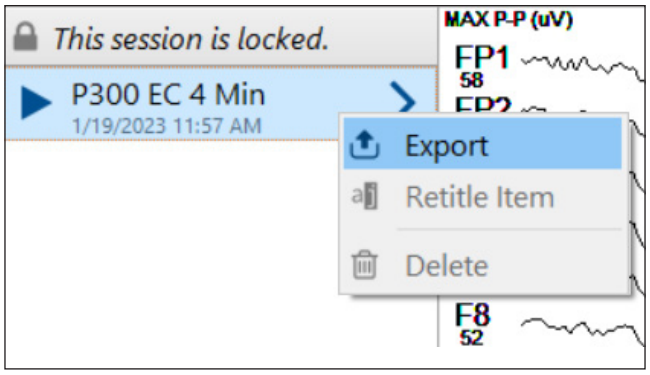


Figure 7-2.

If the Export menu item appears disabled (grayed out) and does not respond to being pressed, it could mean one of the following:

- The protocol was not activated. If this is the case, you either will not see anything in the display, or may still see content for another queue item that was previously activated. Try pressing again on the desired protocol's queue item, and make sure that the review display actually shows the recorded data associated with that protocol.
- The protocol has not been recorded. If its queue item has a title in *italics* and does not show a date/time underneath, it means that the protocol has not been recorded yet, so there is no data to export.
- The item you are trying to activate is not a protocol, but may instead be some other type of item (a form, quality check step, etc.). Please verify that you are activating the correct item in the queue.

After selecting the Export action, the **Export Item** wizard will appear as shown in Figure 7-3. At this point you can begin to choose the desired formats and other options for the export, which are explained over the following pages.

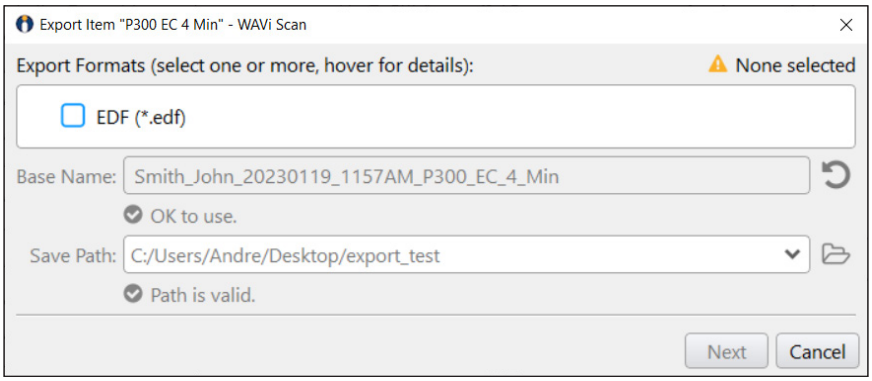


Figure 7-3.

7.3. Choosing Export Formats

The pane at the top of the wizard lists the available export formats along with their standard file extensions. Formats can be added or removed using their associated checkboxes. Each format item also provides a brief popup description, which you can see by hovering the mouse over the format label (Figure 7-4).

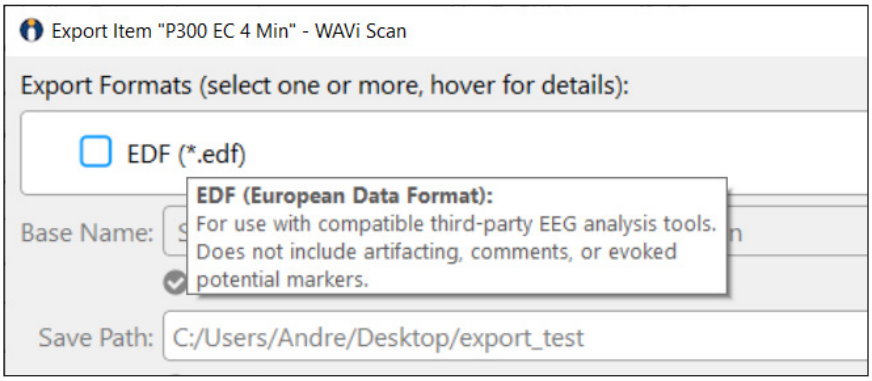


Figure 7-4.

Note that while you can select any combination of export formats, not all protocol types are compatible with all formats. The following subsections explain the export formats currently available in WAVi Scan, their intended use, and any relevant limitations.

7.3.1. European Data Format (EDF)

This industry-standard format is intended for use with 3rd-party EEG analysis tools, such as those typically used by neurologists. WAVi's implementation conforms to the EDF+ standard. Selecting this format will generate one output file with a .edf extension.

There are several important limitations to keep in mind when using the EDF format:

- The black/blue/red artifacting classifications are not included. This is because WAVi artifacting is performed on a per-channel basis, to preserve more usable data for computing qEEG metrics. The EDF format only supports artifact markings for entire epochs, which is typical for most other EEG systems. Therefore, the data will need to be re-artifacted in whatever application is used to open the EDF file, and the results will differ from WAVi's automatic artifacting.
- Protocol comments (both Raw Wave and General) are not included.
- Event markers such as those used during the P300 or Flanker are not included.

7.4. Configuring Options

After you have chosen the export formats you want, the lines below the format box become enabled so you can customize additional options if needed (Figure 7-5).

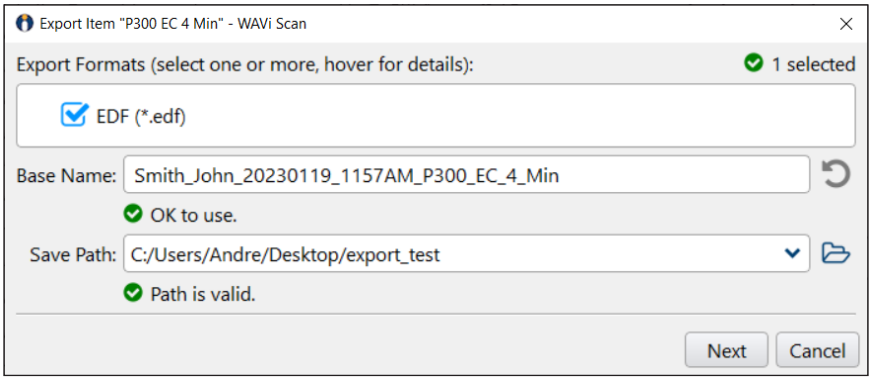


Figure 7-5.

- **Base Name**: This specifies the common name to use for each exported file, preceding the file extension which will be automatically appended. A sensible default name is generated which incorporates the participant's name, the date and local time that the protocol was created, and the title of the protocol. However, you can change this base name to any (non-empty) value you want. To reset the base name to its default auto-generated value, you can press the circular arrow button to the right of the field.
- **Save Path**: This indicates the folder in your computer's file system where the files should be exported. You can either press the folder button to browse to a location, or type it in manually. This path can point to a location in onboard storage, or it may be located on a removable storage device such as an external hard drive or flash drive, but in any case it must already exist in the file system and be accessible while the export wizard is open. If you have used this wizard before, the last used save path will be filled in by default. You can also access a shortcut list of all recently used paths by expanding the dropdown menu at the right of the path box. The validity of the current path is shown below the text box, and the wizard will prevent you from continuing to the next step if the path is not valid.

When you are satisfied with the export options, press the **Next** button.

If the protocol is incompatible with any of the selected export formats, you will see a warning message similar to the one shown in Figure 7-6. You may choose **Yes** to continue with the export, but any problematic formats will be skipped. Alternatively, you can choose **No** to go back to the options page and change your format selections.

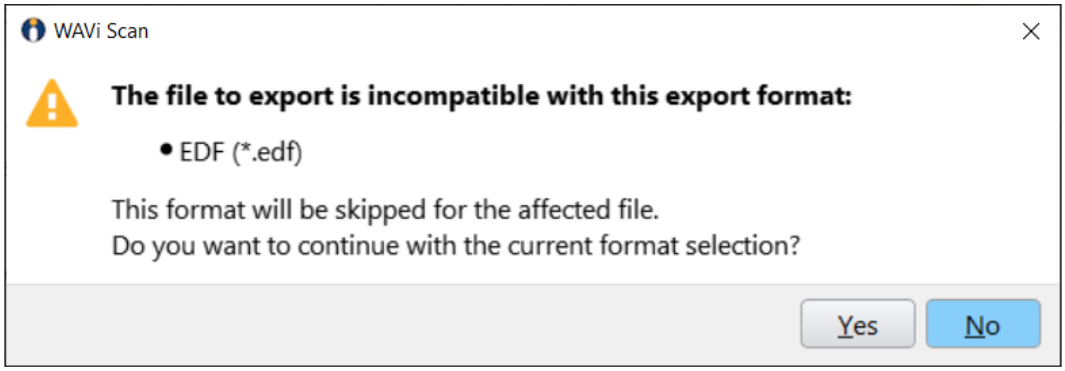


Figure 7-6.

After you have cleared any applicable warnings, the export will begin. Depending on the number of selected formats and the size of the protocol file, this process may take some time to complete. When the wizard has finished, a summary page will explain the results (Figure 7-7). If you would like to see the destination folder containing the exported protocol file(s), you can press the **Show Files** button. Otherwise, press the **OK** button to exit the wizard and return to the session view.

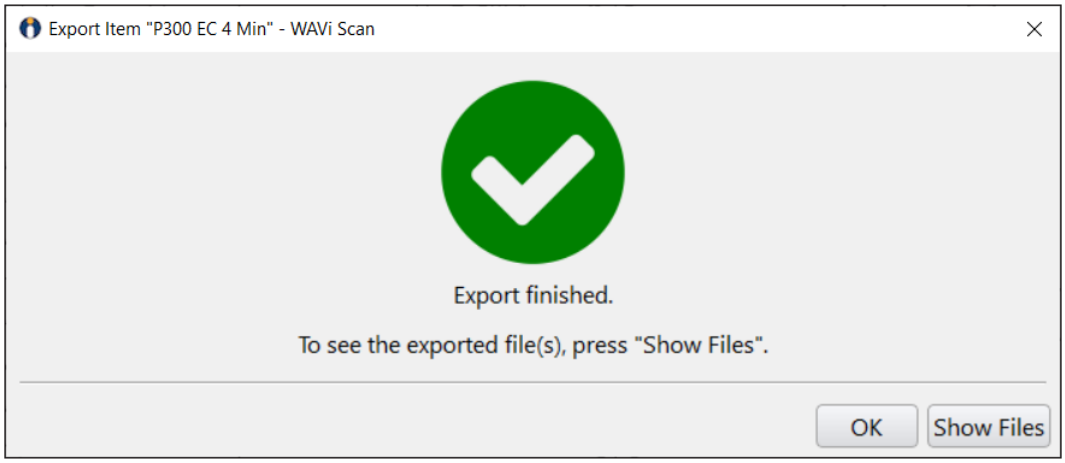


Figure 7-7.

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8. Generating Reports

After you have finished recording EEG data and completed other relevant tasks in a session, you will probably want to summarize the results and possibly compare them against results from previous WAVi sessions. To do this, you can generate a report. WAVi reports are standard PDF documents which can be easily printed and shared with the participant and other healthcare providers. The process for generating a report is typically quick and easy, but there are some details and potential issues to keep in mind.

8.1. Choosing a Report Template

To get started, press the **New Report** button located in the top-right corner of the Profile View (Figure 8-1). This button is only enabled if at least one session exists for the participant.

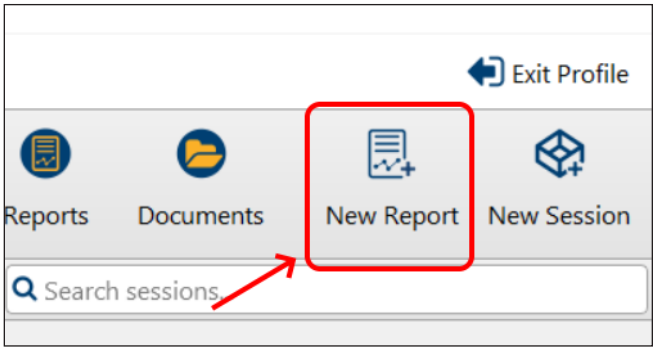

Figure 8-1.

The **New Report** dialog window will appear as shown in Figure 8-2. The system provides a number of report templates which are appropriate for different situations; for details on the available templates and their options, see section 9. Once you have made your template selection, press the **OK** button.

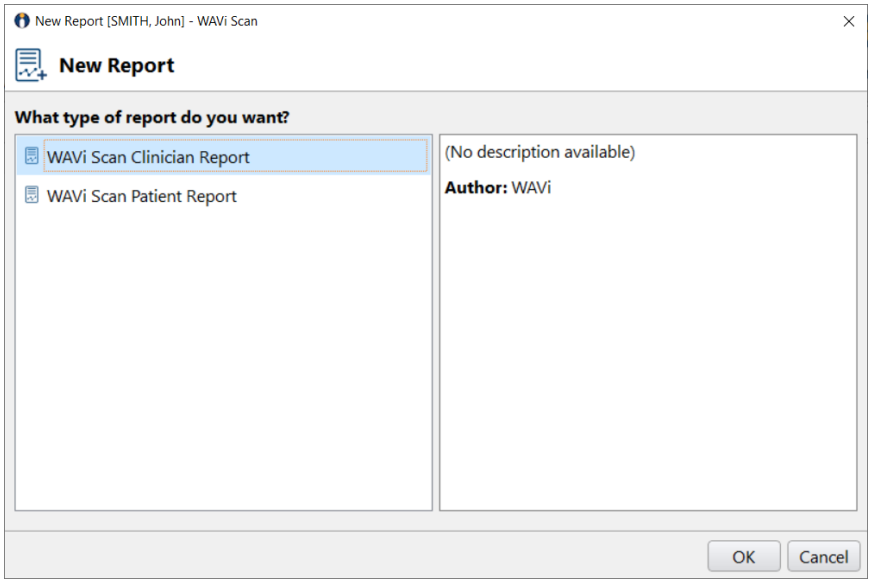

Figure 8-2.

8.2. Choosing Input Sessions

At this point the interface will automatically switch to the Sessions tab if it is not already active, and a yellow message bar will prompt you to choose which sessions to include in the report (Figure 8-3). Depending on the chosen report template, you may select 1, 2, 3, or 4 sessions to compare. Different templates support more or fewer input sessions; see section 9.1 for details.

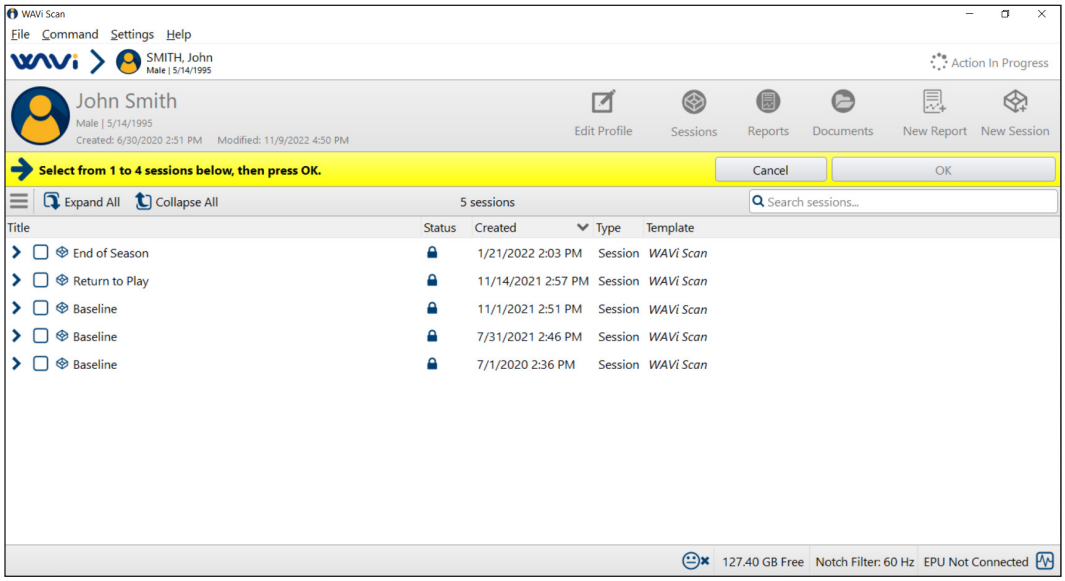

Figure 8-3.

You can quickly show or hide a preview of each session's contents by using either the arrow buttons to the left of the session titles, or the Expand All/Collapse All buttons above the list. The preview feature can be useful if you do not remember which items were touched in a session; for more details, see section 11.2.

If you instead want to reopen a session to verify that it contains the data you need, you must first press the **Cancel** button in the yellow message bar to exit the New Report mode and return to the normal session list interface. To resume generating a new report, you will need to restart the New Report workflow from the beginning by selecting the desired template again as described in section 8.1.

Once you have selected your input session(s), press the **OK** button in the yellow message bar to continue to the next step in the New Report wizard.

8.3. Ambiguity Resolution

If an input session contains two or more protocols of the same type, the system will ask you to choose just one of them to use for the report (Figure 8-4). This step is known as "ambiguity resolution" and only occurs if duplicate protocols are detected within a session.

