The WalkAide® System

Clinician Manual

INDEPENDENCE
one step at a time

INNOVATIVE NEUROTRONICS

Caution: USA Federal Law restricts this device to sale by or on the order of a physician.

INNOVATIVE NEUROTRONICS

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INNOVATIVE NEUROTRONICS

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1.0 Introduction

The WalkAide is a battery-operated, single-channel electrical stimulator that can be used for functional electrical stimulation (FES). It utilizes a Tilt Sensor and accelerometer to control the timing and duration of the stimulation during walking. A Hand Switch on the WalkLink is used by the clinician during set-up to manually trigger stimulation while the Heel Sensor collects additional load bearing data (Figure 2-3). The clinician uses the WalkAnalyst software on a laptop computer to program the Tilt Sensor in the WalkAide. Use of the Tilt Sensor to trigger stimulation eliminates the need for additional components and external wires from a Heel Sensor during regular use.

The WalkAide produces controlled dorsiflexion of the foot during the swing phase of gait. This small medical device attaches to a molded cuff located just below the knee. Two electrodes are specifically placed near the head of the fibula, directly over the motor nerve and proximal musculature. During the gait cycle, the WalkAide stimulates the common peroneal nerve which innervates the tibialis anterior and other muscles that produce dorsiflexion of the ankle. Users of the WalkAide are people who have lost the ability to voluntarily lift their foot during walking, often as a result of damage to the central nervous system from conditions such as stroke, incomplete spinal cord injury, traumatic brain injury, cerebral palsy and multiple sclerosis. This type of stimulation will not work for people who have damage to the lower motor neurons/peripheral nerves.

Figure 1: The WalkAide is a functional electrical stimulator designed for people with foot drop

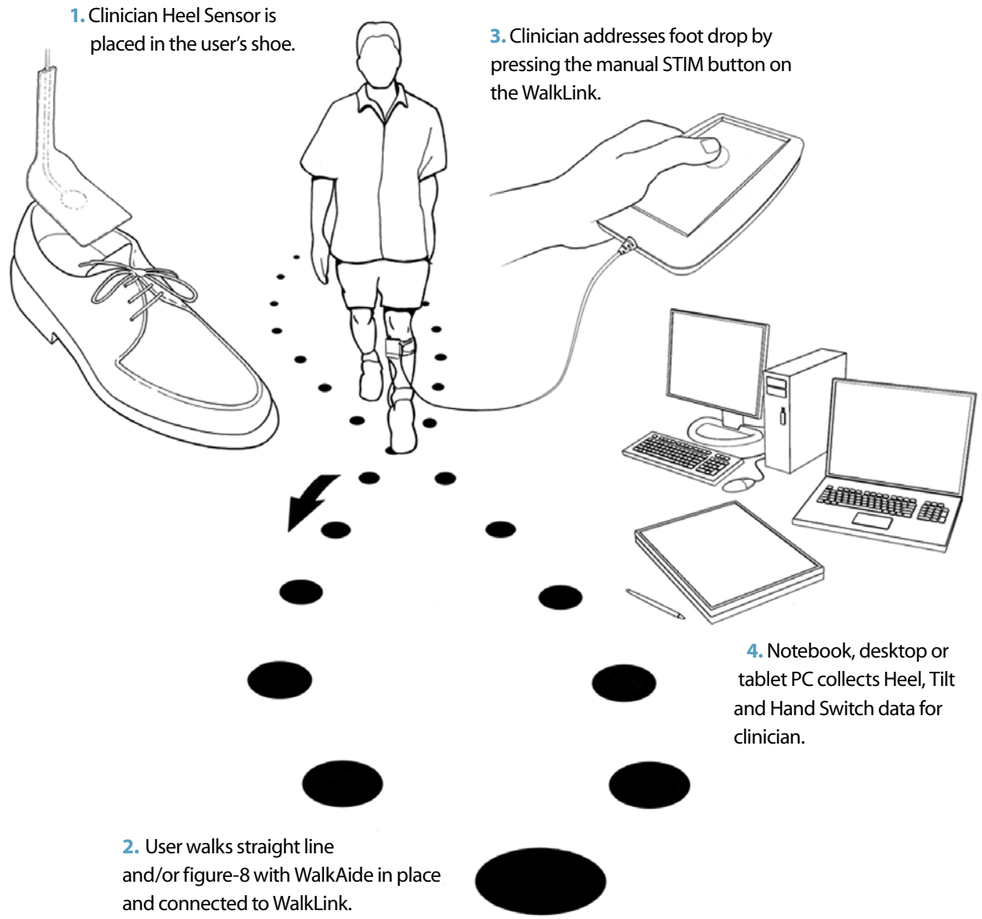


Figure 2: Initial WalkAide set-up procedure using the WalkLink, Heel Sensor and WalkAnalyst software.

1.1 Indications of Use

The Innovative Neurotronics WalkAide System is intended to address foot drop for people who have sustained damage to upper motor neurons in the brain or the spinal cord. During the swing phase of walking, the WalkAide electrically stimulates the common peroneal nerve to control the muscles that create ankle dorsiflexion and may thus improve the user's walking ability. Medical benefits of functional electrical stimulation may include a decrease in muscle disuse, decreased muscle weakness, increased local blood flow, improved muscle strength and voluntary motor control, increased joint range of motion, and enhanced function of the corticospinal pathways resulting in improved lower limb control.

1.2 Contraindictions

- Do not use on persons with implanted demand type cardiac pacemakers or defibrillators.
- Do not place the electrodes in the carotid sinus region (throat). Laryngeal or pharyngeal spasms may occur when the electrodes are placed across the throat or in the mouth.
- Do not place the electrodes over malignant tumors.
- Do not place the electrodes over areas in which symptoms of existing thrombosis are present.
- Do not use if person has a history of seizure disorder.

1.3 Warnings About FES

Monitoring Equipment—The use of FES may interfere with the proper functioning of electronic monitoring equipment such as EKG machines. However, the operation of the FES device will not be affected by the use of electronic monitoring equipment.

MRI—The WalkAide should not be worn while receiving any MRI scan.

Electrodes—The use of electrodes not supplied by Innovative Neurotronics may diminish results or increase risk of burns or discomfort. Do not place electrodes over open wounds, broken skin or metal objects beneath the skin such as surgical staples.

Pregnancy—The safety of FES for use during pregnancy has not been established.

Hospital Equipment—Do not use simultaneously with high frequency hospital equipment (e.g. diathermy equipment). It may result in burns at the site of the stimulator electrodes and possible damage to the stimulator.

Skin Irritation—Improper or prolonged use of electrodes may result in increased risk of skin irritation or burns and decreased effectiveness. Infrequently, there is an allergic response to the electrode adhesive or gel. Do not place electrodes on skin that is already irritated as this will increase the risk of discomfort with stimulation and the risk of further skin irritation or burns.

Medical Supervision—FES should only be used under the medical supervision of a physician and a qualified clinician.

Two-Way Radios—Care should be taken while using FES therapy in close proximity (e.g. less than 1 meter) to devices which emit radio frequencies such as cellular phones or two-way radios as some types of transmitters may cause undesirable stimulation to the user.

Defibrillator—External defibrillation of a person wearing a FES device can damage the device or injure the user even when the device is turned off. Under some circumstances there may be risk of burns under the electrode sites during defibrillation. To eliminate any risk, the FES electrodes should be removed before defibrillation paddles are applied.

Chronic Stimulation—Effects of long term chronic stimulation are unknown in this particular application.

1.4 WalkAide Specific Warnings

Walking—Care should be taken when using the WalkAide for people who experience dizziness or have difficulty maintaining balance. The WalkAide is not designed to prevent falling. Assess user's condition for inability to walk or balance.

Electrodes—The user should not relocate the position of the electrodes within the cuff. Do not use the WalkAide without electrodes.

