Once the electrode placement as been finalized, trace around each electrode on the inside of the cuff with a Sharpie marker or equivalent. This should only be done after all adjustments and walking trials have been completed.

If a **Foot Sensor** is recommended for the client, the insole should be trimmed to fit appropriately inside their shoes.

5.2   Collecting Initial Walking Data

1. Double click the icon labeled '**WalkAnalyst**' on the computer desktop. The program will open with the '**Home**' screen (Figure 15). A lightbulb icon in the upper left corner of the screen will appear yellow if the WalkAide and WalkLink are correctly connected and communicating with the computer.
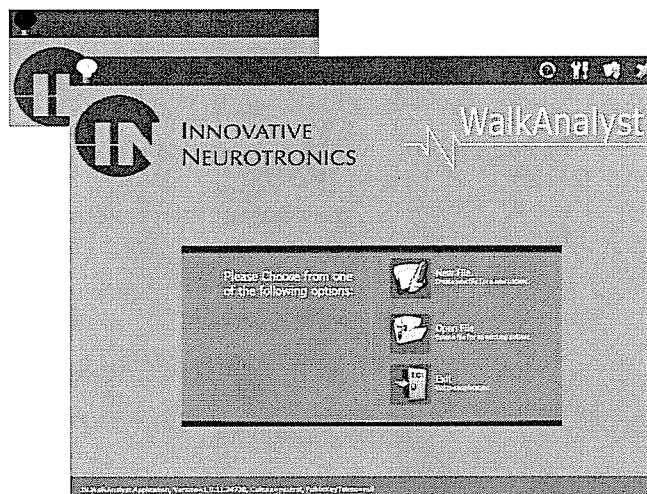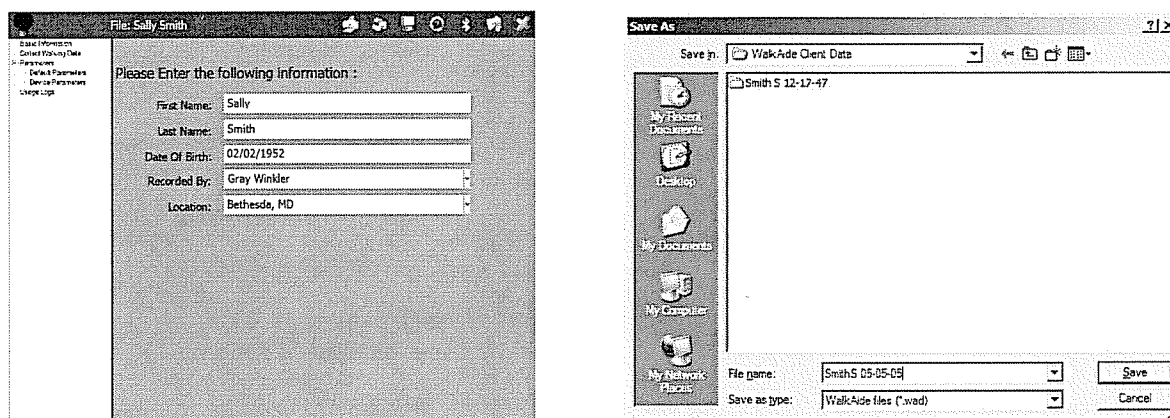

Figure 15 – Home screen.

2. Click on "New File" and enter the Basic Information. Click the 'Save' icon and type in file name (Figures 16 and 17). [*Suggestion: Click on 'My Documents' and create a folder called "WalkAide Client Data". Click on the "WalkAide Client Data" folder and create individual client folders for saving all walking data.*]

Figures 16 and 17 – Basic information and 'Save' screen.

   a. Seven icons appear at the top of the screen. From left to right they represent "Print", "Main Menu", "Save", "WalkAide Help", "Bluetooth Configuration", "Minimize" and "Exit".

3. Click '**Default Parameters**' from the list on the left (Figure 18). Check to see that the WalkAide Stimulation Mode is set to the appropriate setting (Hand) and then click on the '**Send to WalkAide**' icon. Click 'OK' when the default parameters have been successfully sent. If the 'Heel' mode is selected, be sure to connect the heel or foot sensor to the unit or an alarm will be heard two times every two seconds.
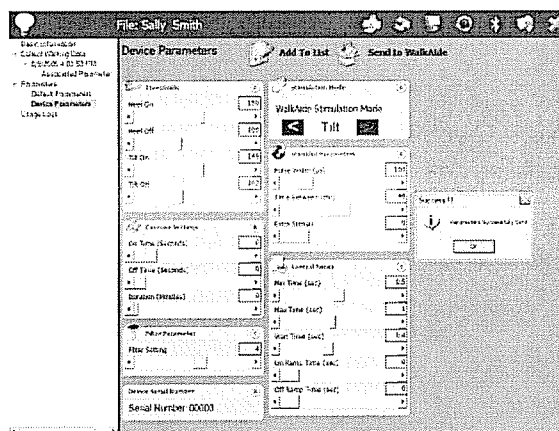

Figure 18 – Default parameters screen.

4. Click on '**Collect Walking Data**' from the list on the left of the screen (Figure 19).
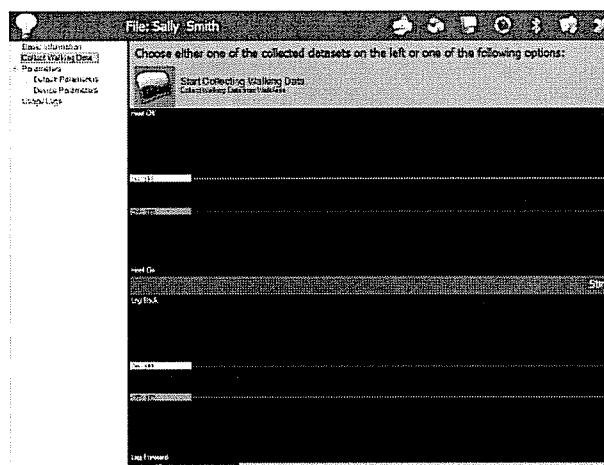

Figure 19 – Collect Walking Data screen.