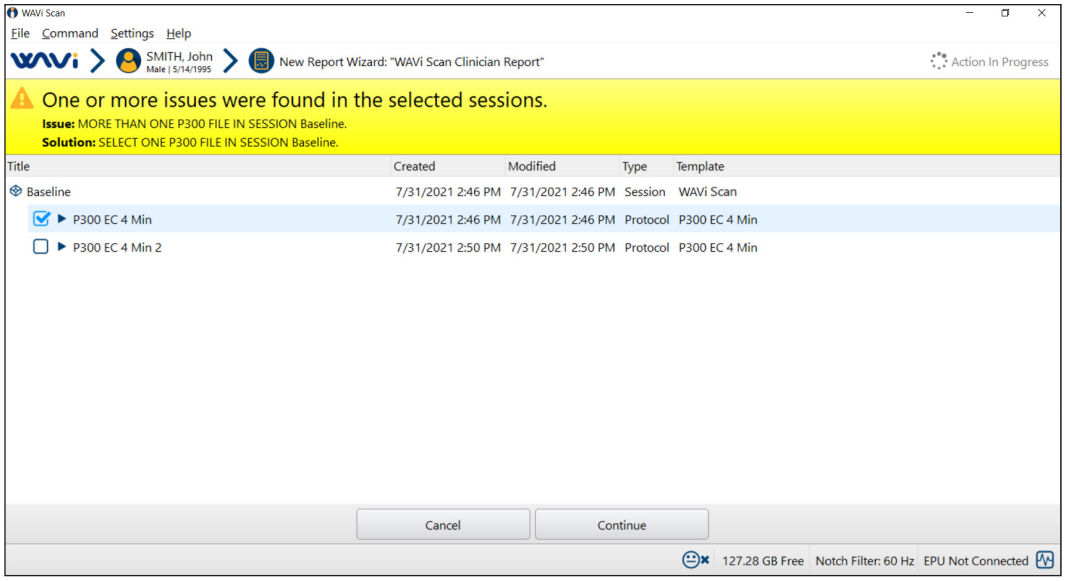

Figure 8-4.

For each detected ambiguity, the yellow warning bar shows a description of the issue and a solution. Check the box next to the item you want to use, then press the **Continue** button. These steps must be repeated until all ambiguities are resolved.

Note that the ambiguity resolution system cannot determine whether protocols actually contain valid or clean data, and thus cannot provide recommendations as to which protocols should be selected. If in doubt, you should go back and review the protocols in question to confirm their contents before restarting the New Report wizard.

8.4. Selecting Options

After you have selected the input sessions and resolved any ambiguities (if applicable), you will see the report options screen (Figure 8-5). Options are divided into two categories: **Basic Options**, which contains the most frequently used settings and fields; and **Advanced Options**, which contains less frequently used items which may be useful to some advanced users. You can see all of these by pressing the tabs located in the upper right corner of the options screen.

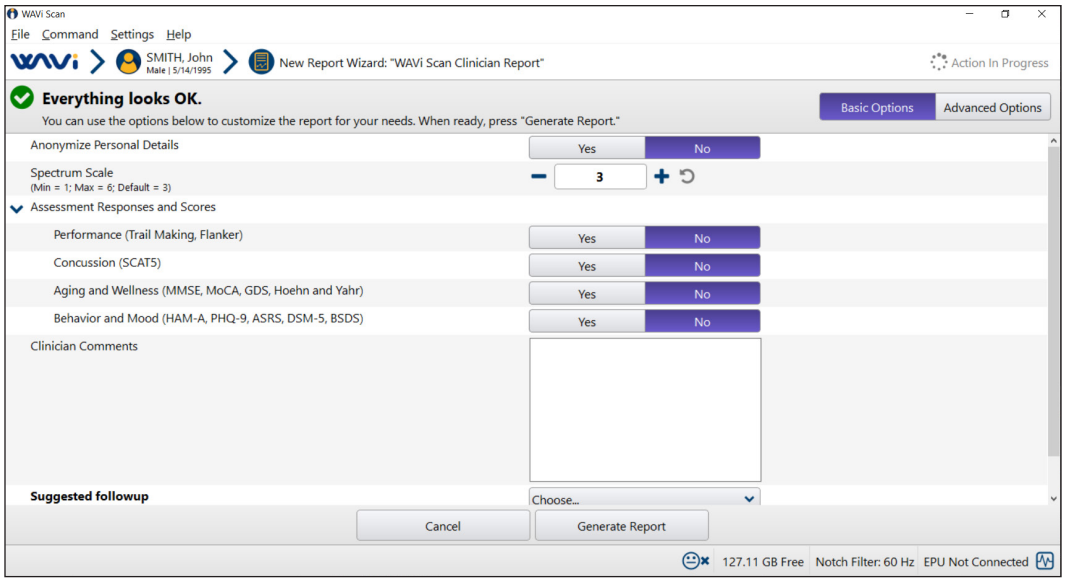

Figure 8-5.

The available options in each category will vary depending on the selected report template. Both the Basic and Advanced options are customizable when generating any report. For a complete listing of the options available in each report template, see section 9.

8.5. Generating and Viewing the Report

When you have finished configuring the options to your liking, press the **Generate Report** button at the bottom of the window. Depending on the number of sessions being compared and the options selected, this process may take a few moments to complete (Figure 8-6).

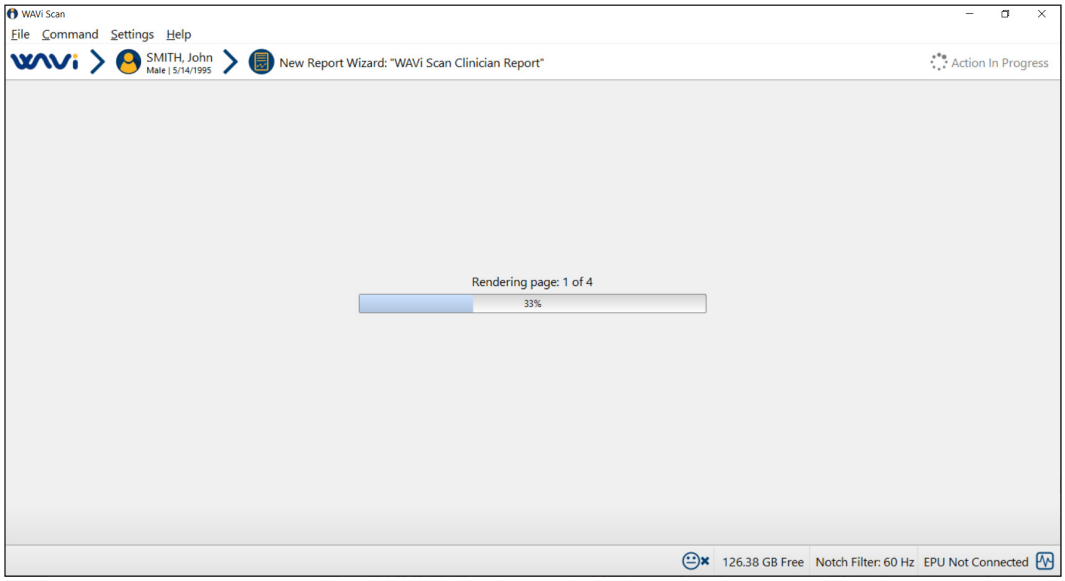

Figure 8-6.

When the new report is ready, a preview will automatically open in your computer's default PDF viewer app (Figure 8-7). This screenshot is just an example for illustration; the actual PDF viewer app may vary depending on your computer's configuration, and thus any discussion of its appearance or features is beyond the scope of this document.

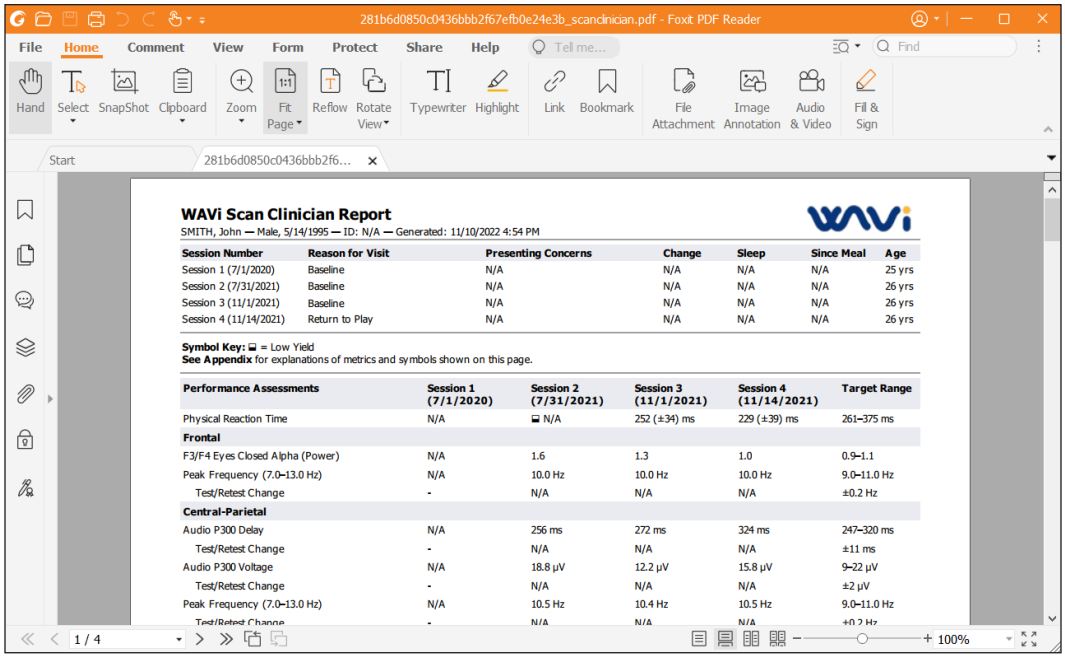

Figure 8-7.

After previewing the report, close the external PDF viewer and return to the report summary screen in the WAVi Scan app (Figure 8-8). To see the preview again, you can press the **Preview** button to re-open the external PDF viewer. Note that you cannot cancel the New Report wizard or make changes while the preview is open in the external PDF viewer.

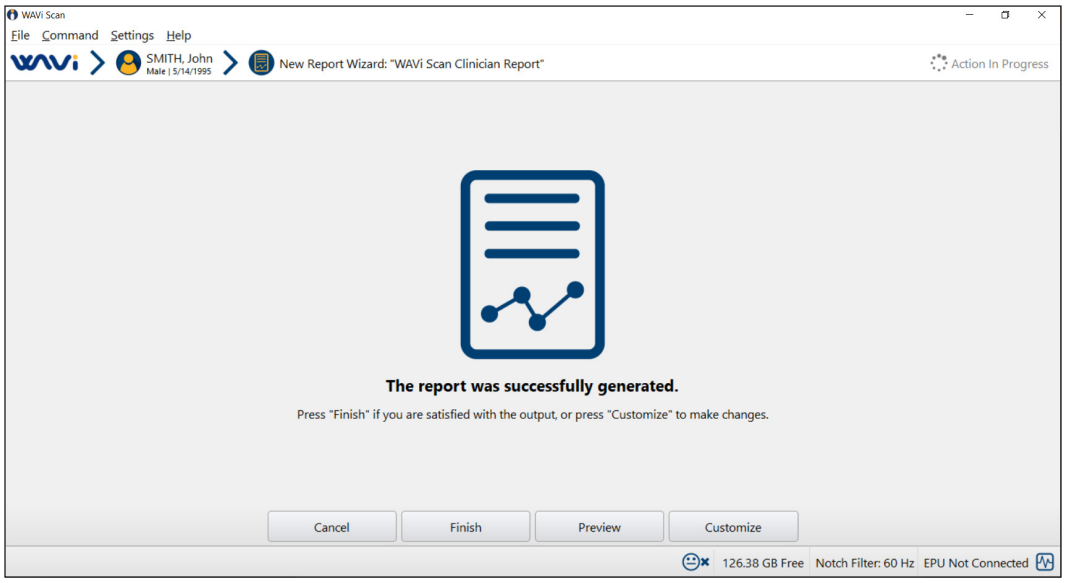

Figure 8-8.

Depending on the content of the selected sessions, the selected report template, and any selected options, some information may be missing or incomplete in the final report. In that case certain fields in the report may be left empty or labeled "N/A." If this happens, you can either cancel the New Report wizard and start over with a different report template, or adjust the options to better suit the available data.

8.6. Making Changes

If you are not satisfied with the report in its current state, you can press the **Customize** button on the summary screen. This will return you to the options screen described back in section 8.4. From there, you can adjust the Basic and/or Advanced options to change how certain metrics are calculated or displayed, as well as add or remove optional pages which may include additional metrics (again, see section 9 for a complete listing of available options). When you are ready, press the **Generate Report** button again to resume the workflow from section 8.5.

You can make changes to the options and regenerate the report as many times as you like, so please feel free to experiment with different options to find the ones that work best for your needs. Note however that if you want to change either the input sessions or the protocols selected in the ambiguity resolution step, you will need to cancel the current report and start over from the first step as explained in section 8.1.

8.7. Finishing the Report

When the report preview looks good to you, make sure to close the external PDF viewer, then press the **Finish** button on the summary screen in WAVi Scan. This saves the final PDF document to the current participant profile, where it can then be accessed from the "Reports" tab. For more information on managing reports, see section 11.3.

Note that once you commit to finishing a report it can no longer be modified, and its content will remain "static." However, you can always generate another report anytime using different inputs and/or options.

9. Report Contents and Options

This section explains all of the contents and options of the reports available in WAVi Scan. For each metric, page, or option, we describe its purpose and note which report templates currently support it. Differences in item naming and/or formatting between reports are also noted where relevant.

9.1. Available Report Templates

9.1.1. Scan Clinician Report

Includes calculated averages and scores for a variety of standard EEG metrics and derived parameters for up to 4 sessions. Can optionally include extra pages with responses to assessment questionnaires, additional graphs and numerical tables. Automatically includes pages for protocol comments, if available. This report is to be used by qualified medical personnel in clinical and/or research settings.

9.1.2. Scan Patient Report

Includes a limited subset of EEG metrics and derived parameters for up to 2 sessions in a simpler "dashboard" graphical format, and provides fewer options than the Clinician report. Does not include protocol comments. This report is recommended to be provided to the patient for educational purposes only.

9.2. Qualifiers and Symbols

If the system determines that issues with data quality may affect the plausibility of a reported metric or value, one or more qualifiers may be shown next to the value. Depending on the context and available space, qualifiers may consist of text labels and/or special symbols. The currently supported qualifiers are explained below.

Low Yield (⬓): This is shown when the amount and/or quality of the acquired data are insufficient to generate an accurate qEEG metric. This may result from the presence of significant artifact.

Questionable Value (**?**): Possibly due to low Alpha or Peak Frequency magnitude relative to background EEG noise.

Excess Synchrony (⧫): A type of artifact which may affect multiple channels equally at the same time. This may be due to improper electrode connections or environmental interference. Excess Synchrony can reduce the accuracy of background EEG metrics.

Manually Modified Artifacting (★): Shown next to titles of sessions in which at least one input file has manually modified artifacting, or next to a computed metric when the original data file has manually modified artifacting.

9.3. Physical Reaction Time

Availability: All reports.

The average time of the physical response to P300 rare tones, derived from mouse or keyboard input. This measure is different from the P300 latency (delay) measure of brain speed. Reported as "N/A" if there were less than 15 physical responses to the rare tones. On the Scan Clinician report this value is displayed as a simple number, while on the Scan Patient report it is displayed in a dial.

9.4. Audio P300 Delay & Voltage/Brain Reaction Time & Voltage

Availability: All reports (with different naming).

The WAVi P300 protocol generates event-related EEG responses which are time-locked to the audio presentation of high tones and low tones on a random basis. High (rare) tones are presented less often than the low (common) tones. The 4-minute protocol administers approximately 200 common and 40 rare tones.

Although the P300 is a positive voltage change occurring approximately 300 milliseconds after the rare tone is delivered, by convention it is displayed in an inverted form as a downward moving voltage (Figure 9-1). On reports we show the amplitude in microvolts (μV) and shortest latency in milliseconds (ms) from the six central-parietal channels (CZ, C3, C4, PZ, P3, and P4) alongside age-matched values into which 66% of participants are expected to fall. Typically, P300 latencies fall between 250-400 milliseconds.

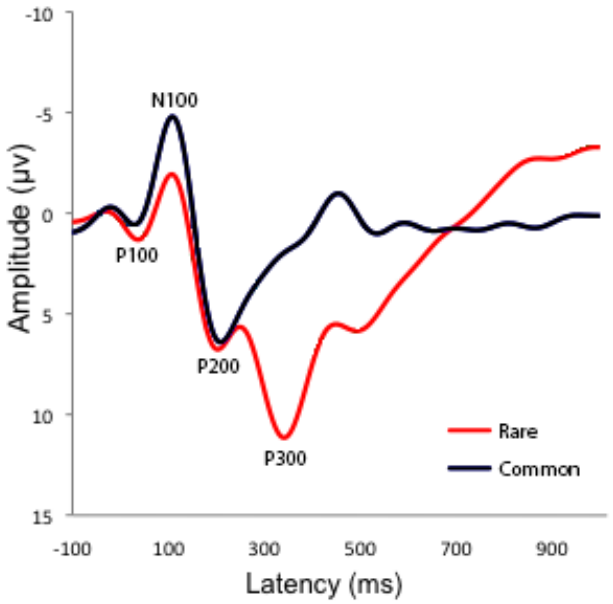

Figure 9-1.

An increase in latency and/or a decrease in amplitude has been observed in various conditions associated with reduced cognitive function. Some clinicians use this non-specific P300 measurement to investigate interventions that increase amplitude and/or decrease latency. Others use P300 as a basis for tracking participant progress. In the absence of a strong P300, longer latencies may be reported and it is suggested that in these cases the P300 waveforms be reviewed (see section 9.12), along with literature associating long latencies with various conditions.

The Audio P300 Delay (or Brain Reaction Time) metric is the fastest Central-Parietal (C-P) latency between 240-499 ms after a rare tone, among locations that are at least 3 µV. It is reported as "N/A" if no C-P location is at least 3 µV, or no C-P location has a yield of at least 20 rare events. This metric is derived from C-P locations with sufficient yield, where "yield" is defined as the number of brain responses to rare tones which contain minimal artifact. On the Scan Clinician report this value is displayed on the first page as a simple number, while on the Scan Patient report it is displayed in a dial.

The Audio P300 Voltage (or Brain Reaction Voltage) metric is the largest C-P amplitude between 240-499 ms after a rare tone. It is reported as "N/A" if no C-P location has a yield of at least 20 rare events, and is reported as "< 0 µV" if the voltage at all C-P locations is less than 0 µV. The "Low Yield" qualifier is shown if:

- Less than 3 C-P locations have a yield of at least 30; OR
- 40% or more data segments contain excessive Delta artifact at the location from which the metric was derived.