Placement—Never use the WalkAide on any area of the body other than the leg.

Stimulation—Stop using the WalkAide if stimulation does not come on at the appropriate time when walking and/or there is a change in the sensation perceived while the stimulation is on.

Environment—WalkAide and WalkLink are not intended for use within flammable environments such as oxygen and anesthetics.

Impact—Care should be taken to prevent excessive impact to the WalkAide Control Module. This includes standing or kneeling on the unit, or impact from any hard surfaces.

WalkLink

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

2. **FCC Radiation Exposure Statement for Portable Devices**
   This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment is in direct contact with the body of the user under normal operating conditions. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

3. The user is cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

1.5 Precautions

Heart Disease—Use caution in applying electrical stimulation to persons suspected of having heart disease. More clinical data is needed to show that such persons will not experience adverse results.

Sensory Deprivation—Use caution when placing electrodes on areas of the skin with reduced response to normal sensory stimuli, due to the risk of skin burns.

Children—FES devices should be kept out of the reach of children.

Epilepsy—Use caution in applying electrical stimulation to persons suspected of having epilepsy. More clinical data is needed to show that such a person will not experience adverse events.

Recent Surgery—Do not use FES following recent surgery where muscle contraction may disrupt the healing process.

Electrodes—Do not use lotion or oil in the area that the electrodes make contact with the skin. Stimulation may not be effective.

Proper Use—The safety and efficacy of FES depends on the proper use and handling of the FES system. Improper use of the device or electrodes can result in injury to the user. Regularly check accessories for wear and replace as needed. Electrodes should be firmly secured to the skin. Never use the WalkAide if it appears to be malfunctioning. If there is a change in the way it usually works (i.e. change in sensation, surging of stimulation, intermittent stimulation) do not use the WalkAide and contact Innovative Neurotronics immediately.

Operating Equipment—The stimulator should not be used while operating potentially dangerous equipment such as automobiles, power lawn mowers or large machinery. Abrupt changes in stimulation level could create a hazard.

Sleeping—The WalkAide should not be worn or used while sleeping or bathing.

Heat and Cold—The use of heat or cold producing devices such as electric blankets, heating pads or ice packs may affect the electrodes or the person's circulation and increase the risk of injury. A medical doctor and clinician should be consulted before using with FES.

1.6 Regulatory Information

FDA is the regulatory agency that governs the process of testing and approval of medical devices. The WalkAide has been classified as a Class II medical device, requiring FDA 510(k) clearance of device safety prior to marketing. Innovative Neurotronics submitted the 510(k) to FDA including extensive testing and design data, and received clearance to market the WalkAide on 09/21/05.

1.7 Adverse Reactions

Skin irritation and burns beneath the electrodes have been reported with the use of nerve stimulators. Do not leave the electrodes in place for long periods of time without checking or cleaning the skin underneath them. It is normal to observe somewhat reddened areas under the electrodes immediately following use; however, the redness should disappear within an hour. Signs of irritation are maintained redness, small pimple-like lesions or blisters. DO NOT continue stimulation over irritated skin. Notify the medical doctor if these conditions persist and and discontinue use of the WalkAide until the problem is resolved.

1.8 Cautions

Functional electrical stimulation is the process of using electrical stimulation to produce a muscle contraction during a dynamic activity, such as walking. Basic rules of FES use include:

1. **ALWAYS** use the WalkAide under the specific instruction of an experienced clinician.
2. **NEVER** use the WalkAide in a situation where an unexpected or unusual stimulus may occur, such as driving or operating motorized equipment.
3. **DO NOT** use the WalkAide if the equipment is not operating properly.
4. **NEVER** use the WalkAide unit with frayed or broken leads.
5. **ALWAYS** handle the unit carefully…do not expose the unit to water, excessive heat or vibration.
6. **DO NOT** place electrodes anywhere other than on one leg below the knee.
7. **AVOID** excessive impact, dropping or kneeling on the WalkAide unit. Although robustly designed, damage may occur that could cause the unit to malfunction.
8. The WalkAide should **ONLY** be used with approved accessories and electrodes.
9. **DO NOT** open the unit other than to replace the battery. The WalkAide has no user or clinician serviceable parts inside the control module enclosure.
10. **TURN OFF** the unit if sitting for an extended period of time.

1.9 Glossary

Term	Definition
Autoset WalkAide Parameters	This calculation process attempts to adjust the threshold settings to more closely match the individual data collected.
Audiable Beep	Optional Biofeedback Feature. Audible signal can be activated to indicate when the stimulus is on.
Collect Walking Data	Collects walking data from the Heel Sensor, Hand Switch and/or Tilt Sensor during: (1) initial data collection procedures, (2) programmed walking trials in either Tilt or Heel mode, and (3) follow-up walking trials for confirmation of effective walking programs or re-optimization.
Collected Logs	Saved Usage Logs listed as date and time stamped events.
Comments	Allows the clinician to document clinical notes in the user's electronic file.
Control Times	Adjust the duration of the stimulation (Min and Max Times); pausing of the stimulation (Wait Time); and initiation and termination of the stimulation (Ramp On, Ramp Off).
Cuff	Pretibial shell that attaches to the leg and is used to hold the electrodes and the WalkAide control module in the correct position.
Default Parameters	A pre-determined set of parameters that must always be sent to the WalkAide before collection of initial walking data for a new user.
Delete	Deletes entire walking trial.
Discard this Walking Data and Begin Again	Deletes current walking trial and returns to the Collect Walking Data screen for collection of another walking trial.
Exercise Mode	Allows the user to repeatedly stimulate the lower leg while the user is resting (NOT walking) for a set period of time as determined by the clinician.

Term	Definition
Exercise Settings	Allows the clinician to adjust the ON time, OFF time and duration of the Exercise Mode function for the individual user.
Filter Parameter	A calculation function that attempts to smooth 'noisy' data; and can also delay or accelerate the onset of the stimulation. Filter parameters need to be applied prior to collecting walking data.
Functional Electrical Stimulation (FES)	A method of applying a low level of electrical impulses to the motor nerve to activate dysfunctional muscles and produce intentional and useful movement.
Hand Switch	A function of the WalkLink whereby pressing the STIM button on the WalkLink sends a command to the WalkAide unit to provide stimulation when the WalkAide is programmed in Hand Mode.
Heel and Foot Sensors	There are two types of load bearing sensors: (1) The clinician Heel Sensor is used during data collection and analysis while testing a potential WalkAide user. (2) The optional full-length Foot Sensor is sent home with users whose gait pattern does not provide sufficient tilt information to reliably trigger the stimulation with the Tilt sensor.
Modified Parameters	Walking parameters that are associated with or derived from the WalkAide unit, Heel Sensor and/or Hand Switch after data collection and processing have occurred (e.g. Zoom, Autoset, Optimize, or manual adjustments).
New File	Creates a new file for a new user.
Open File	Opens an existing file for an existing user.

Term	Definition
Optimize Gait Program	Function of the WalkAnalyst software that computes features of the collected walking data and attempts to configure the ON and OFF thresholds and other parameters to optimize the timing and duration of the stimulation for the individual's gait.
Params as Collected	Walking parameters that are associated with or derived from the WalkAide unit (Tilt Sensor, Heel Sensor and/or Hand Switch) during data collection and analysis.
Peripheral Nerve Stimulator	Determines the viability of the nerve to muscle pathway and allows accurate location of the peripheral nerves, specifically the superficial and deep branches of the common peroneal nerve, for placement of electrodes.
Primary Information	Documents specific information as part of the individuals electronic file: First name, Last name, Date of Birth, Recorded by and Location.
Rapid Adjustment	Settings that allow Rapid Follow-Up-Fine adjustments.
Rapid Programming	Rapid data collection and programming. Default settings are Tilt mode.
Reset Parameters to 'As Collected'	Returns thresholds and control times to the original values. Located on the graph screen; reverses the Autoset / Optimize and manual functions.
Reset WalkAide Log	Resets the "Hours Per Day" and "Stims Per Day" tracking functions.
Reset Zoom to see all Data	Reverses Zoom function, returning to the original data set and entire walking sequence.
Retrieve WalkAide Log	Allows clinician to download most current Usage Log, up to 72 days of "Hours Per Day" and "Stims Per Day" information.
Restore Original	Reverses Autoset / Optimize functions and manual adjustments, returning thresholds and control times to original values.