5. Position the client at the top of the (Figure 8) walking pattern or hallway as shown in Figure 1. Make sure the cuff is properly positioned and there are no dangling cables that might cause the client to trip or fall. Ask the patient to stand, balance and prepare to walk.

6. Ask the client to begin walking and click on the icon labeled '**Start Collecting Walking Data**'. Walk beside the patient and press the '**Stim**' button on the WalkLink to activate ankle dorsiflexion during EACH step of the affected limb from just after heel off to just after initial contact. It is very important to correctly time the stimulus with each step to maximize function of the WalkAide.

7. Data from the WalkAide will appear on the screen from left to right in three panels. When the data fills the screen, the trace wraps around and begins again at the left edge. With notebook computers the display of the data may be delayed somewhat because LCD displays update slower. The data are stored in a buffer before being displayed, so no data are lost, even if the display is not quite in real time.

a. The top panel shows recording from the Heel Sensor. The signal will be high when the heel is off the ground (terminal stance to initial contact) and low when the heel is on the ground (initial contact through terminal stance).

b. The middle panel shows the actual stimulations (represented by short vertical light blue bars – blue or green? In some screen prints they look green and some look blue. Maybe it's just me?!?) applied to the WalkAide each time the stimulation button on the WalkLink was pressed.

c. The bottom panel shows data from the Tilt Sensor. The signal will be high when the leg is behind the body (terminal stance to swing phase) and low when the leg is in front of the body (initial contact to midstance).
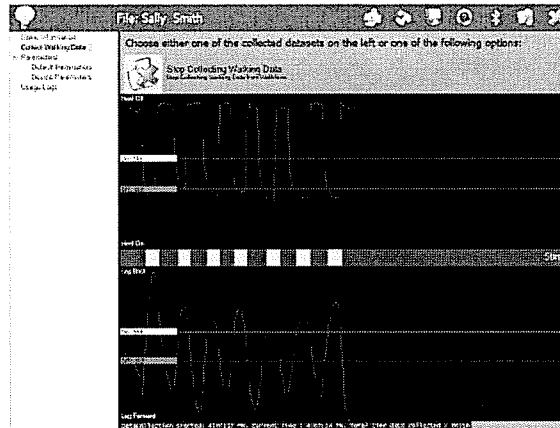

Figure 20 – Stop Collect Walking Data screen.

8. When a sufficient number of steps have been recorded, click on the '**Stop Collecting Walking Data**' button (Figure 20). (Typically, the client might stand up, walk for 10-20 meters and sit down again during a period of recording.)

9. Click on the '**Add Walking Data to List**' button in order to proceed with the analysis of the data (Figure 21). Each walking trial for this client will be saved and labeled with a date and time, with the Associated Parameters listed underneath each trial. These files will be listed on the left side of the screen under '**Collect Walking Data**'.
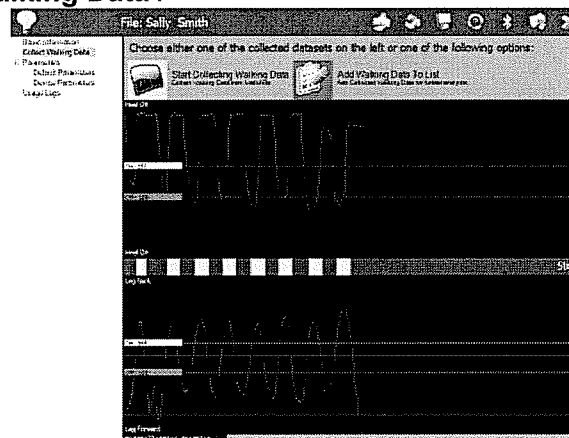

Figure 21 – Add Walking Data to List.

10. Select the specific walking trial for further assessment by clicking on the appropriate date and time label. Two similar Heel and Tilt Sensor graphs are shown separated by an expanded panel. The panel contains up to 3 rows of small intermittent light blue bars indicating the timing and method used to trigger the stimuli. The top (red) row represents the timing of the Heel Sensor stimuli (when used) and the bottom (blue) row represents the timing of the tilt stimuli generated by the Tilt Sensor.

The middle gray row represents the actual stimulations produced by whatever method was used to produce the stimuli (Heel Sensor, Hand Switch or Tilt Sensor).

11. This data analysis page displays the collected data points and color codes these points to indicate when the device would be in 'STIM' mode given the associated parameter settings. When the graph points are colored green, the device is delivering stimulation. Red graph points represent the time period during walking when stimulation is not occurring. As parameter adjustments are made, the stimulation initiation and termination points will change to reflect the adjustments.

12. The goal of data analysis is to align the Tilt Sensor stimulations to either the Hand Switch or the Heel Sensor stimulations. This is achieved by altering the parameters using the '**Autoset Parameters**', '**Optimize Parameters**', and/or manually adjusting the parameters.
   a. If only two inputs were used (for example the Tilt Sensor and the Hand Switch on the WalkLink), the goal is to match the Tilt Sensor stimuli pattern to the actual stimulations delivered by the Hand Switch WalkLink.
   b. Note that clients whose walking pattern does not activate the Tilt Sensor (i.e. insufficient hip flexion/extension) will need to use the Heel Sensor for initial set up and then be provided with the Foot Sensor for safe walking.