On the Scan Clinician report this value is displayed on the first page as a simple number, while on the Scan Patient report it is displayed in a dial.

The target ranges for P300 metrics are taken from Oakley, D. S. et al. (2021). P300 Parameters Over the Lifespan: Validating Target Ranges on an In-Clinic Platform; doi: https://doi.org/10.1101/2021.10.25.465715.

9.5. Peak Frequency (7.0–13.0 Hz)

Availability: Scan Clinician.

This metric is the average of Alpha peak frequency at locations in the frontal, central-parietal, and occipital regions, derived from the P300 EC 4 Min protocol. The target ranges are from Joffe D., Oakley D., Arese Lucini F., Palermo F. (2021). Measurements of EEG Alpha Peak Frequencies Over the Lifespan: Validating Target Ranges on an In-Clinic Platform; doi: https://doi.org/10.1101/2021.10.06.463353.

9.6. CZ Eyes Open Theta/Beta (Power)

Availability: Scan Clinician.

This metric is the participant's average Theta/Beta power ratio at CZ, derived from the Baseline EO 4 Min protocol.

9.7. CZ Eyes Closed Theta/Beta (Power)

Availability: Scan Clinician.

This metric is the participant's average Theta/Beta power ratio at CZ, derived from the P300 EC 4 Min protocol.

9.8. Theta/Beta Ratio

Availability: Scan Patient.

This metric is the participant's average Theta/Beta power ratio at CZ, derived from the P300 EC 4 Min protocol.

9.9. F3/F4 Eyes Closed Alpha Power

Availability: Scan Clinician.

This metric is the average frontal Alpha power ratio between F3 and F4, derived from the P300 EC 4 Min protocol.

9.10. Frontal Alpha Symmetry

Availability: Scan Patient.

This metric is the average frontal Alpha power ratio between F3 and F4, derived from the P300 EC 4 Min protocol.

9.11. P300 Voltage Map/Brain Reaction Voltage Map

Availability: All reports (with different naming).

Shows the distribution of P300 reaction voltages across the head in a topographic (topo) format. These topos are shown on the first page of every report. The P300 topos are interpolated visual representations of the P300 voltage measured at each of the 19 active EEG electrode locations during the P300 protocol. Note: if any black x's are present in the topos, this is an indication of low yield at the corresponding electrode locations. Low yield may result from artifact and/or improper electrode contact.

9.12. Evoked Waveforms Page

Availability: Scan Clinician only (standard).

This page shows graphs of the average responses to the P300 audio stimulus at each location in the standard 10-20 EEG layout, along with graphs for Central-Parietal P300 average, F3-FZ-F4 P300 average, and Central-Frontal N100 average. If only one session is included, each graph compares responses to

the common tones versus the rare tones at that location. If comparing multiple sessions, each graph compares responses to only the rare tones at that location across the sessions.

Waveforms are plotted as voltage (positive down) versus time after stimulus. The negative (upward) peak near 100 ms is the N100, and the positive (downward) peak for the rare tone near 300 ms (dashed lines) is the P300. At each location the number of accepted rare tones (out of 40) are shown, followed by the P300 depth (µV) and latency (ms) at that location.

9.13. P300 Eyes Closed Spectrums Page

Availability: Scan Clinician only (standard).

This page displays magnitude spectra (magnitude versus frequency) for each electrode location. The number below the x-axis represents the frequency with the highest magnitude in Hz (in the 7-13 Hz range), typically Alpha. The current scale and values of the vertical tick marks are indicated by the legend in the top-right corner. Note that if there is no clear Alpha peak, then the P300 metrics on the first page of the report will be accompanied by the Questionable Value symbol (**?**).

9.14. Physical State

Availability: Scan Patient only.

This section includes various answers taken from the Scan Patient Intake form in the previous and followup sessions, if available.

9.15. How to Optimize Your Cognitive Performance

Availability: Scan Patient only.

This section includes optional text provided in the "Recommendations for Client" fields under the Basic Options (see section 9.18.4).

9.16. Protocol Comments

Availability: Scan Clinician only (standard).

If any protocols have comments, these will be automatically included on the report. All raw wave and general comments are included, and may span multiple pages if necessary. Comment pages are included in the same chronological order as their associated protocols were recorded. Comments can provide valuable context for interpreting reported values, and if present should be carefully reviewed and not ignored. For more details on protocol comments, see section 5.

9.17. Appendix Page

Availability: Scan Clinician only (standard).

Always the last page of the report, this page provides a quick reference explaining the metrics, qualifier symbols, terminology, and thresholds for various calculations used on the report. It is important that users carefully read and understand all of the information explained on the Appendix page before interpreting reported results. It is also recommended to always include the Appendix page when sharing the report with the participant or other clinicians.

9.18. Basic Options

Following is a list of all the available "Basic" options which can be used to customize a report. These provide quick access to the most commonly-used fields and settings which are appropriate for typical users.

9.18.1. Anonymize Personal Details

Availability: All reports.

This option allows you to choose whether to omit a subject's name and any other identifying details from the final report. This can be useful if the report will be shared with 3rd parties. Note: this option only applies to standard report elements like the headers on each page. It does not apply to free-form text entered in protocol comments, clinician comments, recommendation fields, or on intake or assessment forms.

9.18.2. Assessment Scores and Responses

Availability: Scan Clinician only.

These buttons allow you choose whether to include optional pages of assessment scores and responses. Most of these correspond to the same categories in the Scan Assessments form. For more details, see section 10.

9.18.3. Clinician Comments

Availability: Scan Clinician only.

This box allows you to enter free-form text that will appear on its own dedicated page. This is useful if you wish to make general observations about a subject, their test results, etc. This text shares a page with the Suggested Followup field (see 9.18.7).

9.18.4. Recommendations for Client

Availability: Scan Patient only.

These optional text fields allow you to enter short recommendations for your client to follow before their next WAVi evaluation. For each field that you choose to fill in, its text will appear on the last page of the Scan Patient report under the section titled "How to Optimize Your Cognitive Performance." If a field is not filled in, its corresponding line on the report will say "No recommendations." For more details, see section 9.15.

9.18.5. Referring Physician

Availability: Scan Patient only.

This box allows you to enter the name of the professional who is ordering the report and making recommendations. This text appears on the first page of the Scan Patient report, or as "N/A" if not provided.

9.18.6. Spectrum Scale

Availability: Scan Clinician only.

This controls the vertical scale factor used on the standard P300 Eyes Closed Spectrums page. You may sometimes need to adjust the default value here, especially if a subject is a strong Alpha producer.

9.18.7. Suggested Followup

Availability: All reports.

This field allows you to enter an approximate followup date when the subject should return for their next WAVi evaluation. On the Scan Clinician report, this field shares an optional page with Clinician Comments (see 9.18.3). On the Scan Patient report, this field is shown in its own section on the last standard page.

9.19. Advanced Options

Following is a list of all the available "Advanced" options which can be used to customize a report. These include fields and settings which are intended for more advanced users, or which are used less often than the Basic Options.

9.19.1. P300 Options

Availability: All reports.

This section contains options for customizing the P300-related graphs and topos. These include the following:

- **P300 Display Threshold:** This specifies the minimum number of "clean" responses to the rare audio tone that must be available for a given electrode location in order to generate a P300

waveform graph for that location. The number of "clean" responses is affected by the amount of artifact in the P300 protocol data. For example, if the threshold is set to 20 but a given location only had 15 clean responses, then that location will be marked as "N/A" and will not have a waveform graph. This is done to prevent the display of large distorted waveforms caused by low yield, which could overlap with the waveforms displayed at adjacent locations. You can adjust this threshold to include more or fewer locations in the P300 graphs, depending on how stringent you want to be. The minimum is 10, the maximum is 40, and the default is 20.

- **Session which sets topo scale:** This allows you to choose the session to which the P300 topo color scale should be referenced. This can be either the first or last session (last is the default). If you are comparing multiple sessions, and the dynamic ranges of the P300 topos (i.e., the difference between their minimum and maximum μV values) are very different, one or more of the topos may appear "washed out" or even as a solid block of color. In these situations, changing this option between First and Last may help to reveal more topo details. However, if the dynamic ranges of the first and last session topos do not have any overlap, it may still not be possible to reveal details in both topos simultaneously.

9.19.2. Optional Coherence Pages

Availability: Scan Clinician only.

This section contains options allowing you to add pages of coherence graphs derived from various types of protocols. Coherence is a measure of the correlation between two EEG locations as a function of frequency and provides information relating to the functional connectivity between cortical regions. Coherence values are represented with colors ranging from deep blue (0% coherence) to deep red (100% coherence). When comparing multiple sessions, the top row of graphs displays standard coherence in Session 1, while line colors for sessions subsequent to Session 1 represent the percent change from Session 1.

Options for Coherence pages include the following:

- **P300 Eyes Closed:** Coherence graphs derived from the P300 EC 4 Min protocol.
- **Eyes Closed Resting:** Coherence graphs derived from the Baseline EC 4 Min protocol.
- **Eyes Open Focused:** Coherence graphs derived from the Baseline EO 4 Min protocol.
- **Eyes Open Focused During Flanker:** Coherence graphs derived from the Flanker EO 4 Min protocol.
- **Coherence Threshold:** Only those coherence values greater than or equal to this value will be drawn as colored lines between locations. You can adjust this value to increase or decrease the number of lines shown in the coherence graphs for Session 1.
- **Coherence Percent Change Threshold:** Only those coherence values whose percent change from baseline is greater than or equal to this value will be drawn as colored lines between locations. If comparing multiple sessions, you can adjust this value to increase or decrease the number of lines shown in the coherence graphs for sessions after Session 1.

- **Coherence Comparison Mode:** When comparing each subsequent session to the first session, either one or both coherences must be above the coherence threshold. The default is "Both." Selecting "Both" usually results in less cluttered graphs.

9.19.3. Optional Table Pages

Availability: Scan Clinician only.

This group of options allows you to add pages of numerical tables derived from various types of protocols. Two types of tables are currently generated:

- Magnitude Band Tables, which list the total peak-peak microvolts within each frequency band at each EEG electrode location. If comparing more than one session, the values for subsequent sessions are color-coded according to their percent difference from the first session.
- Coherence Band Tables, which list the coherences within each frequency band between every possible pair of EEG electrodes. If comparing more than one session, the values for subsequent sessions are color-coded according to their percent difference from the first session.

These tables provide quantitative data for further analysis. If you select any of the options below, both Magnitude and Coherence Band Tables for that protocol type will be generated:

- **P300 Eyes Closed:** Tables derived from the P300 EC 4 Min protocol.
- **Eyes Closed Resting:** Tables derived from the Baseline EC 4 Min protocol.
- **Eyes Open Focused:** Tables derived from the Baseline EO 4 Min protocol.
- **Eyes Open Focused During Flanker:** Tables derived from the Flanker EO 4 Min protocol.

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10. Assessment Scores and Responses

The WAVi Scan system includes electronic versions of standardized clinical assessment tools related to psychiatry and neuropsychological evaluation, which are provided for convenience and are to be used in accordance with the assessment tools' specific instructions. These tools do not interact with any other of the EEG system's hardware or software measures and are stand alone.

10.1. Performance Assessments

10.1.1. Trail Making

Trail Making Tests A and B engage cognitive resources involving visual processing, memory, motor function, spelling, and counting. The Trail Making tests can also provide information relating to visual search speed, scanning, speed of processing, mental flexibility, and executive functioning. Details of test administration are given in sections 3.2.1 and 3.2.2.

10.1.2. Flanker

The Eriksen Flanker task (here referred to simply as "Flanker") is a measure of information processing and selective attention that assesses the ability to suppress inappropriate responses. Here the target is flanked by non-target stimuli which correspond either to the same directional response as the target (congruent flankers), to the opposite response (incongruent flankers), or to neither (neutral flankers). When subjects participate in the Flanker task, the anterior cingulate cortex is activated and is observed to be more active in response to processing incongruent stimuli than congruent stimuli.

Details of Flanker task administration are given in section 3.1.2. The task is scored as a simple comparison of response times between congruent, incongruent, and neutral presentations.

10.2. Concussion Assessments

10.2.1. Sport Concussion Assessment Tool, 5th Edition (SCAT5)

The SCAT5 is a standardized tool for evaluating concussions designed for use by physicians and licensed healthcare professionals. Detailed instructions for use of the SCAT5 can be found at https://bjsm.bmj.com/content/bjsports/early/2017/04/26/bjsports-2017-097506SCAT5.full.pdf ; page 7.

10.3. Aging and Wellness Assessments

10.3.1. Mini Mental State Examination (MMSE)

The MMSE is an instrument for screening cognitive function, commonly used to indicate the presence of cognitive impairment in a person with suspected dementia or following a head injury. Before administering the MMSE, it is important to make the participant comfortable. The table below explains the scoring criteria.

Score	Degree of Impairment	Formal Psychometric Assessment	Day-to-Day Functioning
25-30	Questionably significant	If clinical signs of cognitive impairment are present, formal assessment of cognition may be valuable.	May have clinically significant but mild deficits. Likely to affect only most demanding activities of daily living.
20-25	Mild	Formal assessment may be helpful to better determine pattern and extent of deficits.	Significant effect. May require some supervision, support and assistance.
10-20	Moderate	Formal assessment may be helpful if there are specific clinical indications.	Clear impairment. May require 24-hour supervision.
0-10	Severe	Patient not likely to be testable.	Marked impairment. Likely to require 24-hr supervision and assistance with ADL.

Detailed instructions for use of the MMSE can be found at https://www.psychdb.com/cognitive-testing/mmse.

10.3.2. Montreal Cognitive Assessment (MoCA)

The Montreal Cognitive Assessment (MoCA) is intended to be a means of detecting levels of cognitive impairment. The assessments in the test attempt to gauge areas of language, visuospatial abilities, memory and recall, and abstract thinking, to give a representation of a person's current cognitive ability. There are 11 sections of the assessment, with a total of 30 possible points. The total possible score is 30, with any score higher than 25 considered normal. Any score of 25 or less is considered to be an indication of some form of cognitive impairment, which can predict or identify the onset of dementia in patients.

In order to include MoCA results in the WAVi report, the patient should take the paper version of the test (included or downloaded from https://www.parkinsons.va.gov/resources/MOCA-Test-English.pdf) with the scores entered into the assessment page. Note that each [ ] on the sheet is worth one point.

10.3.3. Geriatric Depression Score (GDS)

This is a screening test for depression symptoms in the elderly. The GDS is used for evaluating the clinical severity of depression and monitoring treatment. It is easy to administer, needs no prior psychiatric knowledge, and has been well validated in many clinical environments. A score of 0-5 is normal while a score greater than 5 suggests depression.

10.3.4. Modified Hoehn and Yahr Scale

The Hoehn and Yahr scale is a commonly used system for describing how the symptoms of Parkinson's disease progress. A modified Hoehn and Yahr scale includes the addition of stages 1.5 and 2.5 to help describe the intermediate course of the disease. It has been shown that HY stage discrimination can be automated, even with patients who cannot support themselves.

The modified Hoehn and Yahr staging is as follows:

- STAGE 0 = No signs of disease.
- STAGE 1 = Unilateral disease.
- STAGE 1.5 = Unilateral plus axial involvement.
- STAGE 2 = Bilateral disease, without impairment of balance.
- STAGE 2.5 = Mild bilateral disease, with recovery on pull test.
- STAGE 3 = Mild to moderate bilateral disease; some postural instability; physically independent.
- STAGE 4 = Severe disability; still able to walk or stand unassisted.
- STAGE 5 = Wheelchair bound or bedridden unless aided.

10.4. Behavior and Mood Assessments

10.4.1. Hamilton Anxiety Rating Scale (HAM-A)

The HAM-A is a common assessment of the severity of symptoms of anxiety in adults, adolescents, and children. Each item is scored on a scale of 0 (not present) to 4 (very severe), with a total score range of 0-56, where <17 indicates mild severity, 18-24 mild to moderate severity, and 25-30 indicates moderate to severe. The scale consists of 14 items, each defined by a series of symptoms, and measures both psychic anxiety (mental agitation and psychological distress) and somatic anxiety (physical complaints related to anxiety).

10.4.2. Patient Health Questionnaire-9 (PHQ-9)

The PHQ-9 is a multipurpose instrument for screening, diagnosing, monitoring and measuring the severity of depression. The PHQ-9 incorporates DSM-IV depression diagnostic criteria with other leading major depressive symptoms into a brief self-report tool. To make a tentative depression diag-

nosis, the clinician should rule out physical causes of depression, normal bereavement and a history of manic/hypomanic episodes. A depression diagnosis that warrants treatment, or a treatment change, requires that at least one of the first two questions be answered as positive ("more than half the days" or "nearly every day") in the past two weeks. In addition, the tenth question, about difficulty at work or home or getting along with others, should be answered at least "somewhat difficult." The recommendations in the table below based on the PHQ-9 test must be made by a licensed health care practitioner.

PHQ-9 Score	Provisional Diagnosis	Recommendation
5-9	Minimal Symptoms	Support, return in 1 month
10-14	Minor Depression Dysthymia, Major Depression, mild	Support, watchful waiting, antidepressant or psychotherapy
15-19	Major Depression, moderately severe	Antidepressant or psychotherapy
>20	Major Depression, severe	Antidepressant or psychotherapy

10.4.3. Adult ADHD Self-Report (ASRS-v1.1) Symptom Checklist

The ASRS is an assessment consisting of eighteen DSM-IV-TR criteria. Ask the participant to complete both Part A and Part B of the Symptom Checklist by selecting the boxes that most closely represent the frequency of occurrence of each of the symptoms. If a score of 4 or more is shown for Part A, then the participant has symptoms highly consistent with ADHD in adults and further investigation is warranted. It has been found that the six questions in Part A are the most predictive of the disorder and are often used as a screening instrument. The frequency scores on Part B provide additional cues and can serve as further probes into the participant's symptoms.