Term	Definition
Save and Analyze this Walking Data	Function that saves and adds the current walking trial as a date and time stamped event under Collected Walking Trials.
Save this Data and Collect More Walking Data Now	Function that saves and adds the current walking trial as a date and time stamped event under Collected Walking Trials, and returns to the Collect Walking Data screen for collection of another walking trial.
Save WalkAide Settings	Saved WalkAide settings listed as date and time stamped events.
Send Parameters to WalkAide	On the walking data graph screen, allows the clinician to send parameters to the WalkAide unit using the WalkAnalyst software and Bluetooth connection.
Send Params	On the Modified parameters screen, allows the clinician to send parameters to the WalkAide unit using the WalkAnalyst software and Bluetooth connection.
Start Collecting Walking Data	Function of the Collect Walking Data process that initiates data collection.
STIM	Abbreviated form of the word stimulation.
Stimulation Mode	Allows the clinician to select from Heel, Hand or Tilt to trigger the stimulation during walking.
Stimulus Parameters	Allows the clinician to adjust the characteristics of the pulses within the stimulus train. Adjustments include Pulse Width, Time Between and Extra Stimuli functions.
Stop Collecting	Function that terminates data collection.
Walking Data Thresholds	Determine the timing of the initiation and termination of the stimulation for either the Heel or Tilt sensors.
Usage Logs	Collects WalkAide usage information, specifically Hours Per Day and Stims Per Day, for the most recent 72 days of walking activity.

Term	Definition
WalkAide	A battery-operated, single channel electrical stimulator that can be used for both therapeutic and functional electrical stimulation.
WalkAide Diagnostic Codes	Six digit readout indicating WalkAide System hardware's internal status / fault.
WalkAide Parameters	Walking parameters currently programmed into the WalkAide unit.
WalkAide Serial Number	Automatically logs and registers the serial number from the WalkAide unit on the WalkAide Parameters screen. The serial number can also be found in the battery compartment of the WalkAide.
WalkAnalyst	Software used by the clinician to interface with the WalkAide unit. This allows data collection, analysis and parameter modification in order to correctly time the applied stimulation to the user.
WalkLink	Provides wireless connection between WalkAide and computer, and also allows manual stimulation during walking trials via Hand Switch.
Zoom Feature	Allows clinician to focus on specific data by highlighting a sequence of consecutive steps with the stylus or mouse.

2.0 Equipment

2.1 Clinician Kit

The **Clinician Kit** consists of the WalkLink, WalkLink Cable, Heel Sensor, Bluetooth adapter, peripheral nerve stimulator, WalkAnalyst software, and the WalkAnalyst System Clinician Manual (Figure 2). The WalkLink requires four (4) AA batteries and the peripheral nerve stimulator requires a 9-volt battery to operate.)

Figure 3: WalkAide Clinician Kit

It is recommended to have a computer that meets or exceeds the following requirements:

- 1.5 GHz processor
- 512 MB RAM (XP) / 1 GB RAM (Windows Vista or Windows 7)
- 200Mb free hard drive space
- XGA (1024x768) video
- One free USB port for Bluetooth Adapter
- Windows XP Professional or Home with SP2/SP3, Windows Vista, or Windows 7

2.2 Patient Kit

The Patient Kit consists of the WalkAide Control Module, WalkAide Electrode Lead Cable, WalkAide Electrodes (pkg. of 4) and WalkAide User Manual. An appropriately sized WalkAide Cuff is ordered separately and the full-length Foot Sensor is an optional item. (Figure 3) The WalkAide requires a single AA battery. Only AA alkaline (1.5 V) batteries should be used and extra batteries should always be available during follow-up appointments.

Figure 4: WalkAide Patient Kit

2.3 Demo Kit

The **Clinician Demo Kit** consists of the same equipment found in the Patient Kit. However, the serial number of the WalkAide unit is listed and tracked as a demo unit. It can be used for trial walking on any number of patients but cannot be sold to a patient as it becomes a used medical device. (Figure 3)

2.4 WalkAide Bi-Flex Cuff

The WalkAide is designed for single-handed application and removal. It may take a bit of practice to develop a routine that works best for each person. The WalkAide is applied directly to the leg and can be easily worn under most clothing. The clinician will find the optimal placement of the electrodes on the initial visit. The electrode placement will be marked on the inside of the cuff via Red and Black Electrode Locators and the position should not be moved by the patient.

Figure 5

Figure 6

The cuff must be positioned on the leg correctly to achieve effective and efficient stimulation. Use the Orange visual indicator as a reference for accurate placement of the cuff. Only use the latch to secure and remove the WalkAide. The Velcro strap is adjusted to an optimal level by your clinician at the initial visit and should not be altered.

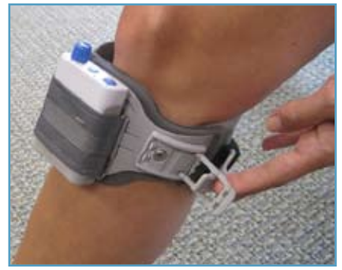


Figure 7

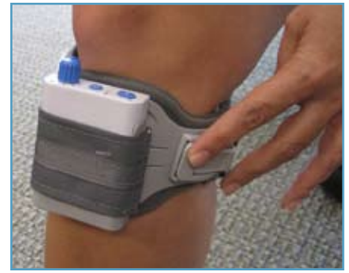


Figure 8

For proper skincare and maximum effectiveness, the electrodes should be replaced every 1 to 2 weeks or immediately upon excessive visible wear. When replacing the electrodes, be sure NOT to alter the placement of the Black and Red Electrode Locators.

Disconnect the black and red leads between the WalkAide and the electrodes then remove the electrodes from the Electrode Locator. Place new electrodes on the Electrode Locators and feed the leads through the holes toward the outside of the cuff. The **BLACK** lead is connected to the electrode on the **BLACK** Electrode Locator. The **RED** lead is connected to the electrode on the **RED** Electrode Locator. Feed the excess wires in the strap pouch as indicated in the image below.