5.3 Adjusting the Client's Parameters

1. Click the '**Autoset Parameters**' button to automatically modify the parameter settings based on statistically calculated values from the recorded heel (if used) and tilt data (Figure 22). Click 'OK' to accept the statistical calculations and standard deviations when the parameter adjustments have been completed.
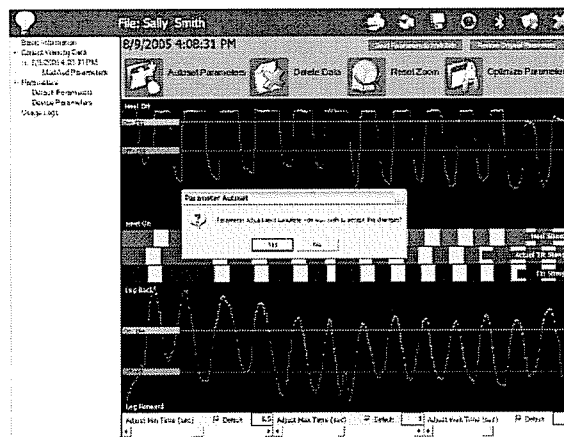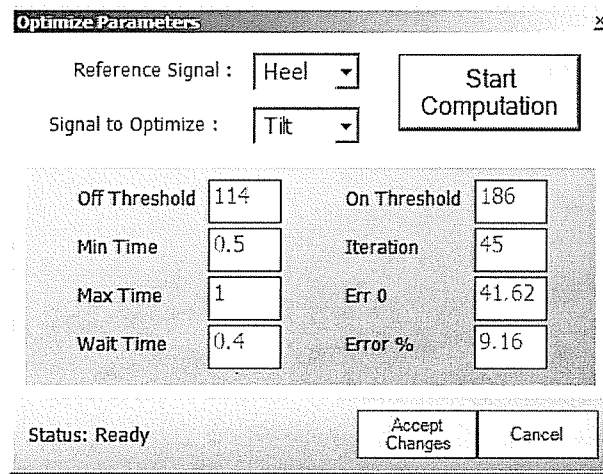

Figure 22 - Autoset Parameters.

2. Click on the '**Optimize Parameters**' button. Choose the desired reference signal (i.e. Heel or Hand) and the signal to be optimized (i.e. Tilt or Heel) and press the '**Start Computation**' button (Figure 24). This process takes a few seconds and will automatically modify the thresholds and time(s) in the tilt data to best match the desired reference signal.

   a. Either '**Accept Changes**' or '**Cancel**' the calculated fit parameters depending on the '**Error %**'. If the error percentage is greater than 20, '**Cancel**' the optimization and manual adjustment of the parameters will be required.
   b. Use both the '**Autoset Parameters**' and '**Optimize Parameters**' functions on a new client. Use only the '**Optimize Parameters**' function on follow-up visits for an existing WalkAide user.

Figure 23 – Optimize Parameters screen.

3. A subset of the collected data may be selected for analysis by clicking in either the Heel or Tilt Sensor window and dragging the light pink zoom box over the "good" data (Figure 24). If selected first, the '**Autoset Parameters**' and '**Optimize Parameters**' buttons will set parameters based only on the selected data. (This may be appropriate for a client with limited walking abilities or an inconsistent walking trial that could not be repeated.)
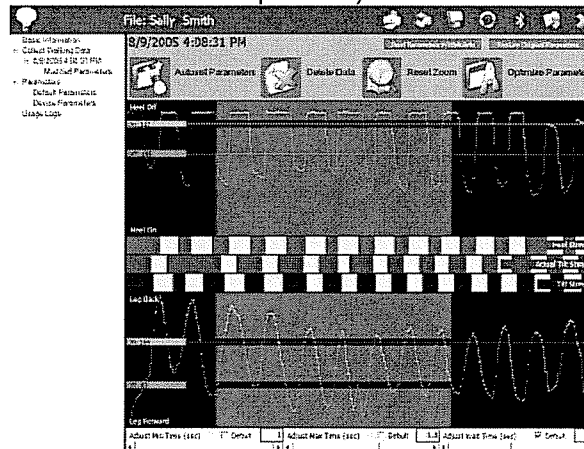

Figure 24 – Zoom screen.

4. Clicking in the middle panel will produce a vertical cursor that can be dragged while the mouse button is down and can be used to check alignment of displayed events. For example, the light blue stimulation bars for the tilt data will be slightly offset from the heel data as dorsiflexion should be initiated just after heel off and should be discontinued just after initial contact. Click the '**Reset Zoom**' button to return to the original data.

5. If the data set is relatively clean (i.e., no missed steps), the stimuli produced using both Tilt and Heel Sensors and their modified parameters will more or less line up with those actually delivered by the Hand Switch. Check in particular that there are few extra stimuli (extra light blue bars in the modified lines) or missed stimuli (absent light blue bars in the modified lines). If the fit is good, save the data in the client's file by clicking on the '**Save**' icon and naming the file or allowing it to overwrite the original file.
   a. The '**Adjust Min Time**', '**Adjust Max Time**' and '**Adjust Wait Time**' sliders are located at the bottom of the screen and allow fine-tuning of parameters. These control times are discussed below.

6. NOTE: The original data can be restored at any point to return to the parameter settings under which the data was collected. Click on '**Restore Original Parameters**' on the data analysis screen or '**Restore**' on the Modified Parameters screen.

7. Click on the '**Modified Parameters**' for the selected trial from the list on left side of the screen (Figure 25). Set the WalkAide Stimulation Mode to the appropriate setting (Tilt or Heel) and click on the '**Send to WalkAide**' icon. Click 'OK' to confirm. The new parameters associated with the client's previous walking trial have now been sent to the WalkAide.
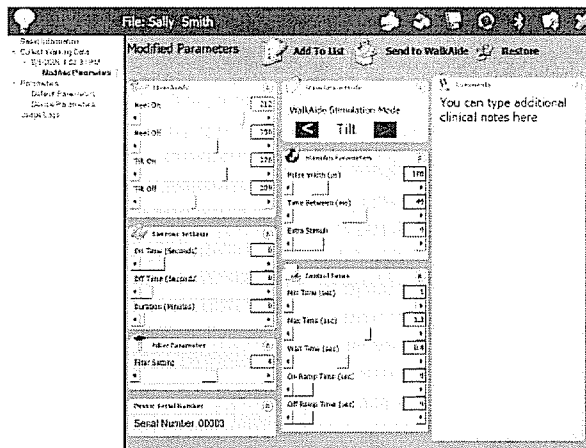

Figure 25 – Associated Parameters screen.

8. Click '**Add to List**' to store the final adjustments under '**Device Parameters**' at the left of the screen.

9. Turn '**OFF**' the WalkAide and disconnect the WalkLink. Turn '**ON**' the WalkAide and ask the client to walk again to verify that appropriate stimulation pattern produces safe and effective walking. The Heel Sensor may also be removed or left in the shoe for further use.