10.4.4. Child ADHD Symptom Checklist (DSM-5)

This checklist is derived from DSM-5 criteria and is best filled out by a parent or guardian. Scores of 5 or less are considered normal.

10.4.5. Bipolar Spectrum Diagnostic Scale (BSDS)

The Bipolar Spectrum Diagnostic Scale (BSDS) is a psychiatric screening rating scale for bipolar disorder. The scale was validated in its original version and demonstrated high diagnostic sensitivity, meaning that most people with confirmed bipolar diagnoses scored high on the BSDS. In a systematic review and meta-analysis looking at the accuracy of self-report scales for detecting bipolar disorders, the BSDS was one of the best performing options where scores of 6 or less are considered normal.

11. Profile Management

So far we have discussed how to set up the WAVi Scan system, create a participant profile, start a new session, acquire and review data, and finally generate and interpret a report. Along the way, you have seen portions of the software related to performing these tasks as part of a typical workflow. In this section, we explain in more detail the interfaces and tools which are available to help you manage and organize all of the participant data stored in your WAVi system.

11.1. Profile View

Upon opening a new or existing profile, you will see the **Profile View** interface (Figure 11-1). This is the starting point for managing all data associated with one individual participant.

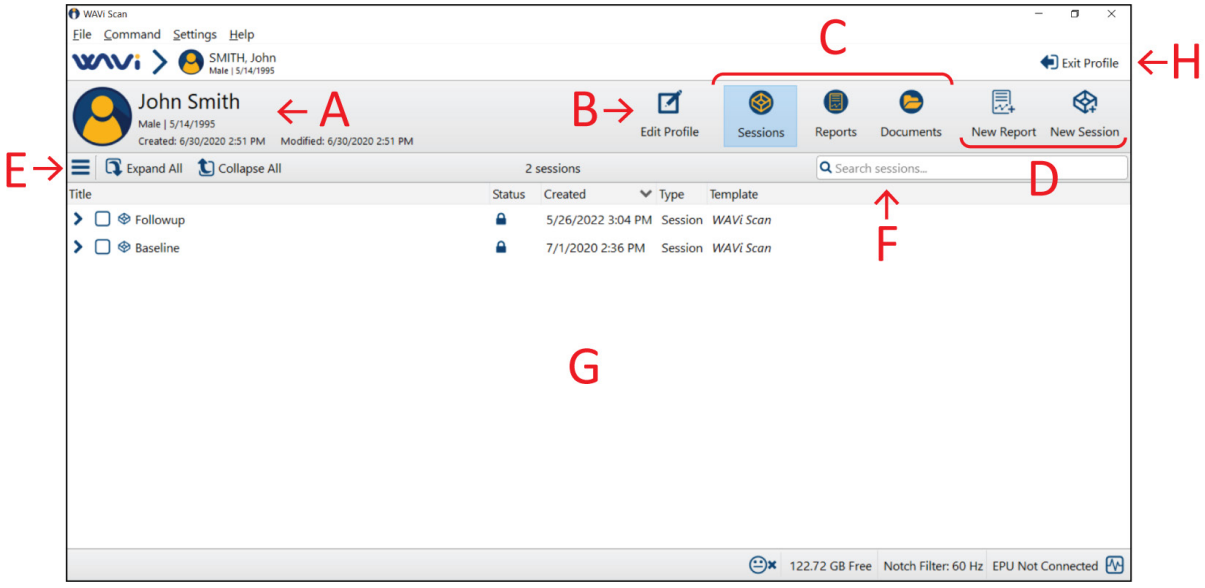

Figure 11-1.

Following is a brief summary of the Profile View interface (indicated by red letters in the figure):

A. Participant's name, gender, birthdate, record ID (if provided), timestamps for when the profile was created and last modified, and optionally a photo.

B. Button to edit the aforementioned personal details of the participant.

C. Tabs for Sessions, Reports, and Documents, with the active tab highlighted.

D. Buttons to create new reports and sessions.

E. Menu button and view actions (context-dependent).

F. Search box (context-dependent).

G. Item list pane (context-dependent).

H. Button to exit profile and return to Profile List view.

11.2. Managing Sessions

When a profile is opened, the **Sessions** tab is activated by default. This shows all of the sessions that have been created for the participant, along with basic details about each session such as when it was created, its lock status (useful if you had to temporarily exit a session in progress), and the template from which the session was created. To open a session for review, double-click its title.

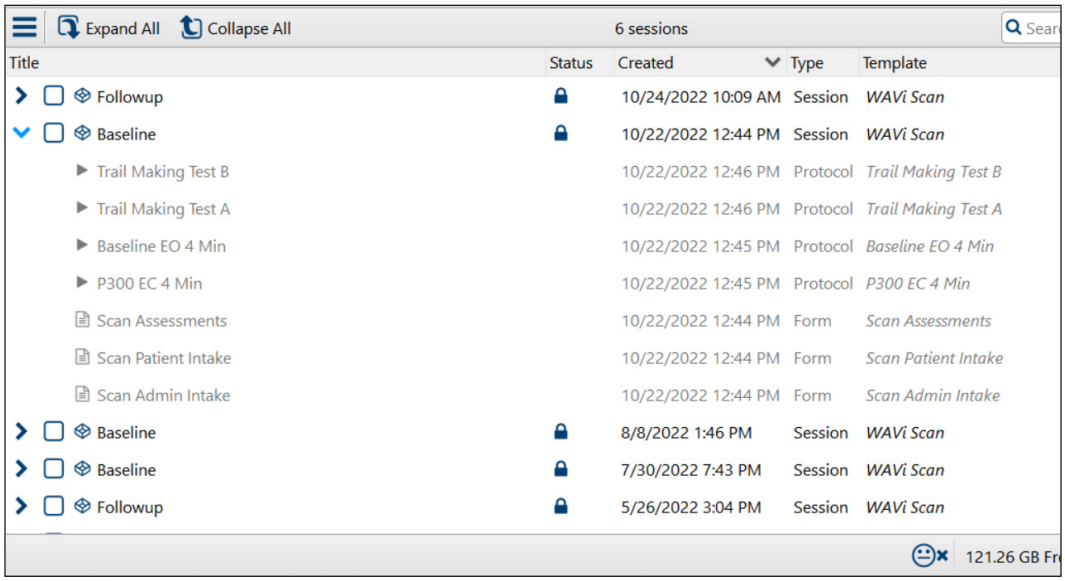

Figure 11-2.

If you just want to see a preview of which items were touched in a session, without actually opening it, you can press the arrow button to the left of the session title (Figure 11-2). Items contained in that session are shown in light gray. (Note that their displayed order depends on the current sort mode of the session list, which may be different from the actual order of those items in the queue for that session.) To close the preview, press the arrow button again. The **Expand All** and **Collapse All** buttons do the same, but for all of the sessions in the session list.

To delete one or more sessions, first select them either using the mouse, or by marking the checkboxes next to the sessions in question. Then either right-click the selected items, or use the Menu button (top-left corner) to choose the **Delete** option. A warning message will ask you to confirm your choice (Figure 11-3). Be careful not to delete sessions with valid data, as this action cannot be undone.

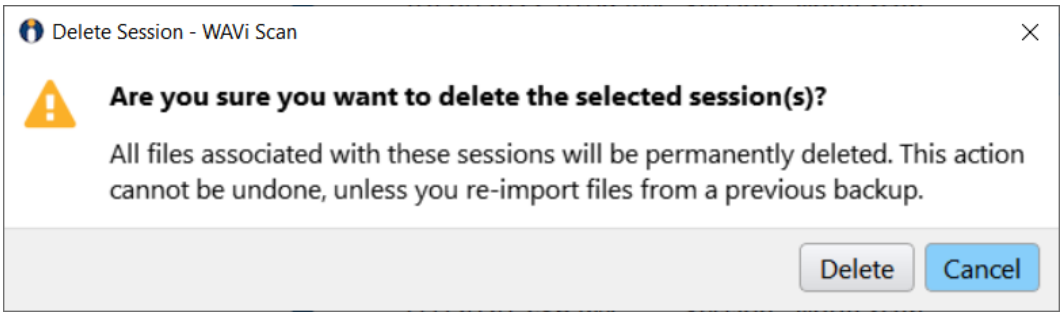

Figure 11-3.

11.3. Managing Reports

Press the **Reports** button to switch to the Reports tab. This view shows all of the reports that have been generated for the participant (Figure 11-4). To open a report, double-click its title.

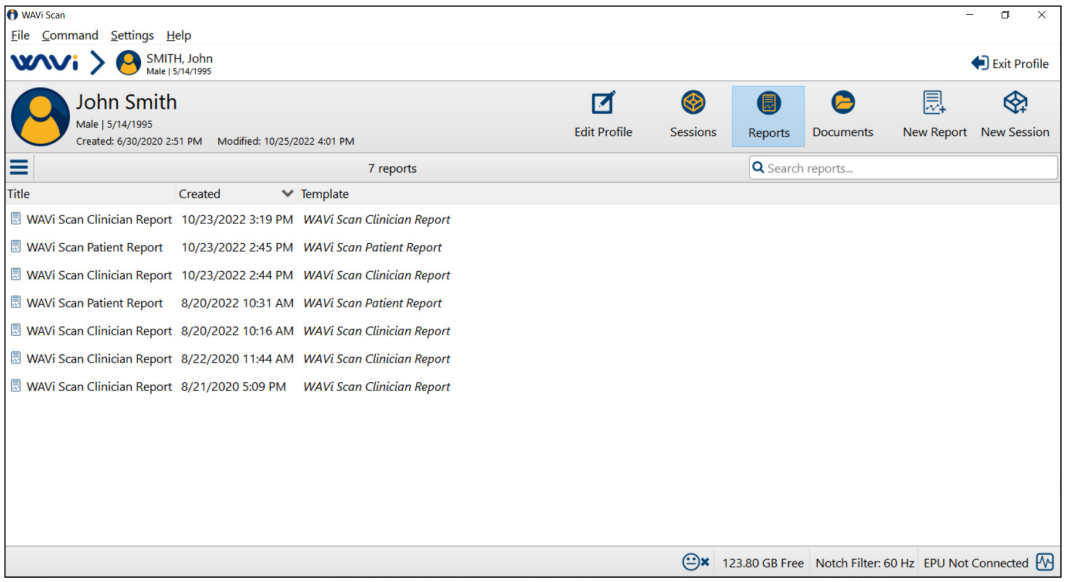

Figure 11-4.

If you need to delete one or more reports, the procedure is the same as before—first select the items, then choose the Delete action and confirm your choice in the popup warning message. Again, be careful not to delete valid items.

11.4. Managing Documents

Press the **Documents** button to switch to the Documents tab. This is where other miscellaneous documents, including consent forms, are stored (Figure 11-5). To open a document, double-click its title.

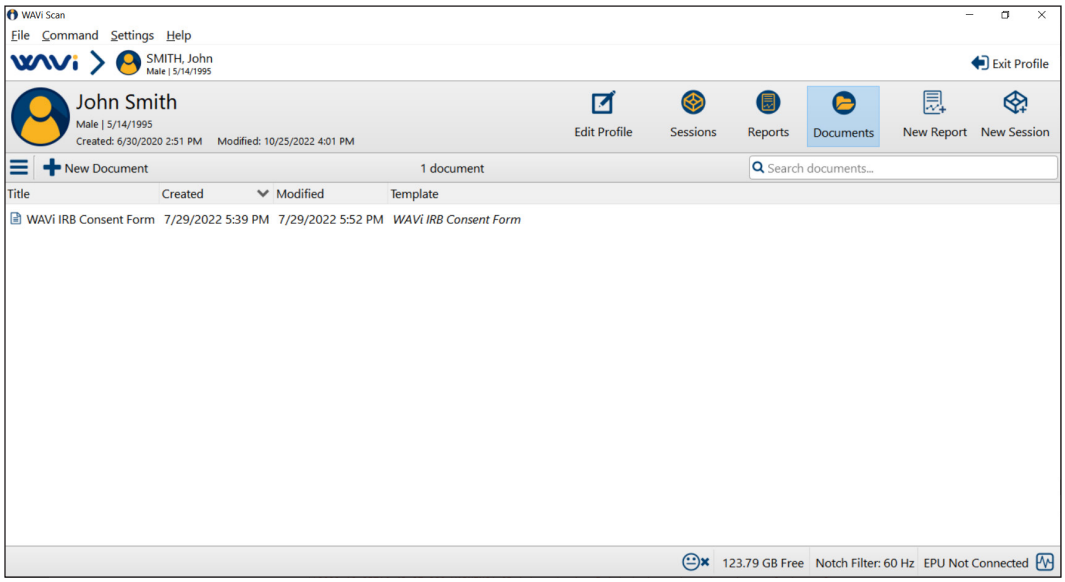

Figure 11-5.

If the participant has not yet completed a consent form, you can add one now by pressing the **New Document** button and selecting the appropriate form in the template dialog window (Figure 11-6). For more details on the consent form, please refer back to section 1.3.1.

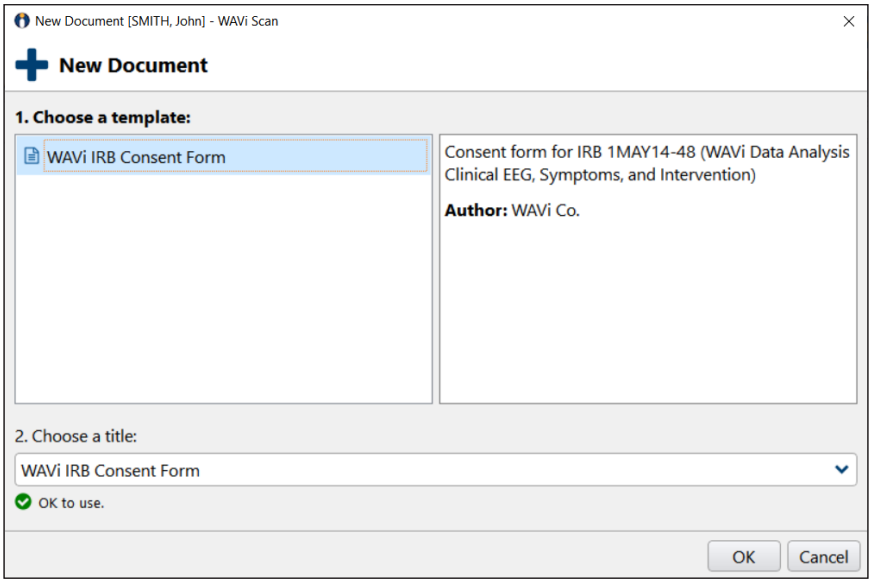

Figure 11-6.

Documents may be deleted if necessary using the same procedure as for sessions and reports.

11.5. Editing Profile Details

Sometimes you may need to update the details in a participant's profile. This can be done at any time by pressing the **Edit Profile** button to the right of the participant's name. This will reopen the same profile editor view that you used to originally create the profile (Figure 11-7).

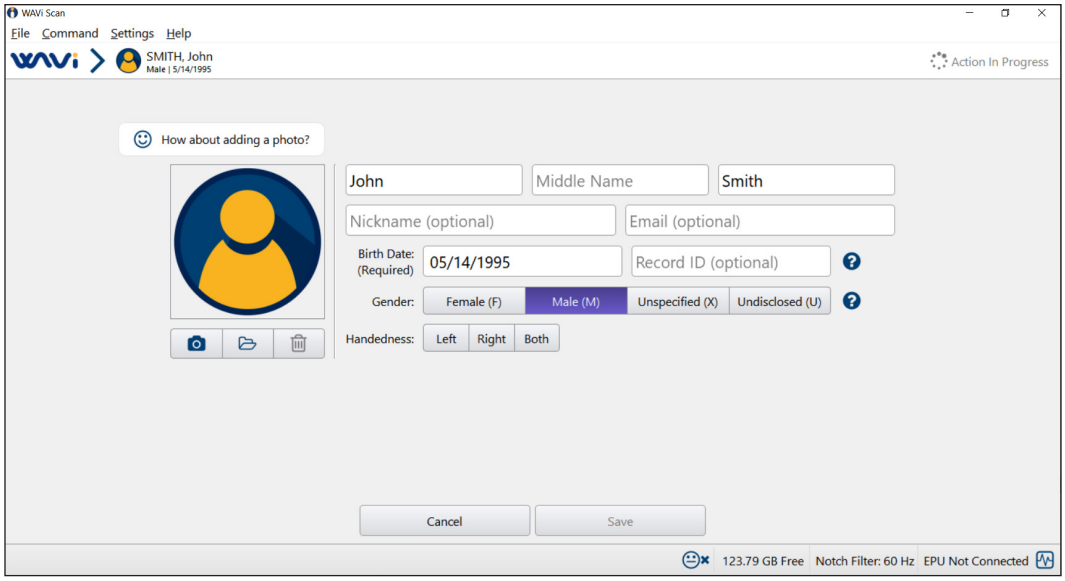

Figure 11-7.

As noted back in section 1.3.1, most of the fields here are optional, with the exception of the birthdate. However it is recommended to fill in as many of these fields as possible, both to ensure the accuracy and personalization of reports, and to enable future data analysis based on anonymized demographics.

If you would like to add a photo for the participant, you can do so by pressing the camera button located under the generic person icon. A popup window will appear showing a live camera preview (Figure 11-8). (Note: if the laptop has more than one built-in camera, or if you are using an external camera, you may need to select the correct one using the dropdown menu at the top of the window.)

Figure 11-8.

Make sure the participant's face is lined up inside the white square, then press the camera icon once to take a photo. To go back to the live preview, press the camera icon again.

When the participant is happy with their photo, click OK to save it to the profile. You can always delete a photo by using the trash can button. Alternatively, if you already have a photo file you wish to use, you can browse for it on your computer by pressing the folder button.

Note that photos are for personalization only and are entirely optional.

11.6. Profile List View

After exiting a profile, you are brought back to the **Profile List** view (Figure 11-9). This is the highest level at which you can perform various administrative tasks involving multiple profiles.