Figure 9

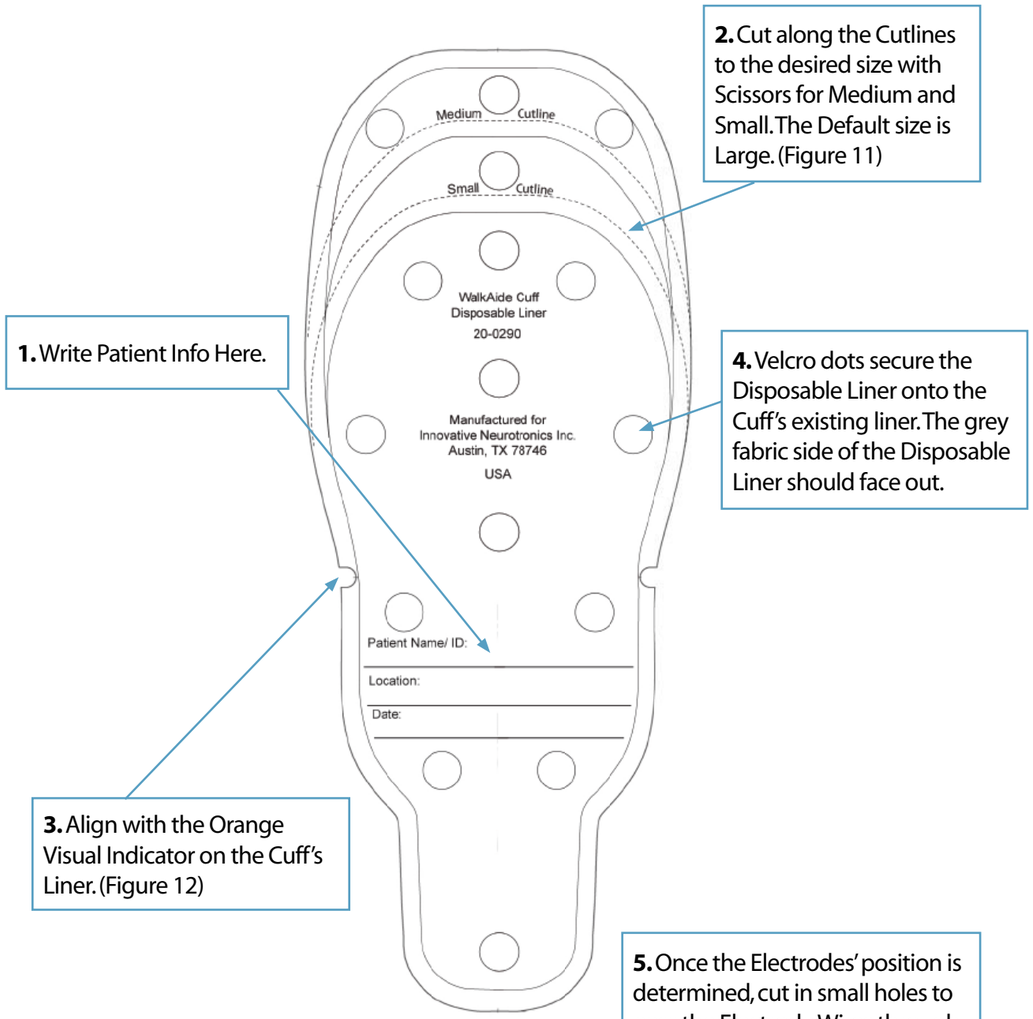
Figure 10

Washing Instructions: To wash the WalkAide Cuff fabric liner; first remove the electrodes, and then remove the liner from the cuff. Do NOT remove the Black and Red Electrode Locators. Make sure to Hand Wash, do not use bleach and line dry only.

Sizing Note for Clinicians: To achieve the minimum size, the strap can be folded multiple times and secured using the double-sided Velcro provided.

2.5 WalkAide Cuff Disposable Liner

The purpose of the Disposable Liner is to serve as a hygienic barrier between patient trials. Additionally, it can shorten preparation time in follow up visits. Each Disposable Liner must be cut to fit the patient's Cuff and the electrodes placement remains on liner for return visits. Remember to use protective sheet over the electrodes to prevent drying.



1. Write Patient Info Here.

2. Cut along the Cutlines to the desired size with Scissors for Medium and Small. The Default size is Large. (Figure 11)

3. Align with the Orange Visual Indicator on the Cuff's Liner. (Figure 12)

4. Velcro dots secure the Disposable Liner onto the Cuff's existing liner. The grey fabric side of the Disposable Liner should face out.

5. Once the Electrodes' position is determined, cut in small holes to pass the Electrode Wires through. (Figures 13 & 14)

Figure 11

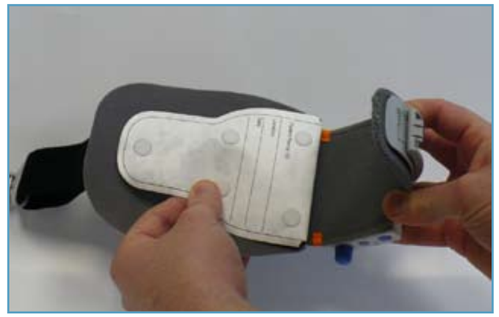


Figure 12

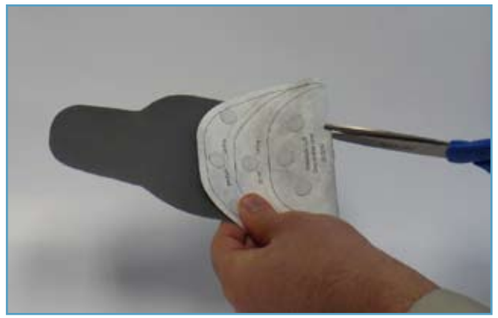


Figure 13

Figure 14

2.6 Symbols and Definitions

Meaning of Symbols


Attention, consult accompanying documents


Type BF Equipment


Indicates Error Signal


Indicates battery location and positioning


Indicates impulse, STIM button


Indicates connector location for Clinician Heel Sensor and optional Patient Foot Sensor


Indicates input/output connector location for WalkLink


Indicates exercise button


Ionizing radiation (Wireless radio transmitter / Bluetooth)

2.7 WalkAide Controls and Indicators

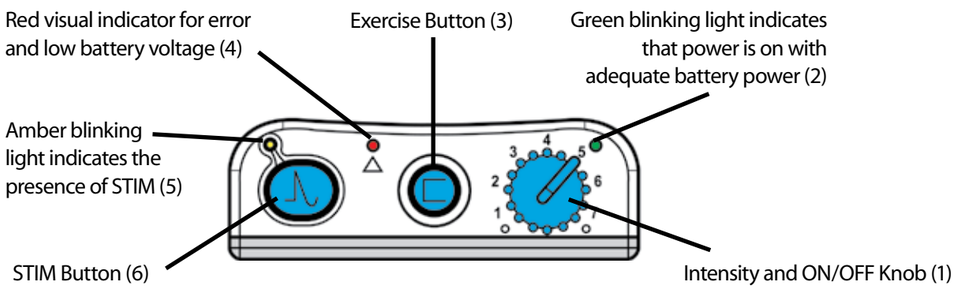


Figure 15: Top view of WalkAide unit

Alarms:

1. Low Battery: An audible alarm of two long beeps every minute with red and green blinking lights indicate low power condition. Change battery.

2. Heel/Foot Sensor: An audible alarm of two beeps every two seconds indicates that Heel/Foot Sensor is not connected, when WalkAide is configured for theHeel/Foot Sensor. Connect the heel switch or change the mode in WalkAnalyst to Hand / Tilt.

3. Device Error: An audible alarm of four beeps every two seconds with red blinking light indicates internal fault. Resend the WalkAide Parameters to WalkAide. Turn unit OFF, wait 5 seconds, turn back ON. Green power light should flash and red alert gone. If red light remains on contact the distributor. (Bad program checksum)

4. Device Error: An audible alarm of three beeps every two seconds with red and green blinking lights indicates internal fault. Resend the WalkAide Parameters to WalkAide. Turn OFF unit, wait 5 seconds, turn back ON. Green power light should flash and red alert gone. If red light remains on, contact the distributor. (Bad data checksum)

5. Rapid beeping: Constant beeping with rapid green light indicates the unit was turned on too quickly to a high level or a new battery was installed without turning off the device. Just turn the device OFF and back ON.

6. Hibernation mode: A non-audible alarm with red blinking light indicates hibernation mode. Establish a Bluetooth connection with WalkAnalyst to automatically clear hibernation mode. If hibernation mode does clear, clear usage log from standard program usage log link.