10. If both the clinician and the client feel that the timing of the stimuli is reliable and useful, then the unit can be sent home with the client. It may also be helpful to test the unit on a variety of surfaces (e.g., linoleum, carpets, ramps and stairs, etc.) before making this decision. If the stimuli are not reliable or helpful, the parameters can be further modified as described in the next section.

11. The client's data file should be saved after every data collection procedure to avoid accidental data loss. The data can always be removed later by using the '**Delete Data**' option.

12. For reference, the WalkAide device serial number will be automatically logged and noted in the '**Modified Parameters**' screen.

5.4   Manual Adjustment of the Stimulation Parameters

Manual adjustment of the parameters can be performed by adjusting thresholds and associated parameters. This process relies on the clinical judgment of the treating clinician.

ONLY use the manual adjustment feature if the pattern of stimulation is NOT desirable after applying the '**Autoset Parameters**' and '**Optimize Parameters**' options. Again, all data for any walking trial can be restored to the original state by clicking the '**Restore**' option.

From the 'Graphs' screen:
  1. The 'On' and 'Off' thresholds of the Heel and Tilt Sensors trigger the timing of the initiation and termination of the stimuli (Figure 26).

a. Stimulation occurs when the sensor value reaches the 'On' threshold.
  i. The 'On' threshold (solid green line) may be too high and the sensor value never reaches it. If this appears to be the problem, lower the threshold by clicking on the green line with the left mouse button and dragging it lower. When the button is released, the modified pattern of stimulation is calculated and displayed.
b. Stimulation terminates when the sensor value reaches the 'Off' threshold.
  i. The 'Off' threshold (solid orange line) may be too low. The value of the sensor must go below this line after one stimulus is complete to allow another stimulus to be generated. If this appears to be the problem, raise the threshold by clicking on the red line and dragging it up.
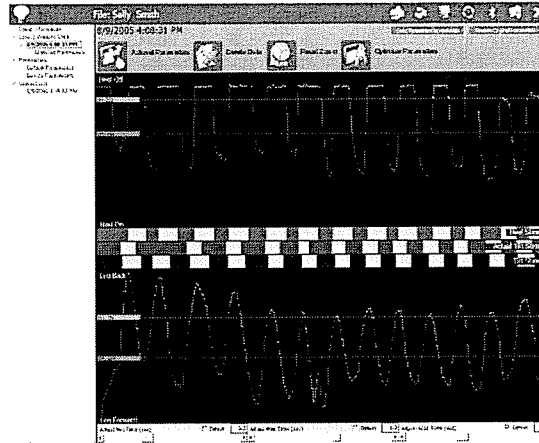

Figure 26 – Adjusting the 'On' and 'Off' thresholds.

c. The reason for having an 'Off' threshold as well as an 'On' threshold is to prevent extra, unwanted stimuli, but the difference between the two levels may be too great depending on the quality of the client's gait. **Also, ensure that the orange line is below the green line.**

2. The **Wait Time** is a specific period of time after each stimulus before a new stimulus can be initiated.
  a. The **Wait Time** may be too long. To avoid the subject getting stimuli too close together, there is a minimum time, known as the Wait Time, after each stimulus, before a new stimulus can be initiated. To see if this is the problem, click and drag the slider in the Wait Time display in the lower right hand part of the screen. Observe the changes in the alignment of the stimulation bars. The Wait Time decreases (or increases) in increments of 0.1s. *(This parameter can also be adjusted from the 'Modified Parameters' screen.)*

3. The **Min Time** sets the minimum period of stimulation that is allowed. (The Min Time always overrides the Max Time.) The **Min Time** ensures that stimulation continues for a sufficient duration that the toe clears the ground during swing phase. If the data from the sensor are noisy, values may occasionally exceed the **On Threshold** and then shortly thereafter go below the **Off Threshold**. That will turn off the stimulus after a period of time that is too small to be effective. To see if this is the problem, click and drag the slider in the '**Adjust Min Time**' display. The values again increase (or decrease) in increments of 0.1 s. *(This parameter can also be adjusted from the 'Modified Parameters' screen.)*

4. The **Max Time** sets the maximum period of stimulation that is allowed. For example, if the client sits down and unloads the Heel Sensor, the stimulus will be discontinued after the value set in **Max Time** has been reached. If during walking there are periods of stimulation that are particularly long, the '**Adjust Max Time**' can be decreased to reduce the period of stimulation. *(This parameter can also be adjusted from the 'Modified Parameters' screen.)*

5. If there are <u>extra periods of stimulation</u> (more than one period per step cycle) this could also be due to several factors:
   a. The **On Threshold** may be too low (and too quickly reached).
   b. The **Off Threshold** may be too high (too difficult for the sensor data to reliably cross).
   c. The **Min Time** may be too short.

<u>From the 'Modified Parameters' screen</u>:
1. Thresholds
   The thresholds can be best adjusted on the '**Graphs**' screen by moving the solid green (On) and solid orange (Off) lines to best capture the peaks and valleys of the stimuli. The threshold values will be automatically transferred to the '**Modified Parameters**' screen.
   a. **Heel On**
   b. **Heel Off**
   c. **Tilt On**
   d. **Tilt Off**