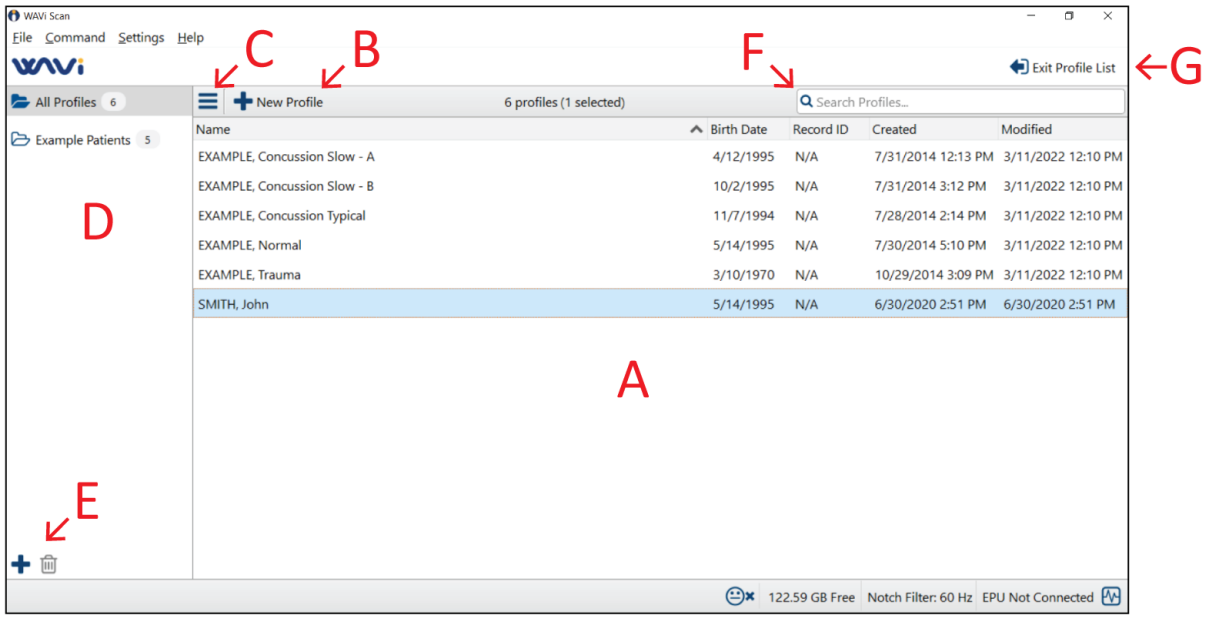

Figure 11-9.

Following is a brief summary of the Profile List interface (indicated by red letters in the figure):

A. Profile list pane.
B. Button to create a new profile.
C. Menu button.
D. Groups pane.
E. Buttons to add and delete groups.
F. Search box.
G. Button to exit the Profile List and return to the Welcome Screen (if enabled).

The following subsections will focus on the various tools and features available in this view.

11.7. Importing Profiles

To import profiles that were previously exported or archived, press the Menu button and choose **Import** (Figure 11-10). Note that this option is only enabled if you are currently viewing the default "All Profiles" group; for more details, see section 11.12.

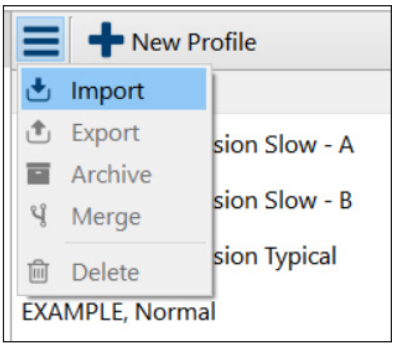

Figure 11-10.

The **Profile Import Wizard** window will appear as shown in Figure 11-11. Initially it will ask you to either browse for or type the folder search path containing the profiles to import. **Make sure to select the parent folder which contains all of the profiles you wish to import; do not select the child folders corresponding to the individual profiles.**

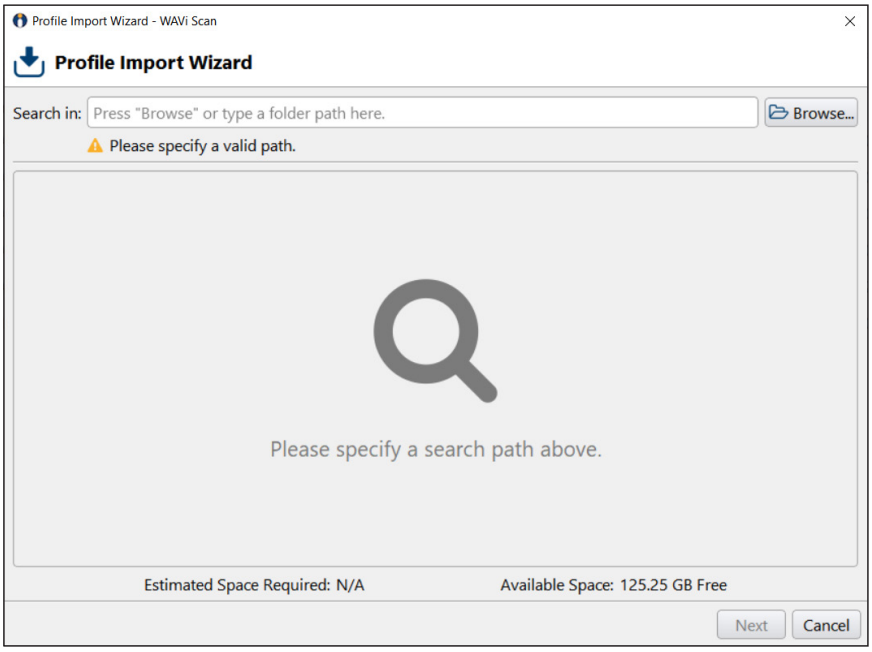

Figure 11-11.

If you have provided a valid search path, the wizard will proceed to automatically find profiles which can be imported, and after a few moments should display them in a list (Figure 11-12). If no profiles are found, or if you are seeing the wrong profiles, check that you have entered the correct search path and try again.

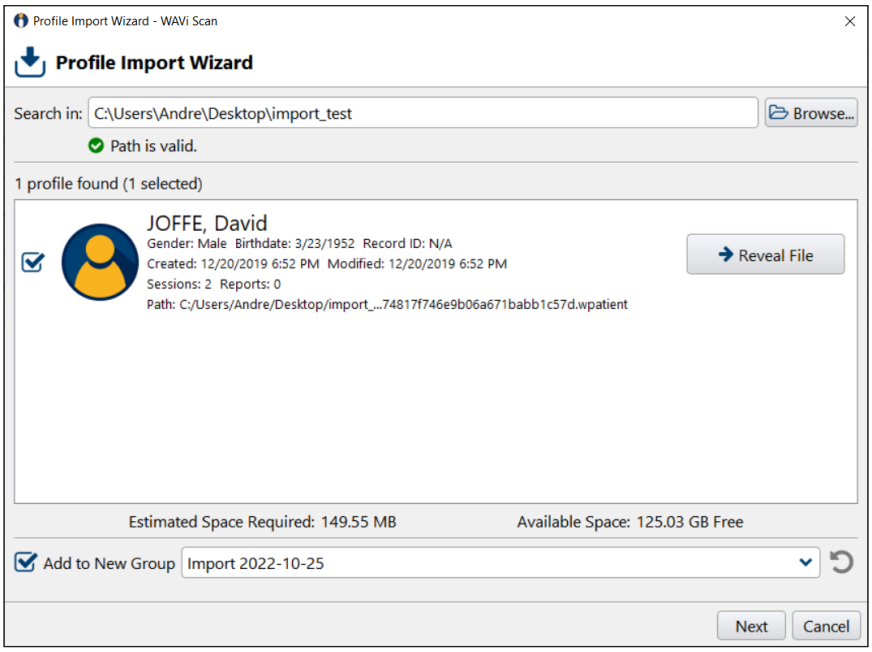

Figure 11-12.

At this point you should take a moment to verify that the profiles found by the wizard are indeed the ones you wish to import. Relevant details of the profiles are summarized, including how many sessions and reports each one contains. If you want to see the location in your file system where a particular profile was found, you can press the **Reveal File** button to open an external file browser window to that location.

To the left of each profile item, there is a checkbox to indicate whether that particular profile should be included in the import. All results are automatically selected by default, but if you want to exclude one or more profiles from the import, you can uncheck their boxes.

Below the list pane are labels to indicate the estimated space required for the selected profiles if you choose to proceed with the import, and the currently available space on the storage volume hosting the WAVi Scan application.

Finally, at the bottom of the window you have the option to automatically add the imported profiles to a new group. A suggested default group name is automatically generated based on today's date, but you can change this to whatever you prefer. If you do not want a new group to be created for this import, you can uncheck the "Add to New Group" option. For more details on profile groups, see section 11.12.

When you are satisfied with your selections, press the **Next** button to start the import process. The original source files are not moved or modified. Note: if you re-import a profile which already exists in your WAVi Scan environment (i.e. the internal system IDs of the profiles are identical), the old and new copies will be automatically merged, preserving the newest files from each. This process happens transparently without notice, so make sure this is what you want before starting the import.

Depending on the number of profiles being imported and the amount of data they contain, the import process may take some time to complete (Figure 11-13). When the wizard has finished, a summary page will explain what was done and what new group, if any, the profiles were added to (Figure 11-14). Press the **Close** button to exit the wizard and return to the Profile List view.

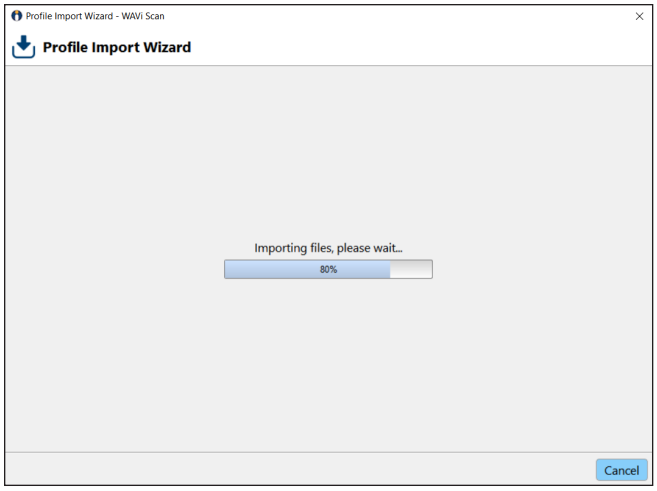

Figure 11-13.

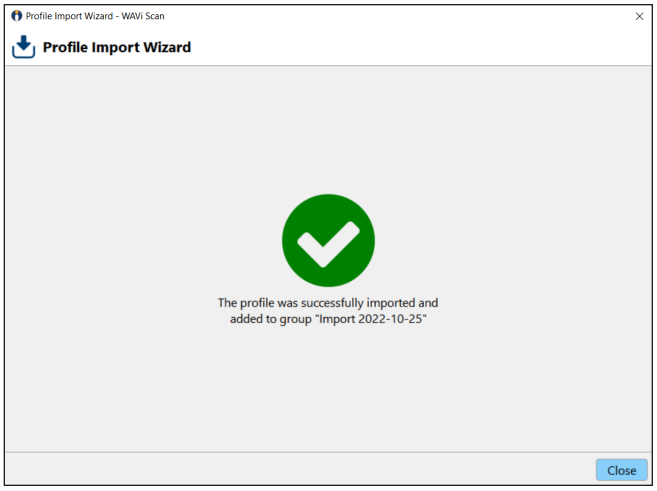

Figure 11-14.

11.8. Exporting Profiles

Sometimes you may need to export one or more profiles and their contents, either for backup purposes or to move them to another computer. Exporting only creates an external copy of a profile and its data; the original is not moved and remains unchanged inside WAVi Scan. To get started, first select the profiles you want to export, then press the Menu button and choose **Export** (Figure 11-15).

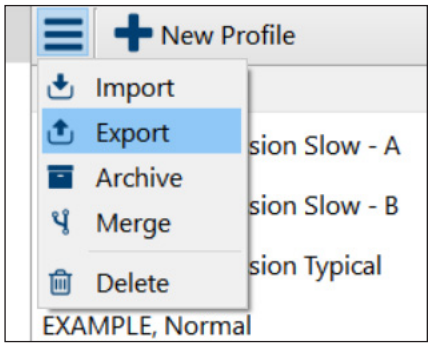

Figure 11-15.

The **Export Profiles Wizard** window will appear as shown in Figure 11-16. The first page of the wizard briefly explains what will happen during the subsequent steps. When you are ready to advance, press the **Next** button.

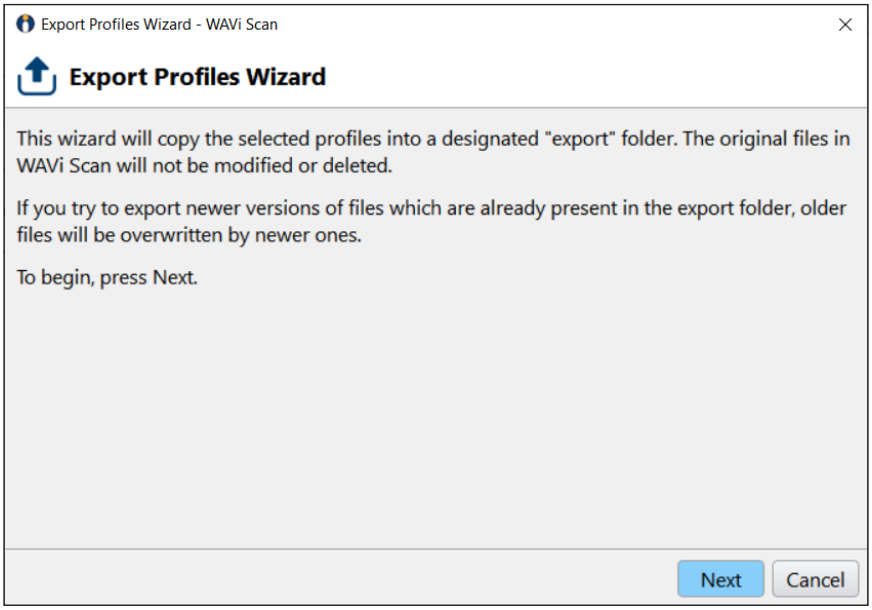

Figure 11-16.

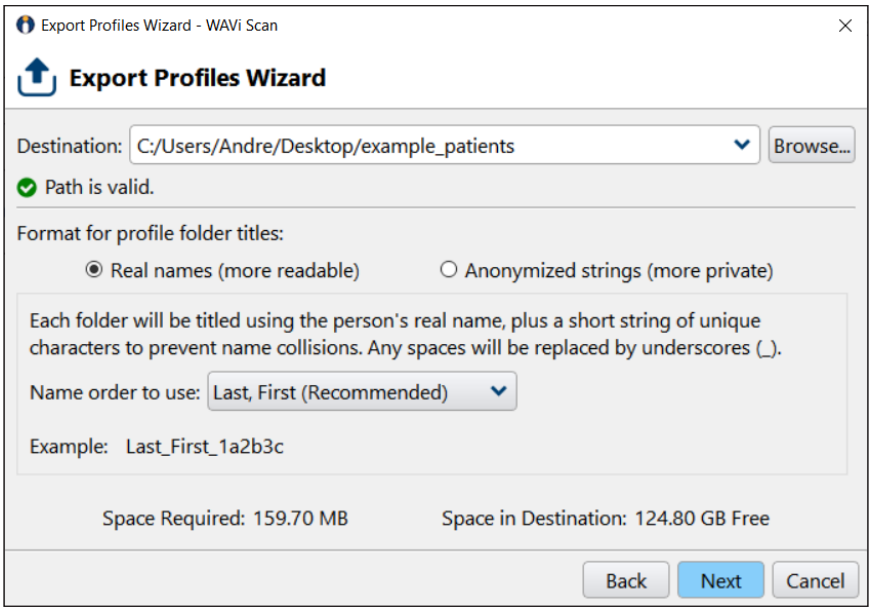

Figure 11-17.

Figure 11-17 shows the step where you can configure settings for the export. The first thing to do is to choose the destination path where the files will be exported. You can either press the **Browse** button and navigate to a folder, or type it in manually if you prefer. This destination path can point to a location in onboard storage, or it may be located on a removable storage device such as an external hard drive or flash drive, but in any case it must already exist in the file system and be accessible while the export wizard is open. If you have used this wizard before, the last used destination path will be filled in by default. You can also access a shortcut list of all recently used paths by expanding the dropdown menu at the right of the path box. The validity of the current path is shown below the text box, and the wizard will prevent you from continuing to the next step if the path is not valid.

Below the destination path are several controls to set the title format of the exported profile folders. Internally, WAVi Scan manages all of its profiles by assigning them unique identifiers composed of random letters and numbers. However, those internal identifiers are long and not really human-readable. So when exporting, it often makes more sense to use a "real name" format, where each exported profile folder receives a title composed of the individual's first and/or last names, along with a few random distinguishing characters. "Real names" is the default option suggested by the wizard, and is suitable for most exporting situations. You can also change whether to use a "Last, First" or "First, Last" order for these readable folder titles. Alternatively, if you want to maintain subject privacy so that personal names are not exposed in the exported folder titles, you can choose the "Anonymized strings" option. This preserves the original randomized identifiers as used inside WAVi Scan.

The title format you choose here is only for your convenience, and does not affect subsequent importing. WAVi Scan can import valid profile folders using either naming scheme.

After you have chosen which title format to use, verify that there is enough space in the destination to hold the exported profiles, then press the **Next** button to begin the export.

Depending on the number of profiles being exported and the amount of data they contain, the export process may take some time to complete (Figure 11-18). When the wizard has finished, a summary page will explain the results (Figure 11-19). If you would like to see the destination folder containing the exported profiles, you can press the **Show Files** button. Otherwise, press the **Close** button to exit the wizard and return to the Profile List view.