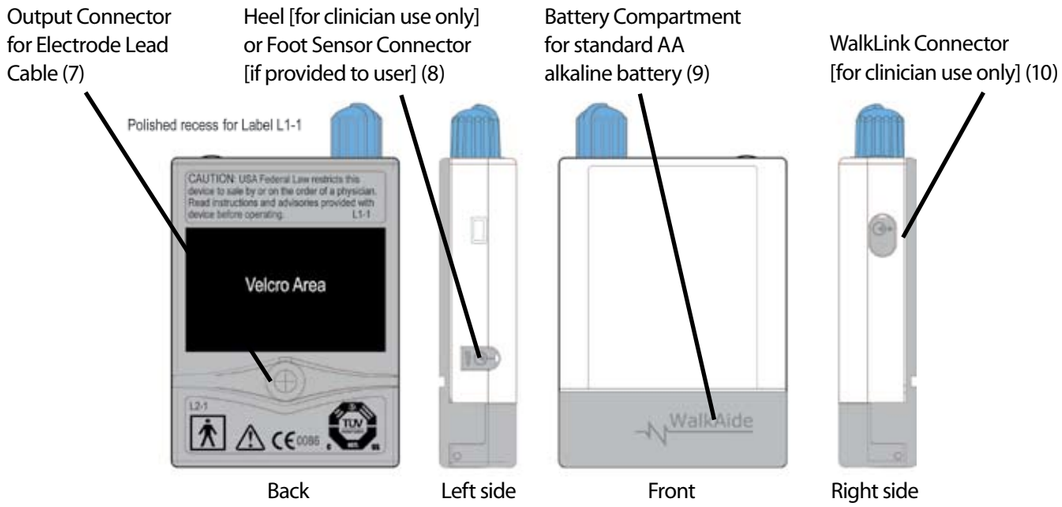


Figure 16: Back, side and front views of WalkAide unit

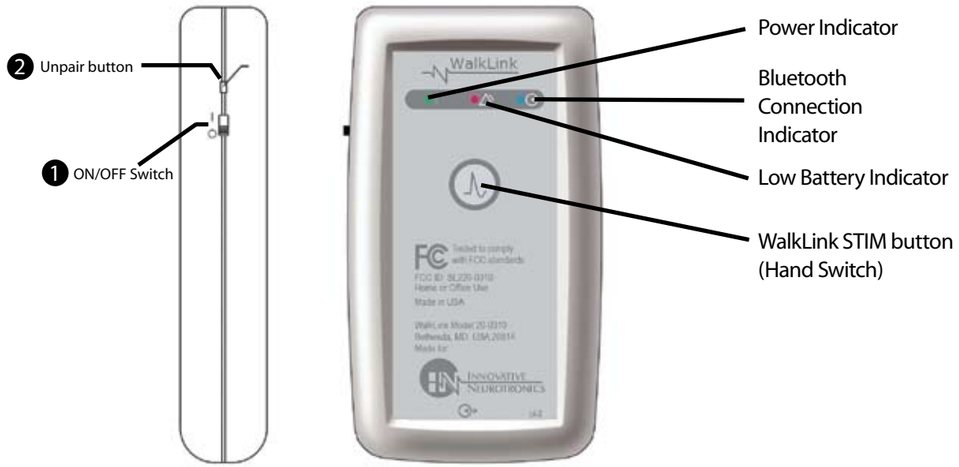


Figure 17: Front and side views of WalkLink unit

3.0 Installation of the WalkAnalyst Program

WalkAnalyst only needs to be installed once in order to run this program. Installation requires administrator or power user rights.

1. Insert the WalkAnalyst CD or flashdrive in the appropriate drive. The PC may have an external CD or USB Port. Make sure it is properly connected and operating correctly prior to inserting the WalkAnalyst CD/flashdrive.

2. The installer should automatically start. Follow the set up instructions that will appear.

3. If the installer does not start automatically, find the appropriate drive icon and open the folder. For Windows XP double click on the Setup.exe file. For Windows 7 or Vista, right click on Setup. exe and choose Run as Administrator. Follow the set up instructions that will appear.

Note: WalkAnalyst installer will detect if Microsoft .NET framework 3.5 installed on your computer. If approriate framework is not installed, user can find it in the WalkAnalyst installation CD/flashdrive or Microsoft Download Center. After framework is installed, restart WalkAnalyst installation again (step 3).

4. The WalkAnalyst program will be installed in the Program Files/Innovative Neurotronics directory unless another directory is selected.

5. Once the program has been installed, an icon will be created on the desktop for quick access. WalkAnalyst can also be accessed from the Windows start menu. For detailed instruction, refer to WalkAnalyst Installation& Bluetooth Configuration Guide provided with the WalkAnalyst Software.

4.0 Set-Up Procedures for WalkLink

1. Turn ON your PC
2. Plug in your Bluetooth USB (Recommendation: use the same USB port at ALL times) see Fig 9.
3. Connect WalkAide & WalkLink, then turn ON both devices
4. Start WalkAnalyst
5. Click on Bluetooth on top-right (initial pairing only)
6. Follow Configuration Wizard (initial pairing only)

The WalkAide device sends real time data to and receives parameter changes from the WalkAnalyst program. In order to avoid connecting a physical cable to the patient, a wireless solution has been created employing Bluetooth radio technology. This technology allows secure short-range communication between electronic devices.

- **Configuring initial set-up process (pairing):** A link must be created from the computer to the WalkLink. This is called the 'pairing process'. Use the guidelines below to accomplish this process.

Figure 18: Flashing green light indicates WalkLink is on

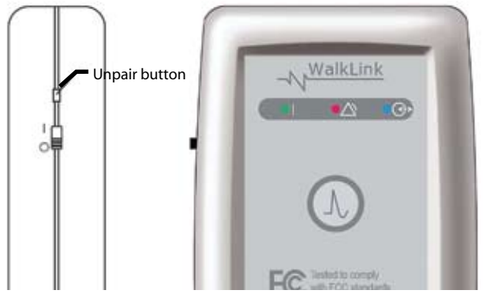


Figure 19: WalkLink unpair button

Note: **The computer and the WalkLink were previously connected using initial set-up program:** Turn on the WalkLink and open the WalkAnalyst software program. The blue light on the front of the WalkLink should begin to blink. The WalkAide can be attached to the WalkLink at any time. The blue light in the upper left hand corner of the WalkAnalyst screen will indicate a solid connection to the WalkLink, and the green light will indicate a solid connection to the WalkAide.

1. **Install the Bluetooth Adapter:** Bluetooth adapter installation varies based on windows operating system editions and types of Bluetooth adapters. For detailed instructions on how to install Bluetooth adapter, refer to the WalkAnalyst Installation & Bluetooth Configuration Guide. (Figure 20)

2. **Prepare the WalkLink Device:** The WalkLink device has an embedded Bluetooth transmitter. Insert four new AA batteries in the device and turn on the power switch, located on the upper left side. Just above the power switch, there is a recessed unpair button. To ensure that the device is ready for initial connection, use a ball point pen and depress this button for one second. Turn the power off, wait ten seconds and then turn it back on. This step ensures that the device is not connected to any other machine, and prepares the Walklink to pair itself to the current computer when installation is complete.

Figure 20: Bluetooth Adapter Hardware Installed

3. **Establish a Connection to the WalkLink Device:** Start the WalkAnalyst software by double-clicking on the WalkAnalyst icon found on the computer's destop. Alternatively, the WalkAnalyst program can be found at Start > Programs > Innovative Neurotronics > WalkAnalyst. **If previously connected walk link is not detected by WalkAnalyst the software will launch in the offline mode. Press the Bluetooth link at top right corner and Bluetooth Connection Wizard will start.** (Figure 21)

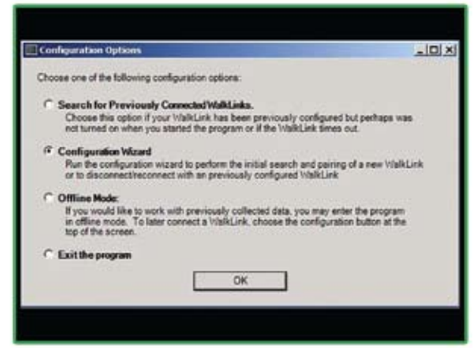


Figure 21: Establishing a connection

If the WalkLink device is ON and ready to be configured, press **OK**. The WalkLink Configuration Wizard will appear. (Figure 22)

Figure 22: WalkLink Configuration Wizard

Note: MAC number on page 24

4. Following the steps on the wizard help screen:

   4.1 **Turn on the WalkLink:** If the WalkLink is on, the left hand LED on the face of the device should show a flashing green light. (Figure 18)

   4.2 **Unpair the WalkLink:** Using the tip of a ballpoint pen, press and hold the unpair button for three to four seconds. (Figure 19)

   4.3 **Reset the WalkLink:** To reset the WalkLink, turn the power off, wait a few seconds and turn the power on.