2. Exercise Settings – Discussed in detail below.

3. Filter Parameter (Figure 27)
   a. If the sensor signal is quite noisy (variable) so stimulation is unreliable; the '**Filter Setting**' can be increased. This will smooth any new data that are collected but will have no impact on any previously collected data. Increasing the filtering (smoothing) introduces some delays. Alternatively, if an earlier stimulus is desired and the data are not very noisy, the filtering may be decreased. The default setting is 4.
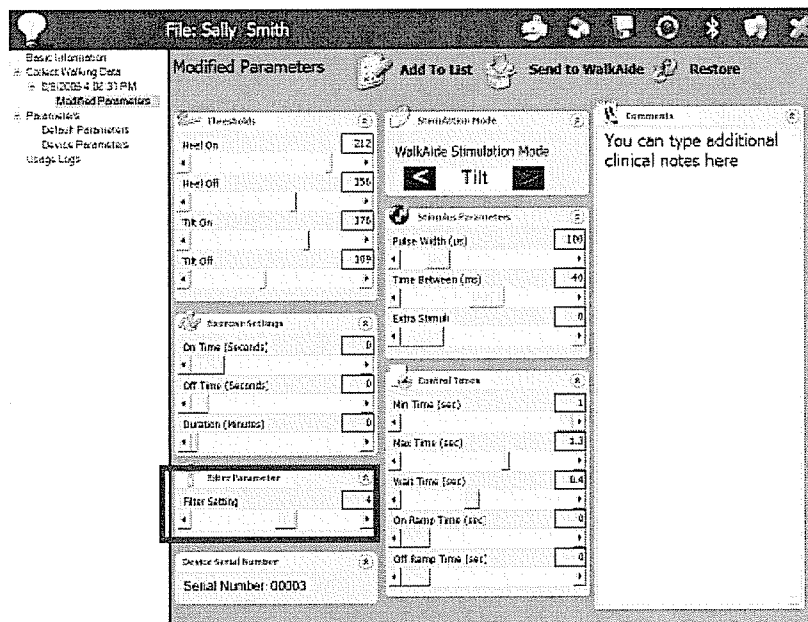

Figure 27 – Filter Setting.

4. Stimulus Parameters – These adjust the characteristics of the stimuli within the pulse train (Figure 28).
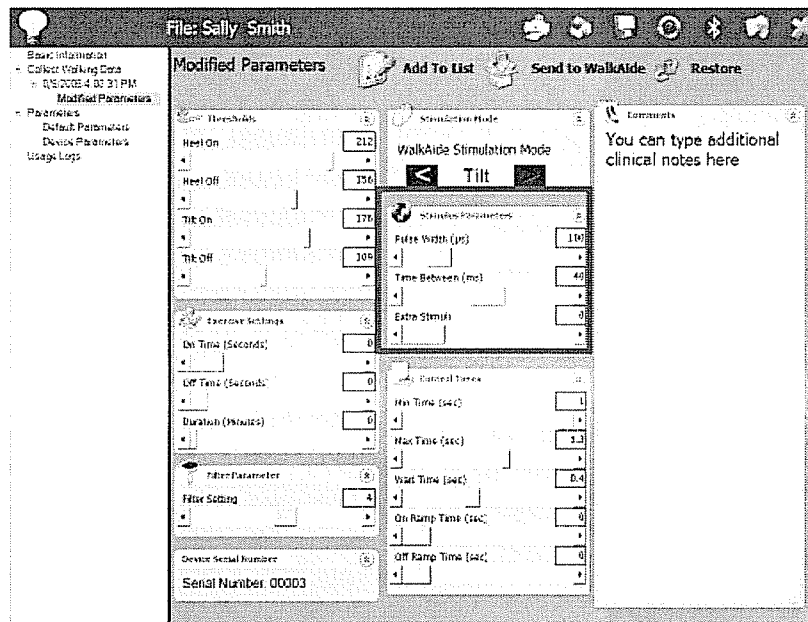
Figure 28 – Stimulus Parameters.

a. The '**Pulse Width**' is the duration of each stimulation within the pulse train and can be increased if the client's foot is not dorsiflexing quickly or strongly enough. Increase the '**Pulse Width**' to allow a lower stimulation intensity level to be used by the client. Decrease the '**Pulse Width**' if stimulation is uncomfortable even at lower stimulation intensity levels.

b. The '**Time Between (ms)**' stimuli is inversely proportional to the stimulus rate. A time of 50 ms represents a rate of 1 stimulus every 0.05 seconds, or 20 stimuli per second. The longer the time in between, the lower the rate. The goal is to have the lowest possible rate to minimize muscle fatigue while still having a smooth contraction. 40 ms (25 stimuli per second) is the default value. Decrease the '**Time Between (ms)**' to provide a more forceful and faster stimulation. Increase the '**Time Between (ms)**' to provide a less forceful and gradual stimulation.

c. The '**Extra Stimuli**' feature is essential when a "quick start" to motion is required. The extra stimuli will provide a faster increase in muscle force at the onset of stimulation (after the first and second pulses). This may be helpful for client's with faster walking speeds.

5. Control Times – These adjust the characteristics of the pulse train (Figure 29).
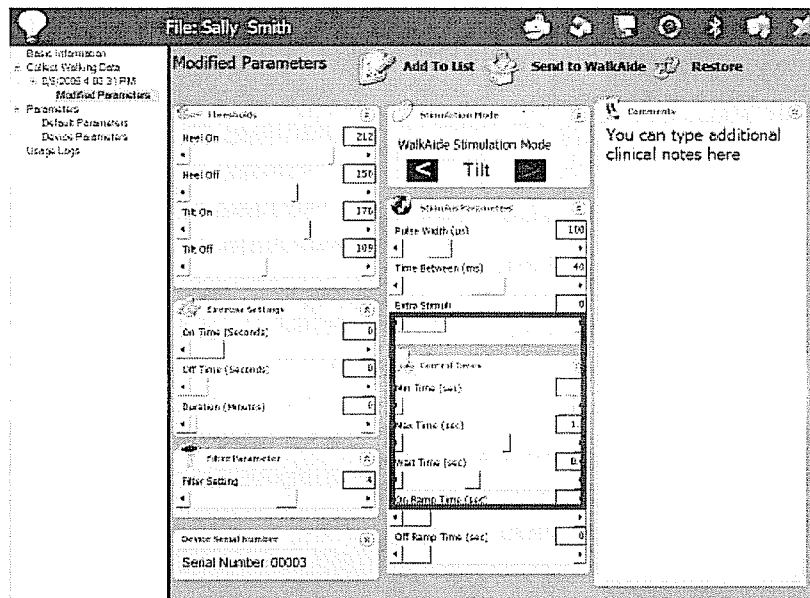
Figure 29 – Control times.