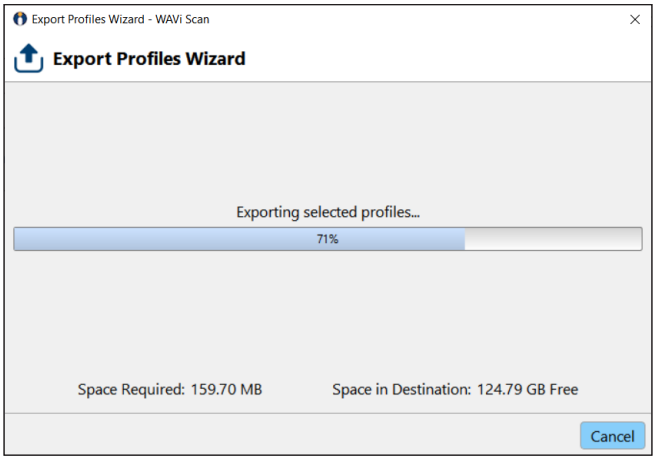

Figure 11-18.

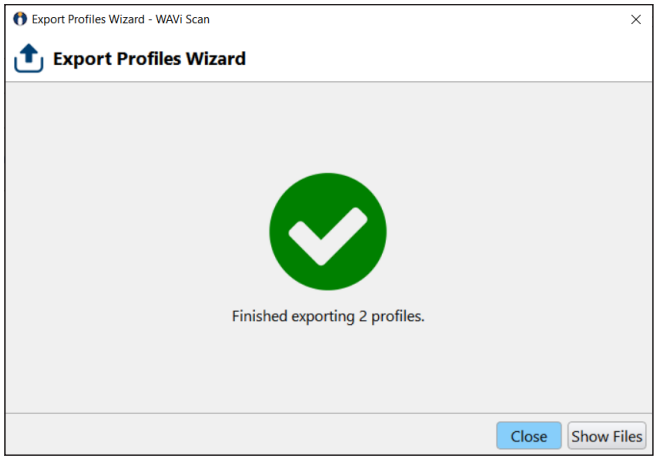

Figure 11-19.

11.9. Archiving Profiles

In addition to exporting copies of profiles on demand, WAVi Scan offers you the option to "archive" profiles. This can be useful for situations where you need to temporarily remove one or more profiles from the software, but intend to re-import them at a future date. You might need to do this if you are running out of onboard storage space, or if your practice has a policy of moving client data into "cold storage" after a certain period of inactivity. In any case, you can think of the Archive action as essentially a combination of the Export and Delete actions, but with some additional safeguards to avoid data loss.

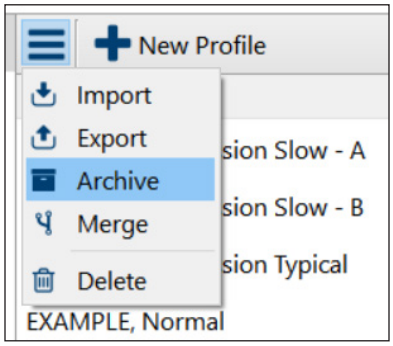

Figure 11-20.

To use this tool, first select the profiles you wish to archive, then press the Menu button and choose **Archive** (Figure 11-20). Note that this option is only enabled if you are currently viewing the "All Profiles" group; for more details see section 11.12.

The **Archive Profiles Wizard** window will appear as shown in Figure 11-21. The first page of the wizard briefly explains what will happen during the subsequent steps. When you are ready to advance, press the **Next** button.

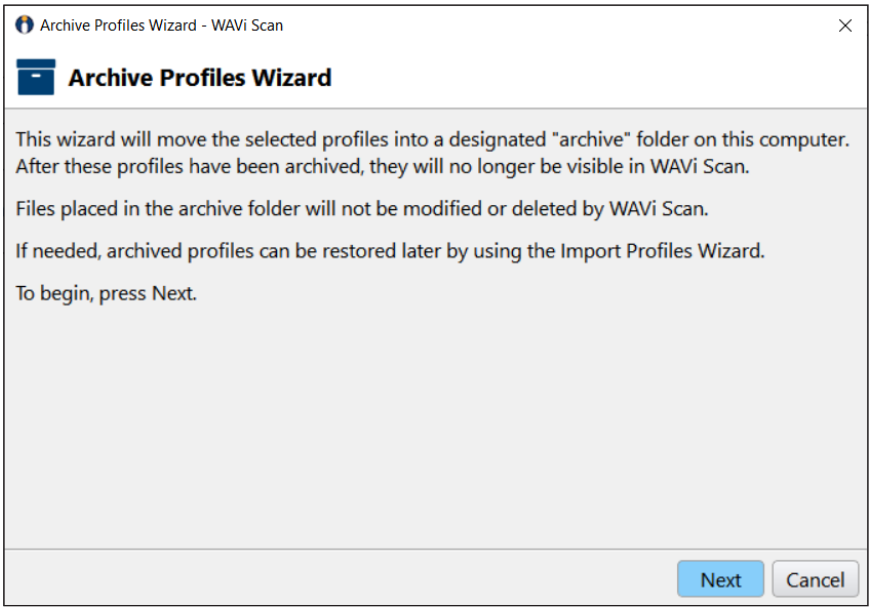

Figure 11-21.

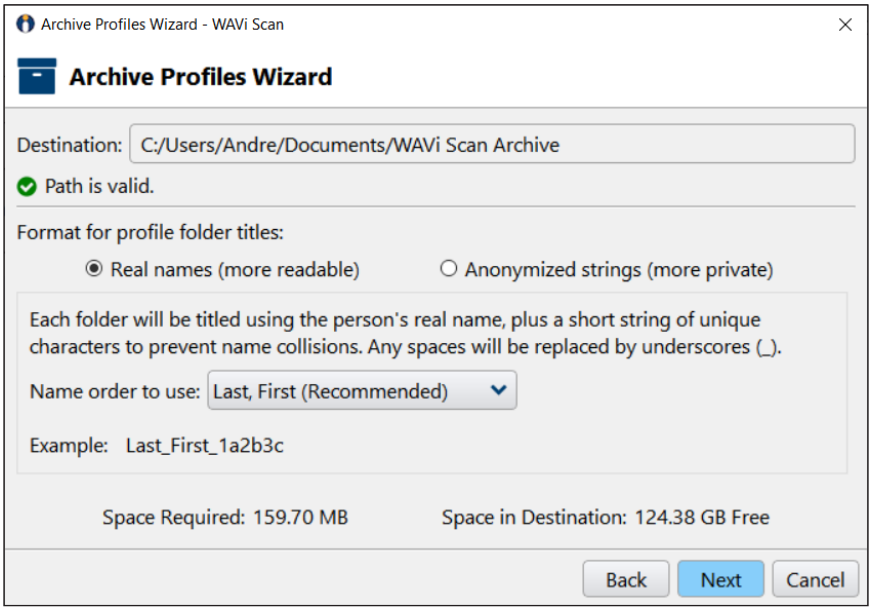

Figure 11-22.

Figure 11-22 shows the step where you can configure the options for the archive process. If you have previously used the profile export wizard, this interface should look familiar and in fact it is almost identical. The only difference from the export wizard is that the destination path is fixed and cannot be changed. Currently, the default archive path is located under your Windows user account's Documents folder, in a special folder titled **WAVi Scan Archive**. This folder is created automatically by the software.

Otherwise, you have the same options for choosing the title format you want for the archived profile folders—using either the default "Real names" option for readability, or the "Anonymized strings" option for more privacy.

When you are ready to continue, press the **Next** button. Depending on the number of profiles being archived and the amount of data they contain, the archive process may take some time to complete (Figure 11-23). When the wizard has finished, a summary page will explain the results (Figure 11-24).

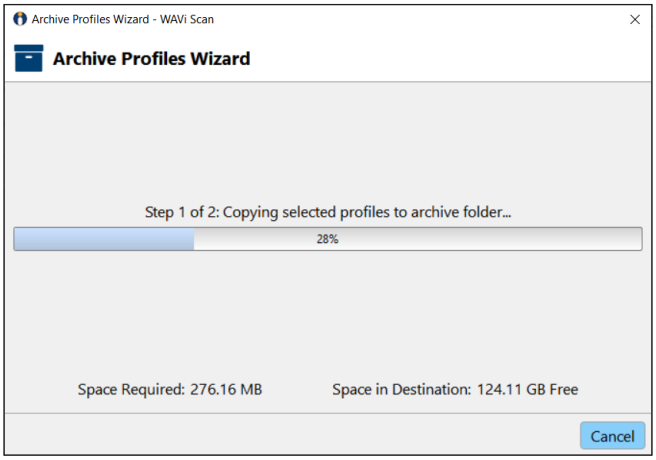

Figure 11-23.

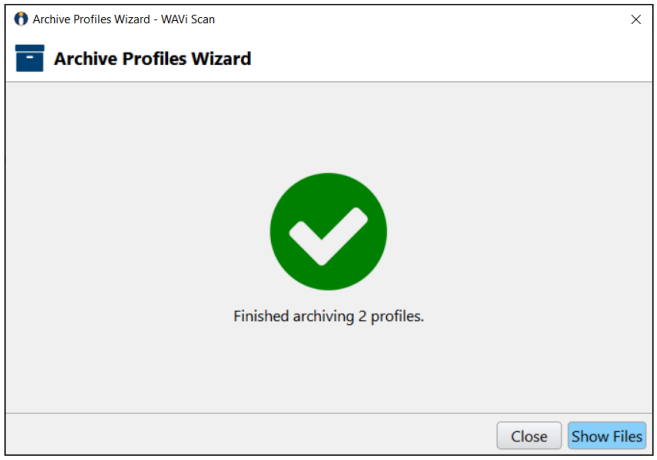

Figure 11-24.

If you would like to see the destination folder containing the archived profiles, you can press the **Show Files** button. Otherwise, press the **Close** button to exit the wizard and return to the Profile List view.

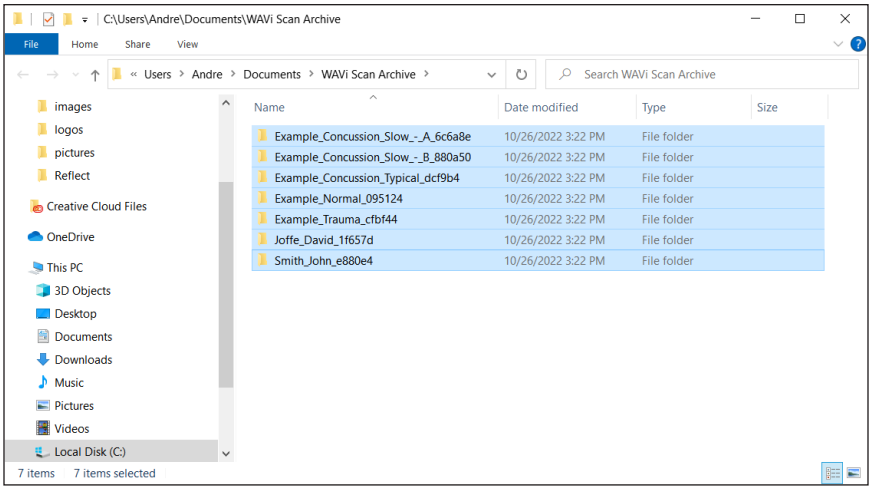

Figure 11-25.

Notice how the original profiles you selected to archive are no longer visible inside WAVi Scan, because they have been moved into the external WAVi Scan Archive folder (Figure 11-25). At this point the profile folders are no longer managed by the WAVi Scan app, and you are responsible for moving and backing them up as necessary in accordance with all applicable standards of healthcare data management.

11.10. Merging Profiles

Occasionally you may end up with two or more profiles belonging to the same individual. This can happen if a duplicate profile was unintentionally created with slightly different personal details, or if you imported profiles that were created on different computers. In such cases, it is advisable to merge the profiles as soon as possible to eliminate redundancy and confusion. To get started, first select the profiles you want to merge, then press the Menu button and choose **Merge** (Figure 11-26).

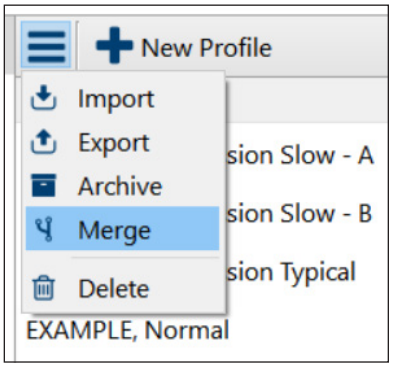

Figure 11-26.

The **Profile Merge Wizard** window will appear as shown in Figure 11-27. The initial page shows a list of the profiles you just selected, with relevant details summarized on each row. In this example we are attempting to merge 3 profiles, but you can merge any number.

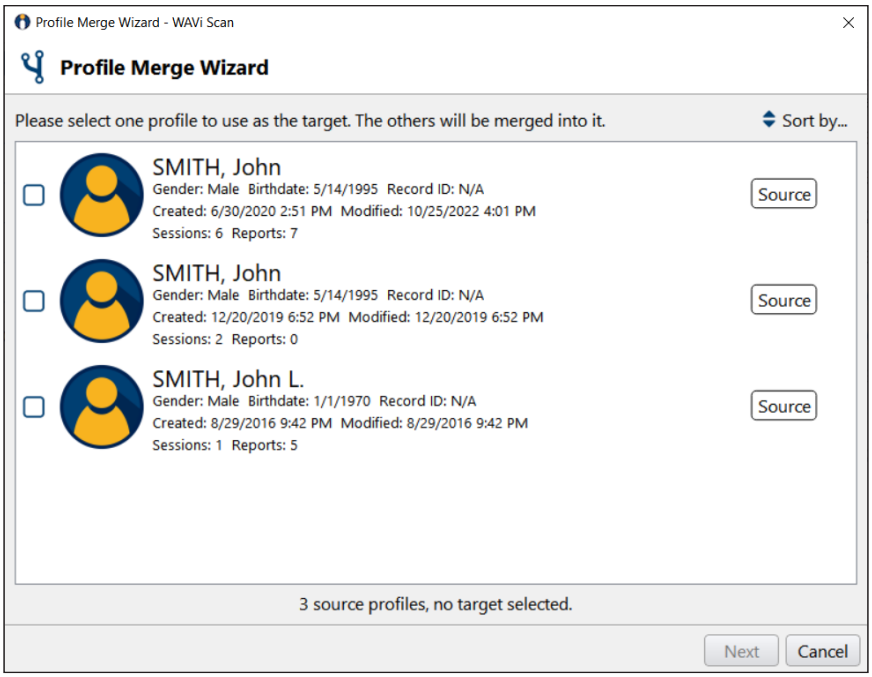

Figure 11-27.

The first step is to select one profile to be the "Target." This is the profile into which the contents of all the other "Source" profiles will be merged. At the end of the merge process, only the target profile will remain, while the other source profiles will be automatically deleted. To select a target, press anywhere on its item in the list. A checkmark will appear to the left of the selected item, and a green "Target" label will be visible to its right (Figure 11-28 on next page).

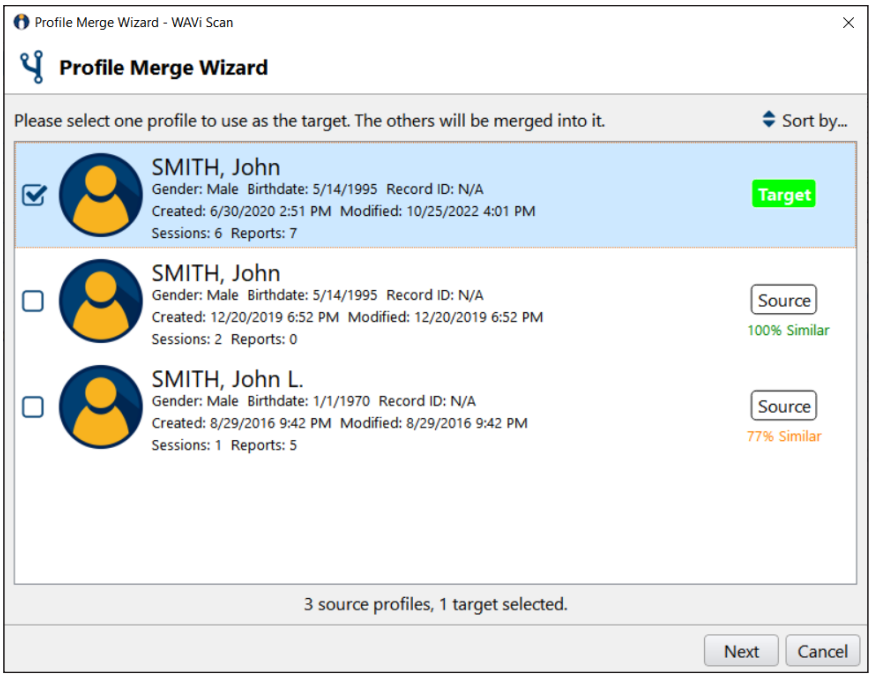

Figure 11-28.

Notice that when you select a target profile, a label appears next to each source profile to indicate how similar it is to the target. The similarity percentage calculation takes into account the names, birthdates, genders, and record IDs (if specified), comparing them against those in the target profile. The similarity percentage is not affected by the number of sessions or reports in the profiles. If any of the similarities are low, it may indicate that those profiles do not belong to the same person, so you should take a moment to double-check that you have selected the correct input profiles. When you are sure that you have selected the target profile you want to keep, press the **Next** button.

If any significant differences are detected between the source and target profiles, you may see a warning message similar to the one shown in Figure 11-29. If you are absolutely sure that the profiles belong to the same person, press **Yes, I'm Sure**. Otherwise, press **No, Let Me Check** to return to the list of source profiles.