Note: **Standard method** will be applicable with most computers with Microsoft Bluetooth stack properly working. Otherwise **alternate pairing method** should be used to pair Walk Link with the computer using vendor provided software, such as Bluetooth Device, My Bluetooth Place, BlueSoleil, etc.

- Standard method only: **Enter the WalkLink MAC Address:** Make sure standard method option is detected. Much like a street address or telephone number, each WalkLink has an address that is used to ensure communication occurs only with that particular device. The MAC address is located on the label on the back of the WalkLink device, just below the serial number.

Figure 23: WalkLink barcode label with serial number and MAC address

ONLY the final three numbers or letters in the MAC address are entered in the appropriate boxes on the computer screen, as indicated by the red square in Figure 23.

- **Connect:** Press the button labeled "5. Connect to WalkLink" to initiate the connection process. Progress can be tracked below the Bluetooth icon noted by the comments: Search Underway..., Clearing Memory…, and finally Creating Connection… (Figure 24)

The wizard will try to establish a connection to a WalkLink with the address specified. The wizard may take a minute or more to complete this process. When finished, a confirmation message will appear. Press 'OK' to launch WalkAnalyst. If the connection is created, the WalkLink device should now have a blinking blue light (in addition to the green power light). (Figure 26)

Figure 24: Connect to WalkLink Process

- Alternate method only: **Select COM Port:** Make sure alternate method option is detected. The COM Port Selection field should be displayed. (Figure 25 Alt) If it is not displayed, press the "Show COM Port Selection" button.

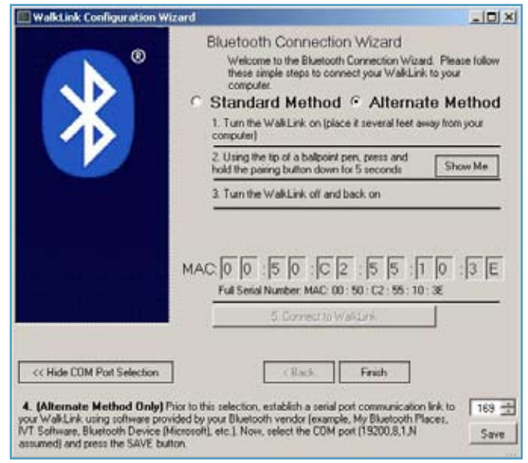


Figure 25 Alt: WalkLink Configuration Wizard

Prior to the selection, establish a serial port communication link to the WalkLink in the software provided by the bluetooth vendor (example, My Bluetooth Place, IVT/BlueSoleil software, Bluetooth Device (Microsoft), etc). Now select the COM Port for the dropdown and press the SAVE button. If the connection is created, the WalkLink device should now have a blinking blue light (in addition to the green power light). (Figure 16)

Figure 26: Blue Light indicates Bluetooth connection

The WalkLink device is now connected. Under normal circumstances there should be no reason to return to the wizard. If adjustments are needed in the future, the Bluetooth connection is dropped, or WalkAnalyst is unable to find the WalkLink device, choose the Bluetooth icon in the upper right corner of the screen. Several options are provided, the most common of which will be to Search for Previously Connected WalkLinks. (Figure 27)

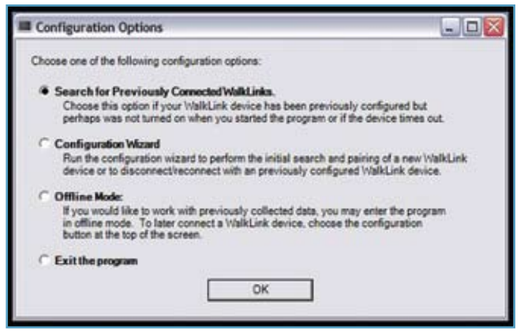


Figure 27: Search for Previously Connected Walklinks

5.0 Overview of Data Collection and Programming Process

Figure 28 outlines the process used to provide the WalkAide for a new user.

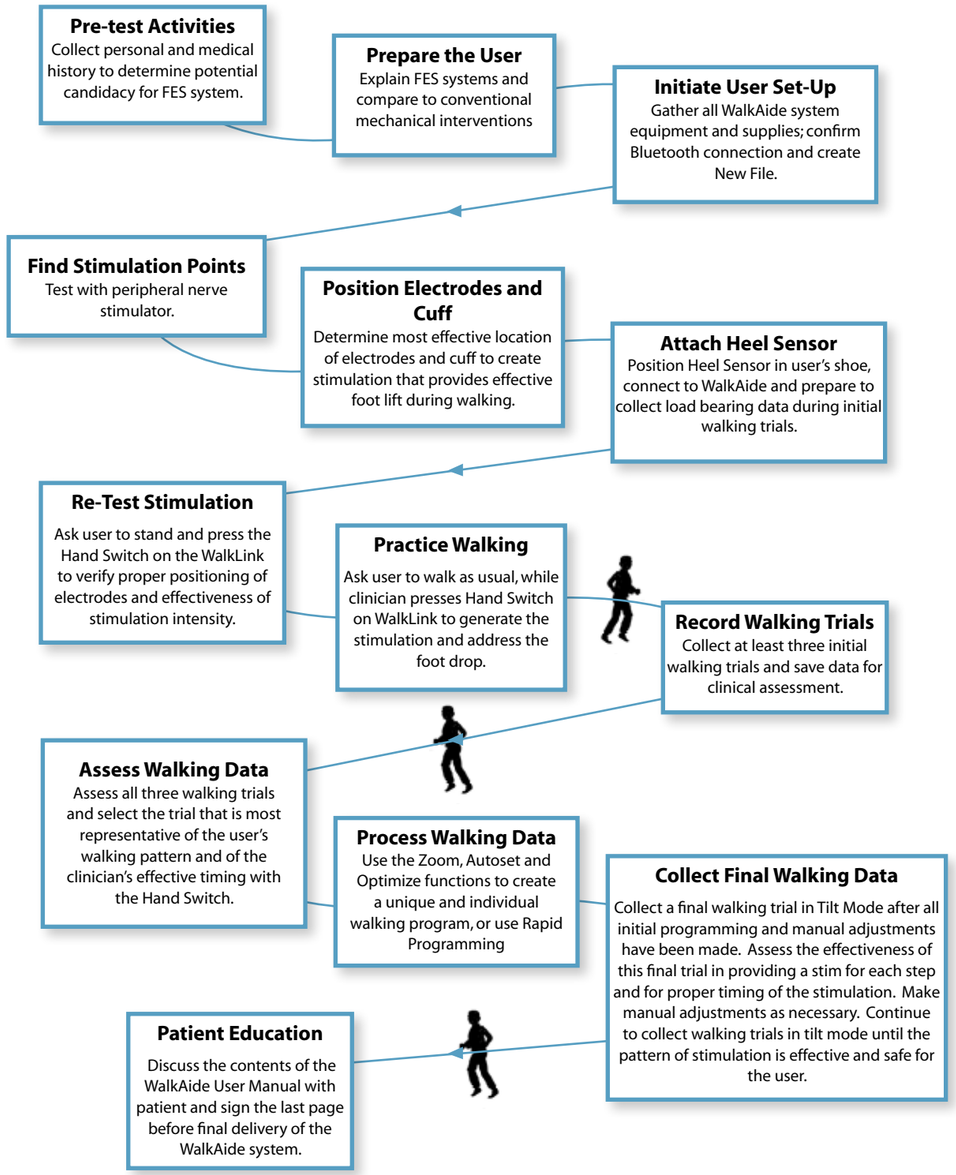


Figure 28: Set up process for WalkAide

5.1 Testing with the Peripheral Nerve Stimulator

There are two primary purposes of the peripheral nerve stimulator testing procedure. The first is to determine the viability of the common peroneal nerve and the degree of innervation of the peroneus longus (superficial branch) and tibialis anterior (deep branch) muscles. The second purpose is to identify initial placement of the posterior electrode to produce a 'balanced' dorsiflexion and eversion movement of the foot/ankle. (Figure 29)