a. The **Min Time (sec)** ensures that stimulation continues for a sufficient duration that the toe clears the ground during swing phase. If the data from the sensor are noisy, values may occasionally exceed the **On Threshold** and then shortly thereafter go below the **Off Threshold**. That will turn off the stimulus after a period of time that is too small to be effective. To see if this is the problem, click and drag the slider in the **Min Time** display. The values again increase (or decrease) in increments of 0.1 s. *(This parameter can also be adjusted from the 'Graphs' screen.)*

b. The **Max Time (sec)** sets the maximum period of stimulation that is allowed. For example, if the client sits down and unloads the Heel Sensor, the stimulus will be discontinued after the value set in **Max Time** has been reached. If during walking there are periods of stimulation that are particularly long, the **Max Time** can be decreased to reduce the period of stimulation. *(This parameter can also be adjusted from the 'Graphs' screen.)*

c. To avoid the subject getting stimuli too close together, there is a minimum time, known as the **Wait Time (sec)**, after each stimulus, before a new stimulus can be initiated. To see if this is the problem, click and drag the slider in the Wait Time display in the lower right hand part of the screen. The Wait Time decreases (or increases) in increments of 0.1s. *(This parameter can also be adjusted from the 'Graphs' screen.)*

d. The **On Ramp Time (sec)** controls the rate of onset or the rise of the initial stimulation level from zero to its set value. Use this to increase or decrease the rate of dorsiflexion of the foot after terminal stance. Increasing the time for ramping "on" the stimulation will result in more gradual dorsiflexion and may be helpful for clients with clonus or spasticity.

e. The **Off Ramp Time (sec)** controls the rate of the fall of the stimulation from its set value to zero. Use this to control foot slap or the rate of plantarflexion during initial contact. Increasing the time for ramping "off" will result in more gradual plantarflexion.

Once the new parameters and the method of stimulation (e.g., Heel or Tilt) are selected, click on '**Send to WalkAide**' icon. Always check '**Device Parameters**' after sending updated values. This will ensure that the values in the WalkAide have been modified and will be saved in the client's folder. The updated parameters can then be tested with the client and new data can be collected for further analysis.

5.5 Exercise Parameters

1. First, click on '**Parameters**' from the list on the left side of the screen (Figure 30).

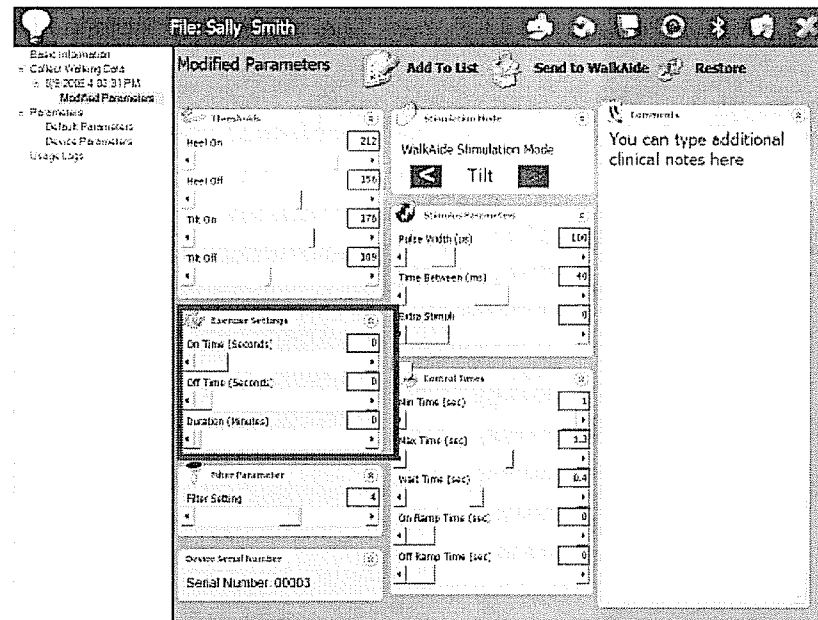2. Click on '**Device Parameters**' to retrieve the current settings.

Figure 30 – Exercise Settings.

3. Under '**Exercise Settings**', use the mouse to drag the scroll bar in order to adjust the '**On Time**', '**Off Time**' and '**Duration**' that are suitable for the client.

4. The ranges of the '**On Time**' and '**Off Time**' are 0-10 sec, whereas the duration is from 0-30 minutes.

5. Click '**Send to WalkAide**' in order to store the new parameters in the WalkAide unit. It is also a good idea to save the modified parameter file for future reference.

Once seated with the leg supported, the client may now activate the exercise mode on the WalkAide unit by pressing and holding down the small blue '**Stim**' button labeled '⟶⏎' for 3 seconds until the indicator light flashes off briefly. This will start the intermittent stimulation using the stored Exercise Settings. Exercise will end once the time set under '**Duration**' is reached. In order for the WalkAide unit to be functional again, it must be turned 'OFF', then back 'ON'. Turning off the unit will terminate the exercise mode sooner.

5.6 Usage Log

1. Click on '**Usage Logs**' listed on the left side of the screen (Figure 31). Click on the '**Get WalkAide Log**' icon to retrieve the information and then click 'OK' once the information has been retrieved.
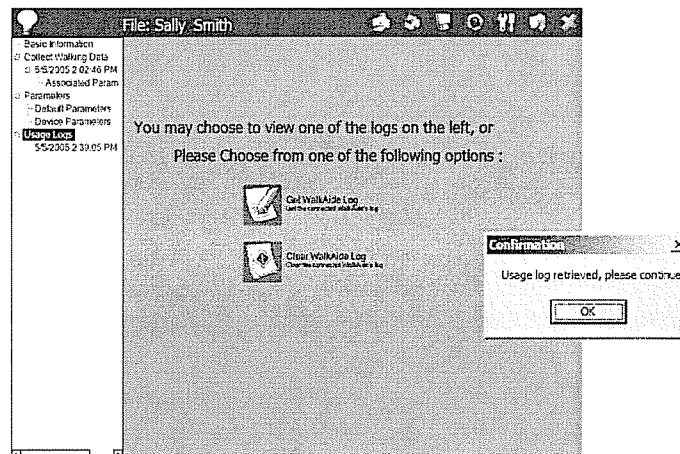

Figure 31 – Get WalkAide Log.