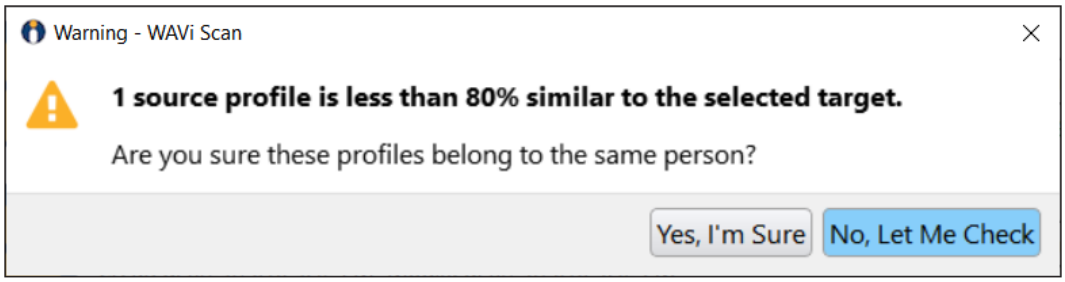

Figure 11-29.

Before the merge process begins, a confirmation message will explain what is about to happen (Figure 11-30). Note that the merging process will not preserve the basic personal details or profile photos from the non-target profiles, so make sure that your selected target has the details you want to keep. When you are ready, press **Yes** to begin the merge.

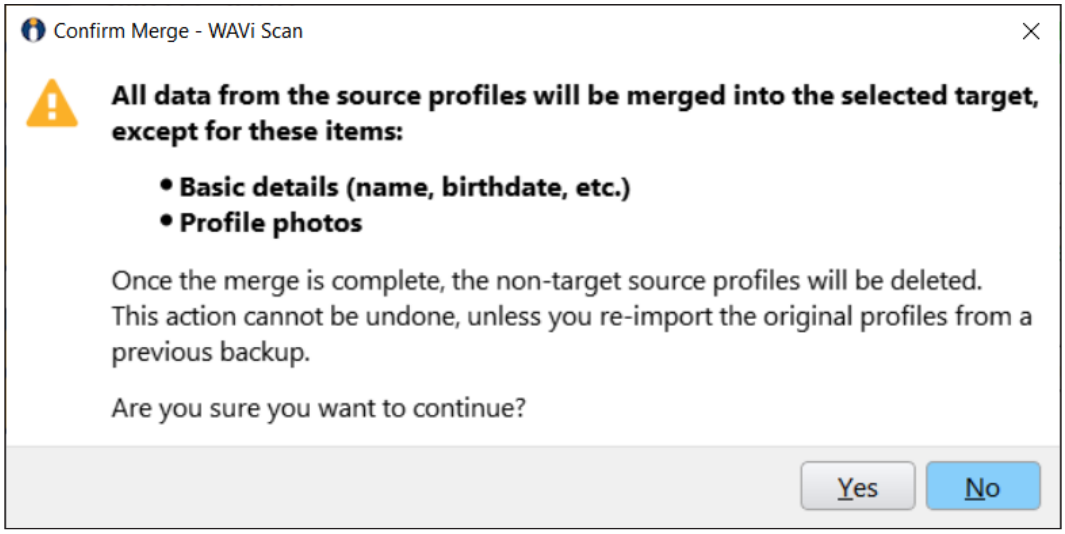

Figure 11-30.

Depending on the number of profiles being merged and the amount of data they contain, the merge process may take some time to complete (Figure 11-31). When the wizard has finished, a summary page will explain the results (Figure 11-32). If you would like to see the final merged profile, you can press the **Show Profile** button. Otherwise, press the **Close** button to exit the wizard and return to the Profile List view.

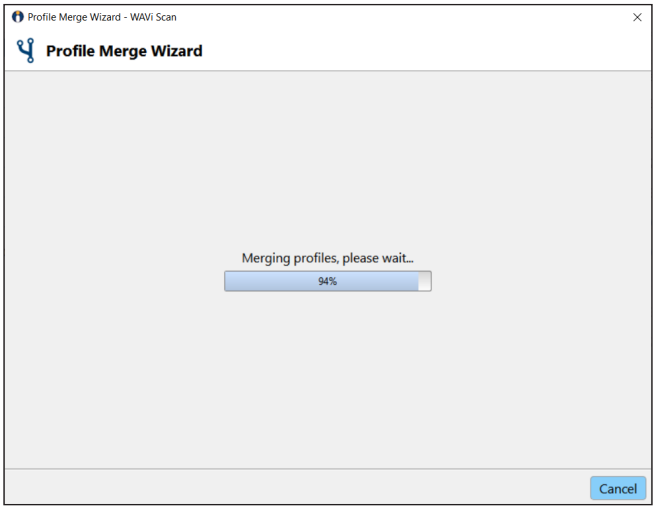

Figure 11-31.

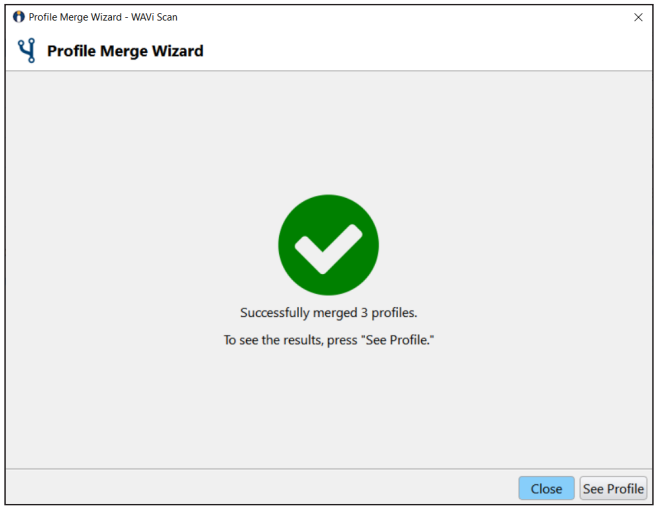

Figure 11-32.

11.11. Deleting Profiles

As a general rule, you should not delete profiles which contain valid data, and should instead consider archiving or merging them. However, sometimes you may have valid reasons to delete a profile, such as if it was created by mistake or for experimentation, or if it is corrupted and you intend to re-import a clean copy from a backup. In such cases, deleting profiles may be appropriate. To do this, first select the profile(s) you wish to delete, then press the Menu button and choose **Delete** (Figure 11-33). Note that this option is only enabled if you are currently viewing the default "All Profiles" group; for more details, see section 11.12.

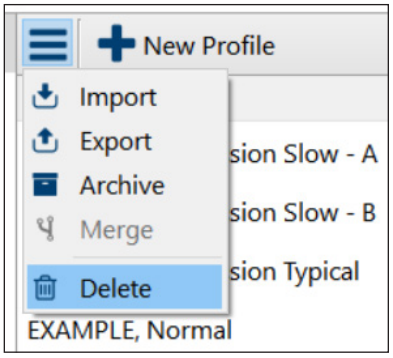

Figure 11-33.

If any of the selected profiles contains data such as sessions or reports (which is often the case), a warning message will ask if you want to archive the profiles instead (Figure 11-34). If you feel that option is preferable, you can press the **Yes, I want to archive** button to switch into the Archive Profiles Wizard. Otherwise, press the **No, I want to delete** button to continue with the deletion process.

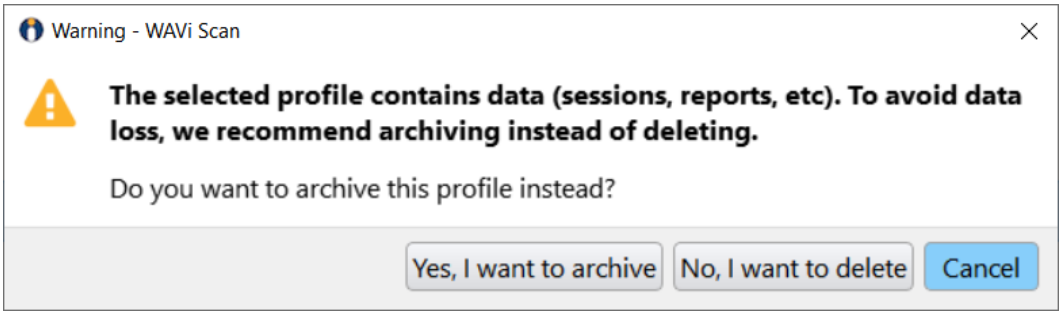

Figure 11-34.

Next you will see a warning message asking you to confirm if you are sure that you want to delete the selected profiles (Figure 11-35). Note that deletion is permanent and cannot be undone, unless you re-import the profile(s) from a previous backup. If you are absolutely sure you want to continue, press the **Delete** button. The profiles will be immediately deleted from the system, and will disappear from the list of All Profiles as well as from any other groups to which they belonged.

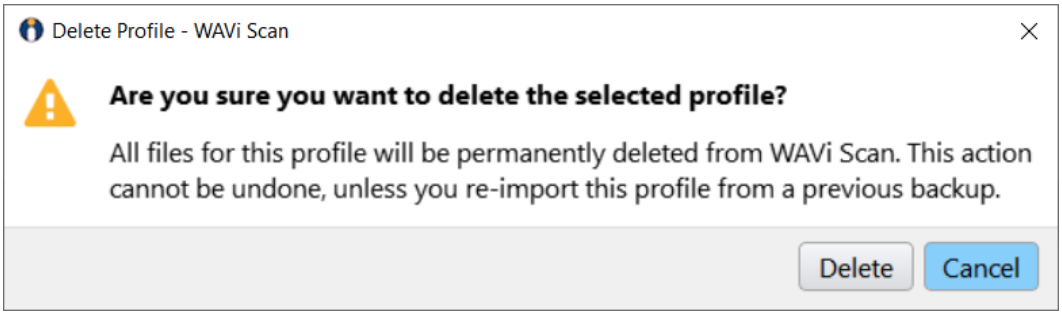

Figure 11-35.

11.12. Using Profile Groups

As you add more participant profiles to the system, it can be helpful to start organizing them into groups. Just like playlists for music, profile groups allow you to define your own categories and choose which profiles to include in them. This can be especially convenient to keep track of participants in different studies, or to sort individuals according to certain criteria. Profile groups are a flexible tool that you can use to optimize your WAVi workflow.

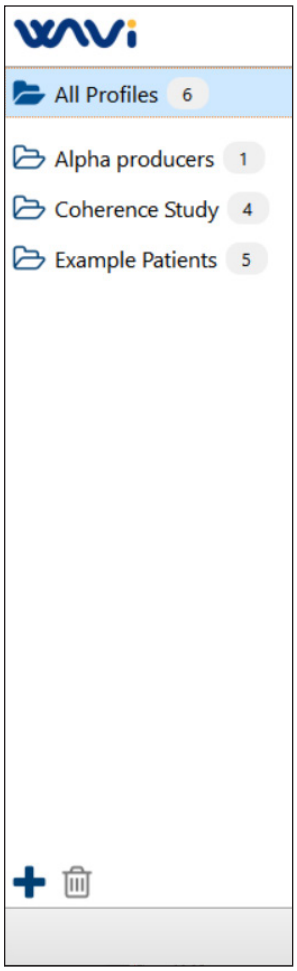

Figure 11-36.

Profile groups are listed in the pane on the left side of the Profile List View (Figure 11-36). The group currently being viewed is highlighted with a solid folder icon. Next to each group, a badge indicates the number of profiles belonging to that group. A profile may belong to any number of groups, and groups may contain any number of profiles.

The system automatically creates one group by default, called **All Profiles**, which is permanently positioned at the top of the group list. The All Profiles group contains every profile in the system, and cannot be deleted or modified. This is the group selected by default when you open the application.

Other custom groups that you create will appear in alphabetical order below the All Profiles group. You can create any number of custom profile groups, and modify or delete them at any time. Note that deleting a group will not delete the profiles contained in that group.

Some profile management actions, including those to create, import, archive, and delete profiles, are only enabled when you are viewing the All Profiles group. This is done in order to prevent users from mistakenly assuming that those actions would only apply to the group currently being viewed, when in fact those actions can affect multiple groups simultaneously.

To manage your custom profile groups, dedicated actions are provided as described in the following subsections.

11.12.1. Creating a New Group

A new custom profile group can be created in a couple of ways. One is to press the **New Group** button ("plus" icon) at the bottom of the group pane. This is fine if you will be choosing group members later. Alternatively, you can select one or more profiles in the current view, then right-click them and choose **Add to Group** -> **New Group** from the popup menu. The latter method allows you to save a step by immediately adding those selected profiles to the new group.

After choosing the New Group action, a dialog window will appear as shown in Figure 11-37. At this point you will need to provide a title for the new group. This can be anything you like, but cannot be empty and cannot exceed 50 characters in length.

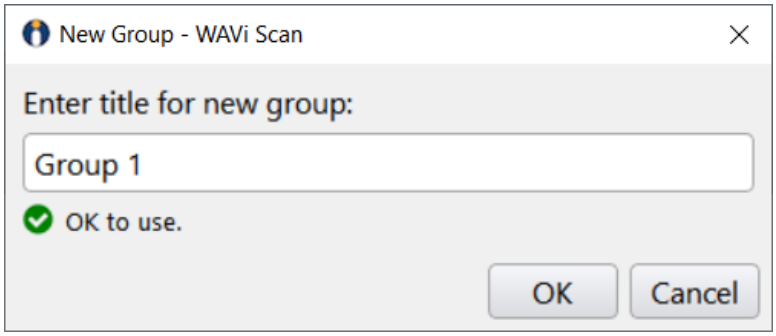

Figure 11-37.

When you have chosen a suitable title, press **OK** to create the new group. If you used the New Group button at the bottom of the group list pane, the view will automatically switch to show the new empty group. Otherwise, the view will remain on whatever group you were already viewing.

11.12.2. Adding Profiles to a Group

As mentioned above, you can select profiles and create a new group containing them in one step. However, more often you will want to add profiles to an existing group. This can be done anytime by selecting one or more profiles in the profile list, then right-clicking and choosing **Add to Group** from the popup menu (Figure 11-38). From there, you can see a list of eligible groups to which the selected profiles can be added, and then click the title of the group you want.

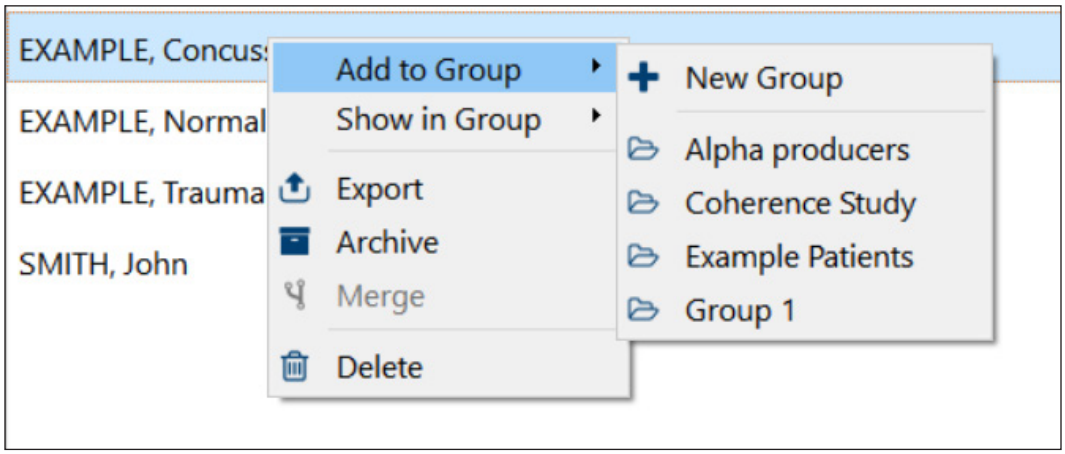

Figure 11-38.

Note that the All Profiles group is not listed as an option here, because it is automatically managed by the system and cannot be modified by users. Also, the popup list of custom groups shows all of them, regardless of whether some already contain the selected profiles. However, re-adding a profile to a group of which it is already a member has no effect, so you do not need to worry about duplicates.

11.12.3. Removing Profiles from a Group

You may remove one or more profiles from a group at any time. This action is non-destructive, and does not delete the profiles from the system or remove them from any other groups.

While viewing the group in question, first select the profiles you wish to remove, then right-click them and choose **Remove from Group "[Group Name]"** in the popup menu (Figure 11-39).

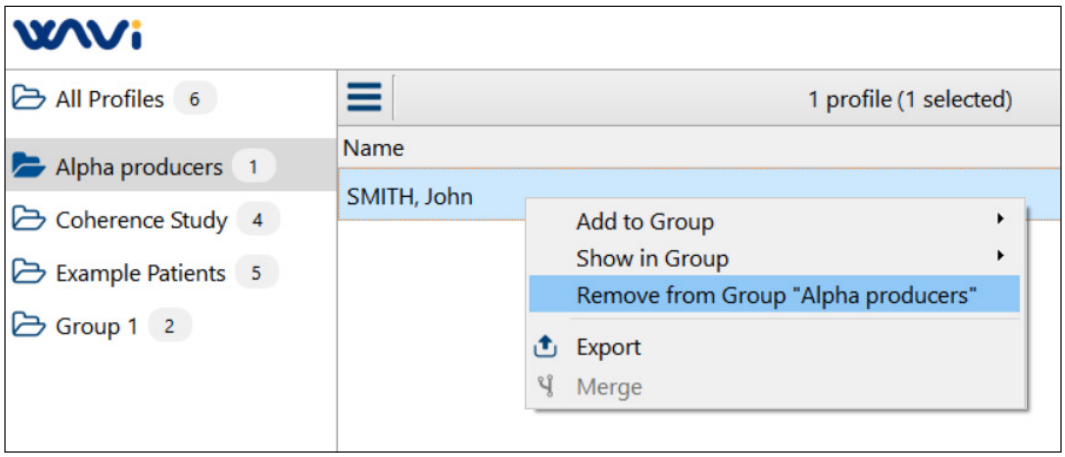

Figure 11-39.

A popup message will ask you to confirm your choice (Figure 11-40). Choose **Yes** to remove the profile(s) from the group, or **No** to keep them in the group.