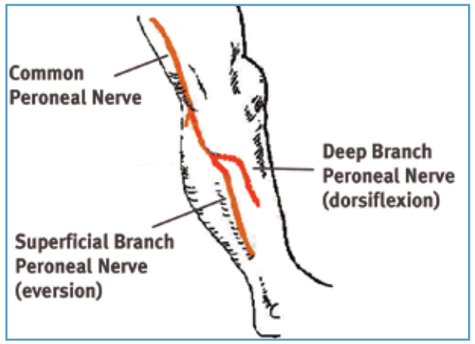


Figure 29: Superficial and deep branches of the common peroneal nerve

Prepare the peripheral nerve stimulator by pressing: (1) **ON**, (2) **50 Hz** and (3) **Twitch**; then (4) set the intensity dial in **between 0 and 1**. The orange power indicator light will be seen to indicate that the peripheral nerve stimulator is on. (Extra 9V batteries should always be available) The red light on the peripheral nerve stimulator will flash when a circuit between the stimulator, the nerve and the muscle is completed. (Figure 30)

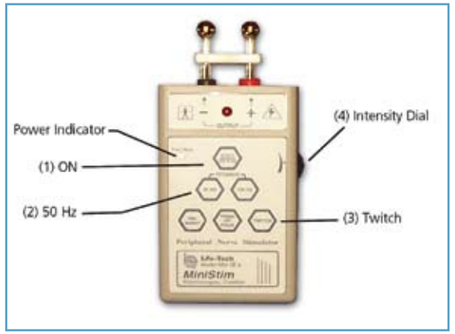


Figure 30: Peripheral nerve stimulator

1. Always prepare the user for the testing procedure by providing a thorough explanation of the process and always ask for continuous feedback during the procedure.

2. The user should be comfortably seated in a chair with the affected leg resting on a low stool. The leg should be relatively extended, with just slight knee flexion to simulate the position of the leg at terminal stance during walking, when the stimulation will be initiated. The heel should be somewhat supported, with the foot close to a neutral alignment.

3. Clean the skin in the area around the head of the fibula with soap and water and wipe dry. Failure to adequately prepare the skin may cause improper contact and provide less than ideal stimulation

4. Identify (and mark) the head of the fibula. The common peroneal nerve runs posterior and distal to the head of the fibula. (Figure 29)

   - The superficial branch innervates the peroneus longus to produce eversion.
   - The deep branch innervates the tibialis anterior to produce dorsiflexion (and inversion in a non-weightbearing condition).

5. Wet the area around the head of the fibula generously with water. Place one hand on the lower leg in a position to be able to feel the contraction of both the peroneus longus and tibialis anterior muscles.

6. Identify the intersection of a line dropped vertically behind the head of the fibula and horizontally below the head of the fibula. This is a good starting point to test for viability of the common peroneal nerve. (Figure 31)

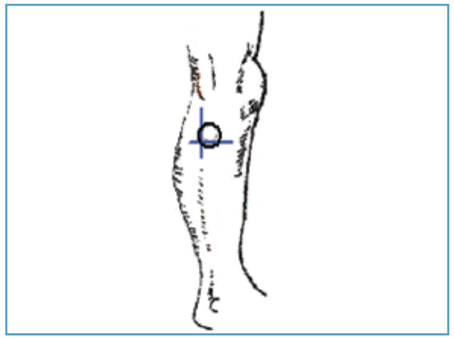


Figure 31: Starting point for testing with the peripheral nerve stimulator

7. Position the peripheral nerve stimulator against the leg so that the black-based silver node is posterior and the red-based silver node is anterior. Press the peripheral nerve stimulator firmly into the leg, keep the stimulator perpendicular to the leg. Gradually turn up the intensity dial on the peripheral nerve stimulator until muscle contraction is evidenced. Most often, this will be contraction of the peroneus longus when the superficial branch of the common peroneal nerve is stimulated. (Figure 32)

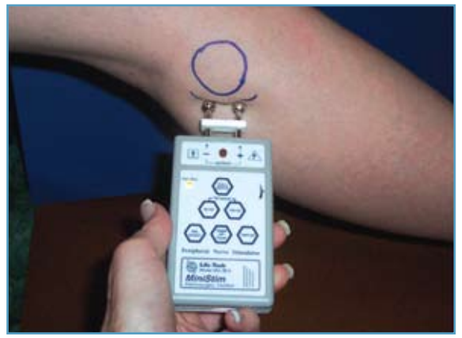


Figure 32: Initial placement of the peripheral nerve stimulator

8. Slide or shift the peripheral nerve stimulator slightly anteriorly to find the deep branch of the common peroneal nerve and to produce a contraction of the tibialis anterior muscle. Watch and feel for any slight twitch of the tibialis anterior muscle. Once the twitch is discovered, stop sliding the peripheral nerve stimulator and start increasing the intensity level until a more functional dorsiflexion movement is produced.

9. Balance the eversion and dorsiflexion movements with very slight shifting of the peripheral nerve stimulator. After determining the most appropriate 'balance' point, mark the location of the posterior black-based node on the leg. This is the starting point for placement of the posterior electrode. (Figure 33)

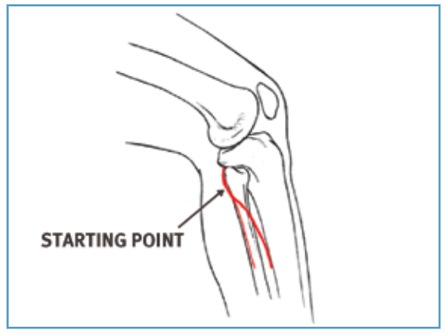


Figure 33: Mark the location of the posterior black based node to identify the initial placement for the posterior electrode.

The location of the branching of the common peroneal nerve varies between individuals, sometimes splitting posterior to the head of the fibula and sometimes splitting anterior to the head of the fibula. Slow and methodical testing of the area will identify the most appropriate starting point for placement of the posterior black electrode. (Figure 34)

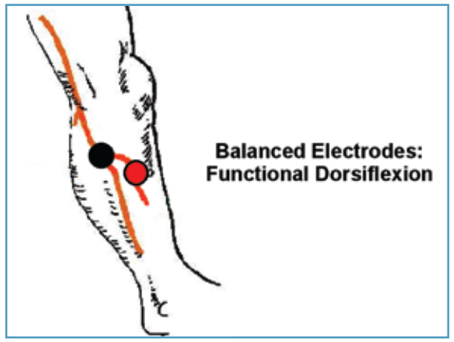


Figure 34: The goal is to produce a functional and balanced dorsiflexion

5.2 Electrode Placements and Final Preparations for Walking

1. Make sure the WalkAide is turned OFF and attach the electrode lead cable to the back of the WalkAide, running the cable to the right to fit a right leg and to the left to fit a left leg. This allows plenty of cable length to attach the electrodes and also prevents excessive bending or flexing of the electrode lead cable.

2. Attach the WalkAide to the cuff on the medial flattened area. Position the cuff around the mid-calf region and secure in place below the potential electrode sites. This places the WalkAide in a convenient location to hook up the electrodes.