2. Under 'Usage Logs' on the left of the screen, click on the appropriate date/time of the most recent file downloaded.

3. In the 'Graphical View', two sections of bar graphs will appear (Figure 33). The top blue bar graph shows the **total hours of stimulation each day** while the bottom red bar graph shows the **total number of stimuli per day**. The stimuli from the exercise mode are <u>NOT</u> included. If desired, the vertical sliders on the left of the graphs may be used to change the scale of the graphs by dragging it up and down. This would be used in the event that the graph was either too small to be readable or contained bar graphs that reached the top of the displayed information.
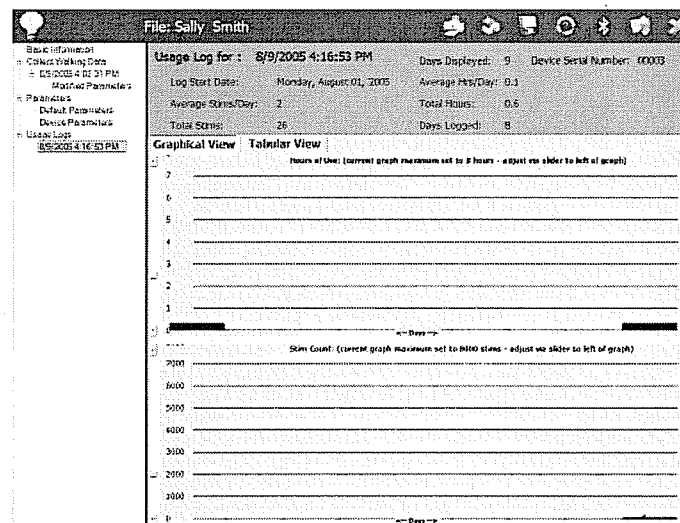

Figure 32 – Usage Log Graph screen.

4. In the 'Tabular View', the days, hours and stimulation count are listed in a chart (Figure 33).
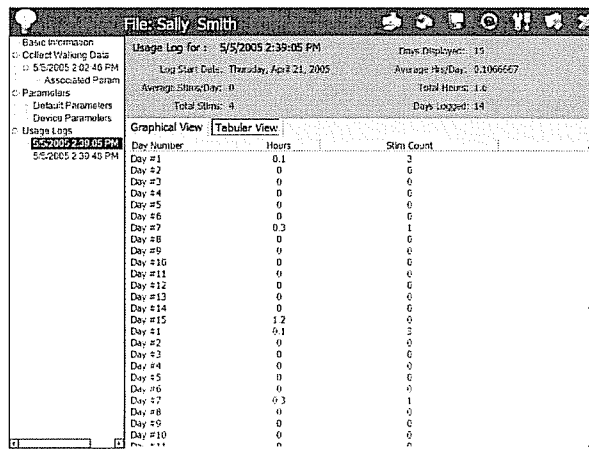
Figure 33 – Usage Log Tabular View screen.

5. A report of the walking trial or usage log may be printed (Figures 34 and 35). Click on the '**Print**' icon in the upper right corner of the screen. Select any one of the walking trials to print a report showing the data analysis screen and modified parameters. Select any one of the usage logs to print a report showing the graphical and tabular view screens.

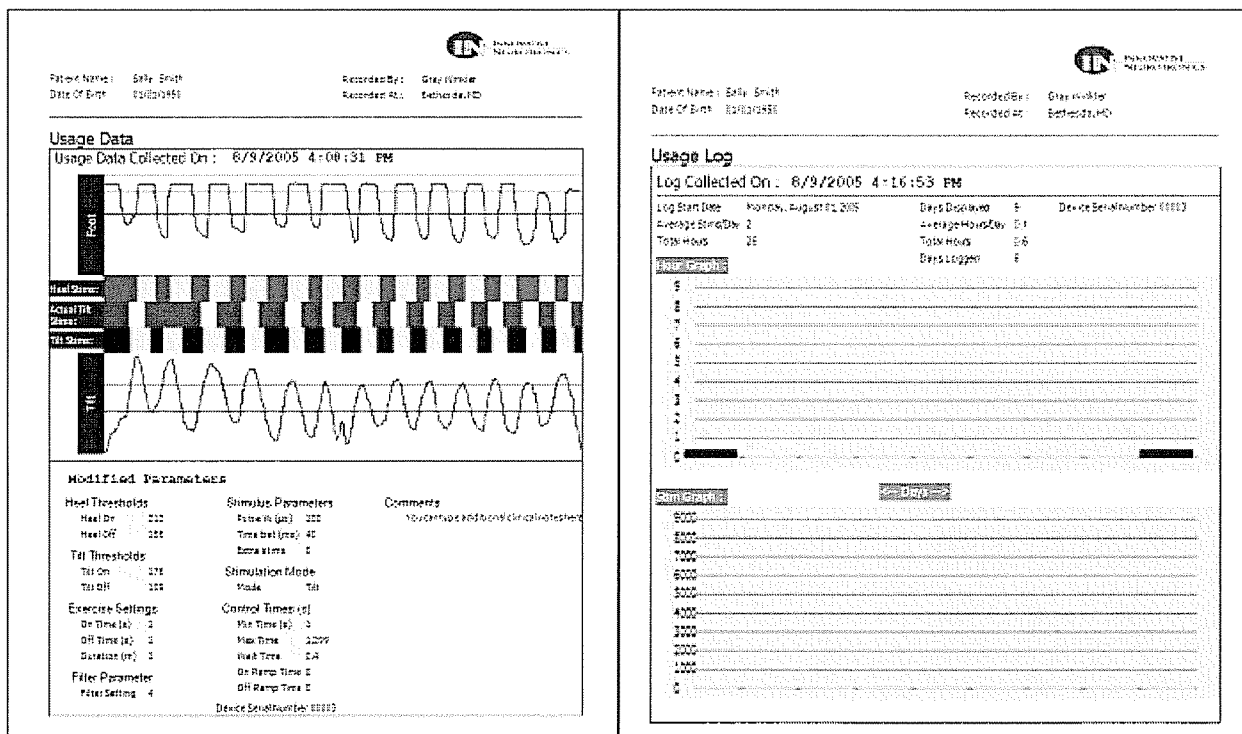**Fig 34 and 35 – Usage Log Reports**

6. Click on '**Usage Logs**' again and then click on the '**Clear WalkAide Log**' button to reset the WalkAide unit log file so it can keep the log for the next month. The log will collect data for up to 72 days.