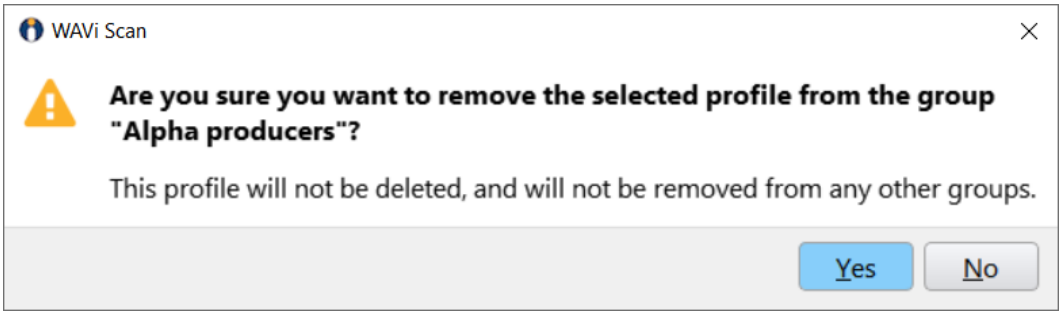

Figure 11-40.

11.12.4. Viewing Group Members

You can see the members of any group simply by selecting the group's item from the group list. The profile list pane will be automatically filtered to show only the members of the current group. If you do not see the profiles you expected, check that you have selected the correct group.

To quickly check whether a profile already belongs to a particular group, you can right-click that profile and choose **Show in Group** from the popup menu. This is helpful when you have many groups and do not want to open and look through each one. You can then choose a group title from the menu, and the Profile List View will automatically switch to show the selected profile within that group.

11.12.5. Retitling a Group

Sometimes you may wish to give an existing group a different title. This can be done at any time by right-clicking the group's item in the group list, and choosing **Retitle Group** from the popup menu (Figure 11-41).

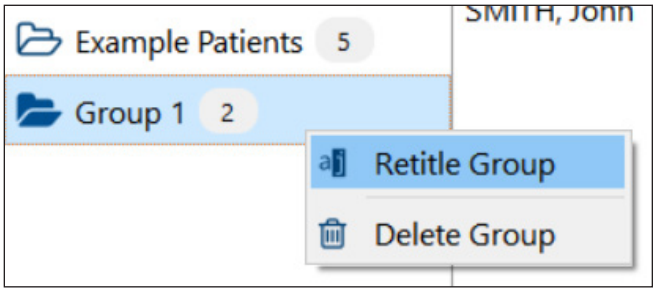

Figure 11-41.

A dialog window will appear where you can type a new title for the group (Figure 11-42). This must be different from the current title, cannot be empty, and cannot exceed 50 characters in length.

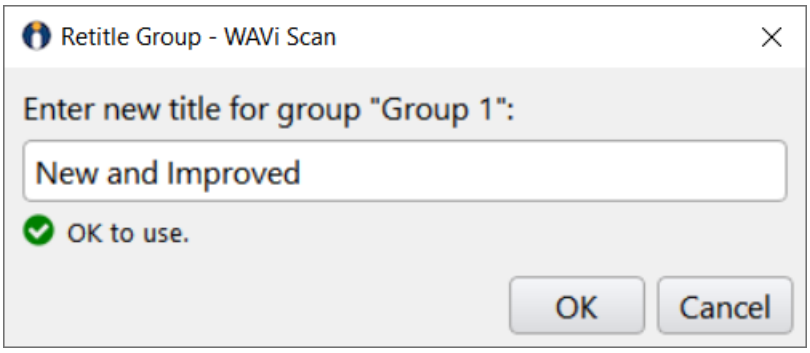

Figure 11-42.

11.12.6. Deleting a Group

If you no longer need a custom group, you can delete it either by selecting it from the group list and then pressing the **Delete Group** button (trash can icon) at the bottom of the list, or by right-clicking the group item and choosing **Delete Group** from the popup menu. A warning message will ask you to confirm your choice (Figure 11-43). Remember that deleting a group does not delete the profiles contained in that group.

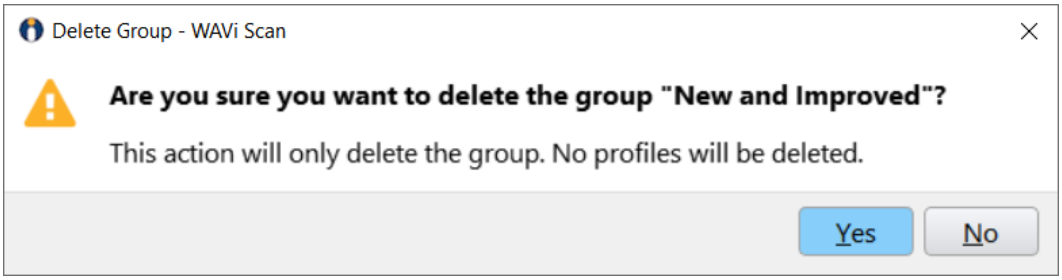

Figure 11-43.

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12. System Settings

The software provides a number of persistent settings which can be customized to your preferences. To access these, go to the menu bar of the main app window and choose the **Settings** item. The Settings window will appear as shown in Figure 12-1. Each setting is described in detail below.

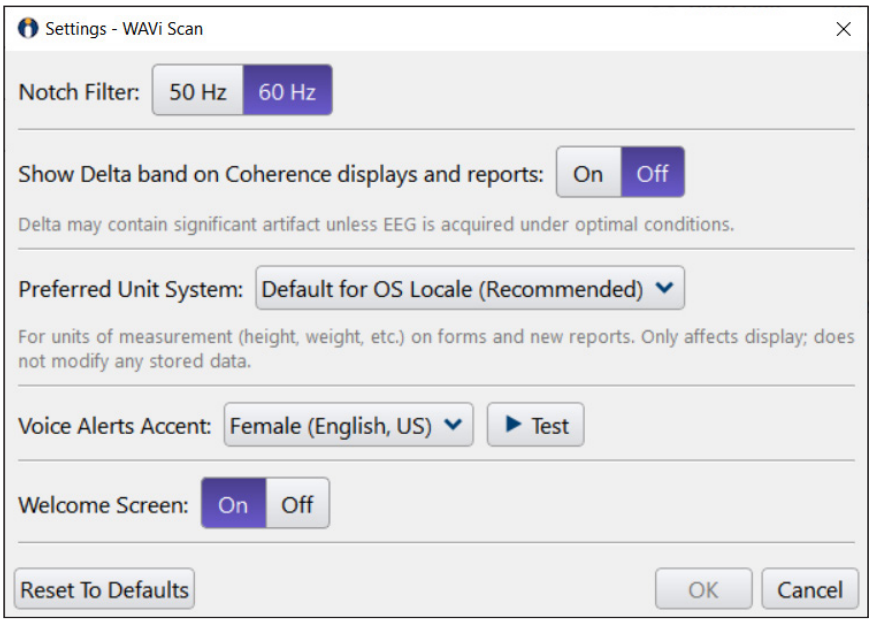

Figure 12-1.

12.1. Notch Filter

This sets the electrical mains frequency to filter out when displaying EEG signals. In most of the Americas and some parts of Asia it is typically 60 Hz, and elsewhere it is usually 50 Hz. When reviewing data acquired in a geographic locale with a given mains frequency, the Notch Filter should always be set to match, otherwise the display will look very noisy. Note that this setting only affects displays, not stored data. The current Notch Filter status is indicated by a label in the bottom-right corner of the main app window.

12.2. Show Delta band on Coherence displays and reports

The Delta frequency band (1.0-4.0 Hz) may contain significant artifact if EEG is not acquired under optimal conditions, and may not be reliable for analysis. We recommend leaving this setting Off for normal usage, but you can turn it On if necessary. This setting affects the Coherence review display mode when reviewing EEG protocols, and report content such as graphs and tables where multiple EEG frequency bands are distinguished. Note that this only affects displays, and does not modify any stored data.

12.3. Preferred Unit System

This setting controls whether to use the International System of Units (Metric), or United States Customary Units for displaying units of measurement (height, weight, etc.) on forms and new reports. This setting only affects displays, and does not modify any stored data. The default is to use the unit system specified by the operating system's locale, but you can choose to override this with your own preferred unit system at any time.

12.4. Voice Alerts Accent

The system provides a number of voice alerts to help users take corrective actions and improve data quality in certain situations. Currently, voice alerts may accompany various warning messages shown in the Instant Review mode and also when first reviewing an EEG protocol right after recording it. The accent used for the voice alerts can be changed via a dropdown menu. You can then press the Test button to hear a sample of the currently selected voice accent. The Voice Alert feature itself can be turned On or Off via a button in the status bar of the main app window. (Voice Alerts are turned Off by default.)

12.5. Welcome Screen

By default, the Welcome Screen is shown at app startup, and again after exiting a profile if more than 2 minutes have elapsed since the profile was opened. This feature is designed to encourage privacy by hiding the list of all profiles from view until the test administrator needs access to it, which is typically in between sessions with different participants. If this feature is not relevant in your practice, it can be turned off to streamline navigation.

12.6. Reset to Defaults

Press this button to reset all settings to their factory defaults. A popup message will ask you to confirm your choice.

12.7. Applying or Canceling Changes

When you are finished with the Settings window, press **OK** to apply your changes, or **Cancel** to discard them. All of the settings controlled here are persistent between app launches.

13. Troubleshooting

13.1. Headset Fit

There may be challenges fitting the headset on some participants. Applying and adjusting the headphones can help to secure the headset more firmly onto the head. Make sure not to overtighten the fit or cause discomfort to the participant.

13.2. Contact and Signal Quality

Although obtaining consistently clean signals may be challenging, most issues with poor signal quality can be remedied with a little time and patience. Keeping both yourself and the participant relaxed and calm is essential to acquiring clean data.

After all locations have been checked using the Contact view and the Instant Review function, follow the headset manufacturer's guidelines to achieve better contact for any locations still showing red or unacceptable connections. Using the mouse or touch screen, select individual electrode locations to receive immediate visual feedback on contact improvements (Figure 13-1).

Figure 13-1.

Important: Do not rely solely on observing a green contact at a particular electrode location. It is equally important to monitor raw waves using the Instant Review function to verify sufficient signal quality prior to recording a protocol.

13.3. Hairstyle Challenges

There are many different hairstyles which can present challenges when trying to achieve a clean signal. However, successful scans have been performed on nearly every hairstyle. Follow the headset manufacturer's guidelines for how to deal with specific hairstyle issues. While it may take longer to obtain acceptable contact, it is important to remain calm and keep the participant at ease throughout the entire setup process. Adjusting the headphones can also help to secure the headset more firmly onto the head.

13.4. Raw Wave Monitoring

To improve drifting raw wave signals, use general troubleshooting techniques. The term "drifting" here describes EEG waveforms which deviate significantly above or below the horizontal areas to the right of the EEG electrode names. Obtaining a clean signal may take some time. Just remember that it is possible to obtain data for everyone, but sometimes more effort is required. The most important tip is to have patience.

If no raw EEG signals can be observed, try the following:

1. Exit the WAVi Scan app.
2. Unplug the EPU cable from the laptop.
3. Re-attach the EPU cable to the laptop, and wait at least 15 seconds.
4. Restart the WAVi Scan app.
5. If EPU is still not detected, a computer restart may be necessary.

If any troubleshooting involves a software restart, you should reopen the same session to retain all intake information and prevent the participant's profile from becoming cluttered with incomplete sessions. Note that the session must be reopened before it becomes locked.

13.5. Connection Issues (Intermittent or Loose Connections)

If noisy signals are still present after completing contact improvement techniques, check EPU connections. If the EPU is not completely attached to the headset, the display will show either random noise or no signals at all.

Sometimes even though a green contact circle is displayed for a particular electrode location, the corresponding EEG signals may still be drifting. This may be due to the electrode making contact with only the hair and not the scalp, causing a poor connection that needs to be modified.

13.6. Significant Amounts of Signal Noise

In some rare cases, signal noise may persist even if good contact is being shown by the contact check function. If this happens:

- Check that the EPU is properly connected to the headset.
- Check the ground and ear electrodes.
- Check the room for nearby electrical devices that may interfere with signals, such as mobile phones.
- Excess muscle tension or participant movement may play a role in generating extra noise. Make sure that the participant is both calm and relaxed.

To solve the problem it may sometimes be necessary to replace the headset. If the problem occurs with a different headset as well, but only intermittently, check for external electrical noise. Call WAVi customer support if the problem continues and does not improve with WAVi troubleshooting techniques.

13.7. Dead Channels

On rare occasions a headset channel may fail. If the failed channel is an EEG channel, it may appear in the raw wave display as a flat line. If the failed channel is the ground and/or an ear reference, all of the other channels may appear very noisy. As long as the failed channel is not the ground (G on the head display), you can still collect data and complete the session. Immediately following the session, contact WAVi customer support.

13.8. Power Interruptions

If the EPU becomes disconnected from the laptop while recording a protocol, you should first stop recording, then reconnect the EPU and wait for it to reinitialize. (If it does not reinitialize, try the procedure listed in 13.4). You can then add a new replacement protocol to the queue and start recording again when ready.

When the laptop's internal battery is sufficiently charged, the EPU may be operated without connecting the laptop to AC mains power. Runtime will depend on the laptop's battery capacity, so the battery level should be carefully monitored to ensure that power is not lost. The laptop's AC power adapter should be reconnected if the battery level drops too low. If the laptop runs out of power while recording a protocol, reconnect the AC power adapter and restart the laptop. Restart the software, reopen the participant's profile, and navigate back into the session that was in progress. Add a new replacement protocol to the queue, and start recording again when ready.

Note: it is recommended to delete any interrupted protocols in a session to avoid confusion later; see section 3.4 for details.

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14. Care and Maintenance

14.1. Post-Session Cleaning and Maintenance

After all testing is complete, use alcohol prep pads to wipe off any gel or saline drops from the EPU, headphones, and any other applied parts. Make sure all connectors and ports are clean and dry. Follow the headset manufacturer's recommendations for cleaning the headset and its parts.

When not using the WAVi Scan app, make sure to disable Airplane mode and allow the laptop to connect to the internet so that scheduled system updates can occur.

14.2. Lifetime Care

Although the system is designed for ease of use, it should always be handled with care. Rough or improper handling may adversely affect the system's operation. Please note the following:

- Use only alcohol prep pads to clean the components of this device. Do not use other cleaning agents or solvents on any system components.
- Never immerse the EPU in liquids of any kind.
- Never expose the EPU to extreme temperatures.
- As with any electronic device, protect the EPU from impact, exposure to moisture, liquid spills, sand, dirt or debris.
- Periodically inspect for any signs of damage.
- Inspect the EPU contacts for corrosion before every use. If any corrosion is observed, immediately contact WAVi customer support.
- The EPU is not user-serviceable except to ensure the connectors and contacts are clean before use.

14.3. Operation, Storage, and Transport

The system should be operated within the following ranges:

- Ambient temperature range: 32F (0C) to 104F (40C)
- Relative humidity range: 5% to 95% non-condensing
- Altitude range: -15m (-50ft) to 3,048m (10,000ft)

If the EPU is stored or transported in temperatures outside the range indicated above, allow it time to return to room temperature before operating.

Always store and transport all system components in the bag or case provided with your kit.

14.4. Disposal

If the laptop PC and/or EPU become inoperable, or are no longer needed, please return them to WAVi for proper disposal. Do not throw out, recycle, or reuse the laptop PC for other purposes without first securely backing up and removing all patient data.

If any other electronic parts (such as headphones, cables, or other accessories) become inoperable, or are no longer needed, you can either:

- Return the equipment to WAVi for proper disposal.
- Dispose of the equipment via appropriate e-waste recycling facilities in your area. Never discard electronic parts with normal landfill trash.

Other non-electronic system parts may be disposed via normal landfill trash or appropriate recycling facilities.

For disposal recommendations specific to your needs, please contact WAVi customer support.

15. Technical Specifications

15.1. System Specifications

Software version: 1.1.0

EPU hardware version: F

EPU firmware version: 15

EPU dimensions: 2.6 in L x 2.5 in W x 1.25 in H

EPU weight: 3.1 oz

Number of EEG channels: 21

- Channels 1-19: 10-20 active EEG electrode sites
- Channel 20: A1 left ear reference
- Channel 21: A2 right ear reference
- Channel FPZ: Headset ground
- Channels 1-19 referenced by default to linked A1 and A2.

Amplifier type: DC, differential

A/D resolution: 24 bits

Input range: +/- 400 mV

Input impedance: >= 1 GOhms

Common-mode Rejection Ratio (CMRR): >= -115 dB

Amplifier bandwidth: 0 - 100 Hz

EEG channel bandwidth: 0.5 - 40 Hz

Sampling rate: 250 samples/second

Maximum displayed spectral accuracy (in software): 0.5 Hz

Input-Referred Noise: <= 3.0 µV (+/- 1.5 µV) peak-to-peak (30 Hz BW, G = 6)

Sensor contact quality monitored via 62 Hz low amplitude sine wave signal

EVP audio tones: 65 +/- 5 dB

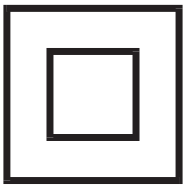
Data connection to host PC: USB

USB communication speed: 256k baud

EPU power supply: Over host PC USB connection

Laptop AC power adapter: BF-rated power supply

15.2. Symbols Used

Symbol	Standard No./ Standard Title	Standard Reference No./ Symbol Title	Symbol Meaning
	IEC 60417 / Graphical symbols for use on equipment	5333 / Type BF applied part	Identifies a type BF applied part complying with IEC 60601-1
	IEC 60417 / Graphical symbols for use on equipment	5172 / Class II equipment	Identifies equipment meeting the safety requirements specified for Class II equipment according to IEC 61140
	ISO 7010 / Graphical symbols - Safety colours and safety signs - Registered safety signs	M002 / Refer to instruction manual / booklet	Indicates that the instruction manual / booklet must be read
	IEC 60417 / Graphical symbols for use on equipment	5032 / Alternating Current	Indicates that the equipment is suitable for alternating current only; to identify relevant terminals
	IEC 60417 / Graphical symbols for use on equipment	5031 / Direct current	Indicates that the equipment is suitable for direct current only; to identify relevant terminals