5.7   Additional Information

1. A stimulus may be produced when connecting or disconnecting the WalkLink or the Heel/Foot Sensor from the WalkAide unit. **Always turn the WalkAide unit 'OFF'** before connecting or disconnecting any accessories.

2. Zoom feature: When in the **Graphs** screen, place cursor at the beginning of the desired data, press and drag the cursor to the end of the desired data. This will zoom into the selected data. To return to the entire data click on the '**Reset Zoom**' button at the top of the screen.

3. It is a good idea to retrieve and save the parameters and usage log from the WalkAide unit each time the client returns for follow-up. This allows the parameters to be easily restored if needed and documents the usage of the WalkAide.
   - ▢ Click on '**Device Parameters**' and then click on '**Add to List**' at the beginning of each visit.
   - ▢ Click on '**Usage Log**' and then click on '**Get WalkAide Log**' at the beginning of each visit.

4. It may be necessary to modify the parameters each time the client is seen, especially during the early periods of recovery. The walking trials with the Hand Switch can be performed or manual adjustments made to the WalkAide parameters. However, DO NOT send new parameters back to the WalkAide unless the previous parameters have been saved.

6.0   Use and Care of the WalkAide and Accessories

Cleaning the WalkAide - The client should use a damp cloth and a mild detergent to wipe any stains off the WalkAide unit.

Washing the Cuff - The WalkAide control module and electrodes must be removed from the cuff. The plastic insert and cuff can be machine washed in COLD water only. HANDWASHING is recommended to extend the life of the material. The cuff should then be hung to dry and NOT placed in a dryer.

Storage - The WalkAide system should be stored in a resealable plastic bag in an area where temperatures do not exceed 120 degree F or fall below 40 degrees F. The electrodes should be covered with the plastic backing when not in use. This will keep them from drying out.

Battery - If the WalkAide is to be stored for an extended period of time and not used, remove the battery from the battery compartment.

Transport - The WalkAide, WalkLink and accessories should be kept in their respective storage cases whenever shipping or transporting to prevent damage. The cuff and electrodes should be kept in sealable plastic bags to prevent damage to the cuff and drying out of the electrodes.

7.0   Troubleshooting Problems

1. **Lightbulb shows black in WalkAnalyst program despite the cable connections at both the laptop and the WalkAide unit.**
   Possibilities:
   - There is a loose connection.
   - The WalkAide is not turned on.
   - The WalkAide battery needs replacing if pressing down on the '**Stim**' button on the unit does not show a red-green light.
   - The WalkLink is not charged.
   - The Belkin USB Bluetooth Adapter is not properly seated.

2. **No stimulation despite the amber light when pressing the 'Stim' button on the WalkAide unit.**
   Possibilities:
   - Check the electrode leads to ensure that they are not broken.
   - Replace self-adhesive electrodes or enhance contact with water or gel.

3. **Intensity of the stimulation is weaker at the same setting.**
   Possibilities:
   - WalkAide battery is weak.
   - The cuff may need to be shifted as the electrode placements are slightly off.
   - Wet the electrodes and/or skin to improve conduction.

4. **Occasional sharp stimuli.**
   Possibilities:
   - The cuff is not adequately tightened causing it to shift with motion. Ensure proper positioning of cuff and tighten the strap. Avoid tight, slim-fitting pants.
   - Check skin under electrodes for open areas.
   - Press firmly over each electrode to ensure total contact with skin.

5. **Red light is flashing with 4 beeps every two seconds.**
   Possibilities:
   - Indicates a fault has occurred in the control module. Turn 'OFF' the light blue intensity knob by turning counter-clockwise to "0". Wait 5 seconds and then turn 'ON' again to see if the green light if flashing. If the red light remains lit, the WalkAide unit must be returned to Innovative Neurotronics for repair or replacement.
   - Contact Innovative Neurotronics at 888-88ININC (888-884-6462) for shipping instructions.

6. **Red light is flashing with an audible beep every minute**
   Possibilities
   - Low battery condition. Change the battery

7. **Red light flashing with audible 2 beeps every two second**
   Possibilities:
   - If the unit beeps two times every two seconds, you may be in 'Heel' mode. When in 'Heel' mode, the Heel or Foot Sensor must be connected to the unit.
   -

8. **Red light is flashing with no audible alarm**
   Possibilities:
   - Time clock in the WalkAide unit for usage log has stopped working. Need to reset the WalkAnalyst program to 'Clear WalkAide Log'.
   - Time clock battery needs replacing. Send back to Innovative Neurotronics.

9. **The green light does not flash when the WalkAide is turned 'ON'.**
    Possibilities:
    - Make sure the light blue intensity knob is turned to "1" or higher. There will be a clicking noise when the knob is turned from "0" to 'ON'.
    - A new battery may be needed.

8.0   WalkAide User Instructions

Additional information on safety considerations, skin care, operating instructions and changing batteries is included in the WalkAide User Instructions. Please read this information and review it with each client as needed.

9.0   Technical Information – Specifications

Size	3.2"(H) x 2.4" (W) x 0.81" (T)
Weight	3.09 ounces
Power Source	One 1.5 Alkaline AA battery
Maximum Current	115 mA at 500 ohm; 78 mA at 1 K ohm
Maximum Voltage	78 V at 1 K ohm; <150 ohm at 1 M ohm
Number of Modes	1
Number of Channels	1
Pulse Type	Asymmetrical Biphasic
Pulse Width	50-250 microseconds (Adjustable)
Maximum Stimulation Period	5 second
Stimulation Trigger Source	Tilt or Heel Sensor
Controls and Indicators	See Figures 4 and 5

Contact Information

If further assistance is required, please contact:
Innovative Neurotronics, Inc.
2 Bethesda Metro Center, Suite 1200
Bethesda, MD 20814
888-88 ININC or 888-884-6462