3. Moisten the electrode with water. Place the back electrode over the mark identified during the testing procedure with the peripheral nerve stimulator and the front electrode on the upper 1/3 of the tibialis anterior muscle belly. (Figure 35)

4. Connect the electrodes to the WalkAide electrode lead cable. Make sure the **BLACK** lead (negative) is connected to the **BACK** electrode and the **RED** lead (positive) is connected to the **FRONT** electrode. (Figure 35)

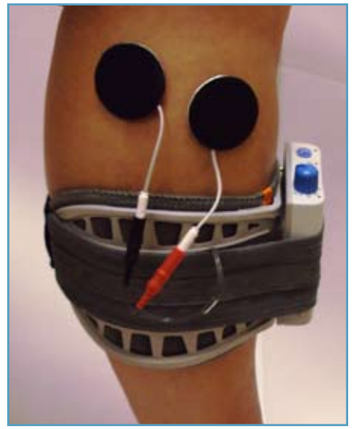


Figure 35

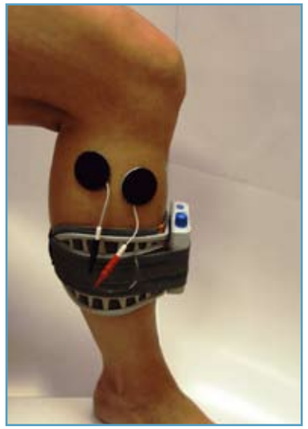


Figure 36: Placement of electrodes, cuff and WalkAide unit for initial testing

5. Turn the WalkAide ON by turning the blue Intensity Knob in a clockwise direction to the 1 (on) position. An audible beep will sound and a green light will flash intermittently to indicate that the unit is on. ALWAYS start at a low level of intensity and gradually increase during the testing procedure.

6. While maintaining total contact over the electrodes with one hand, test STIM. This can be achieved by pressing down on the large blue STIM button on the WalkAide (labeled √), the Hand Switch on the WalkLink (if it is connected to the WalkAide and if Default Parameters have been previously sent), or exercise mode to initiate the stimulation. (Figure 37)

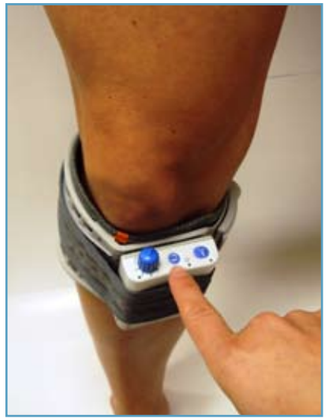


Figure 37: Place unit in exercise mode

7. Once the optimal electrode positions have been found, place Black & Red Markers over the electrical (Black-Back-Red-Ahead). Turn off the WalkAide, release the cuff strap and properly align the cuff over and around the pretibial region. (Figure 38A and 38B)

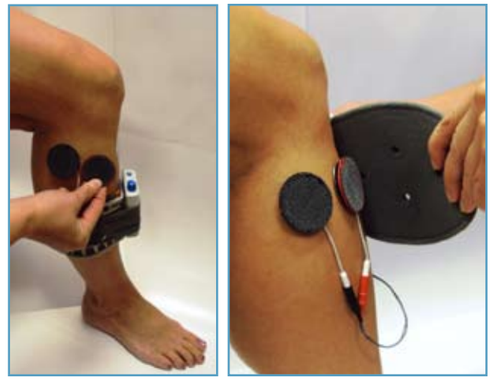


Figure 38A and 38B: Carefully align the cuff over the electrodes and secure to the leg

Helpful Hints: Electrode placement determines patient comfort and direction of foot movement.

- Generally, shifting the black electrode more posterior and proximal elicits more eversion; and shifting the black electrode more anterior and distal elicits more dorsiflexion. (Figure 39) Anatomical variations are common.

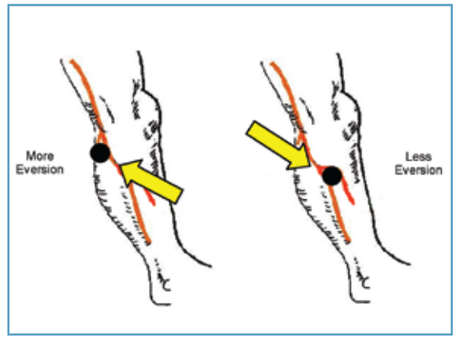


Figure 39: In general, the posterior black electrode determines the direction of the foot lift

- Anatomical variations may include (Figure 40):

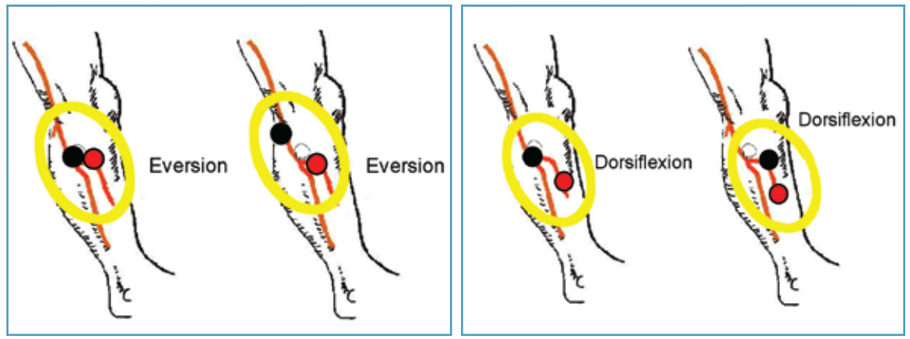


Figure 40: Final placement of electrodes relates to individual user requirements

Recommendations:

- Always begin by identifying the starting point for the black electrode
- Adjust the spacing between the black and red electrodes to achieve the desired function and contraction of muscle.
- If the contraction is not optimal initially, consider using the Exercise Mode prior to final placement of the electrodes to "wake up" the neural pathways.
- Make small movements when shifting the electrodes to determine final electrode placements in order to detect subtle changes in muscle contraction/function.
- Leave the electrodes on the skin until final placement is identified to prevent dissipation of the water and to maximize user comfort. If the electrodes lose contact with the skin, rewet and reapply.
- Evaluate functional foot movement during sitting and standing before asking the person to walk, assuring a safe and effective foot lift for safe walking. Function can differ with changes in patient position due to movement of the peroneal nerve.

Data Collection:

1. Place the clinician Heel Sensor in the user's shoe on the affected side and connect its cable to the WalkAide unit. It is best to have the patient use a firm-soled shoe and walk on a hard tile floor during the initial data collection procedures. (Figure 41)

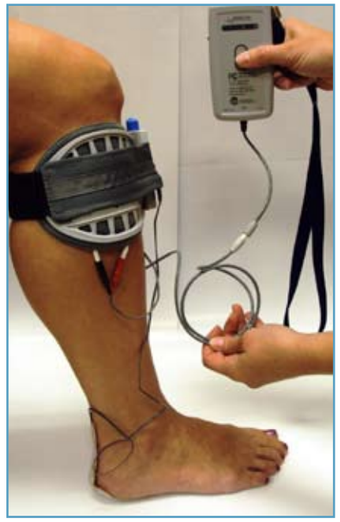


Figure 41: Clinician heel sensor in place and WalkLink connected

2. The WalkLink cable must be connected to the WalkLink unit and the WalkAide for collection of all walking data.
3. Turn the WalkAide ON and adjust the intensity to the same level determined during initial fitting.
4. A walking area that allows a minimum of 6 – 8 consecutive steps in walking speed is ideal for the data collection procedures. A hard tiled floor is best for data collection but firm, low pile carpeting is acceptable.
5. A full-length Foot Sensor is recommended for the user, it must be ordered in addition to the Patient Kit. The Foot Sensor must be trimmed to fit appropriately inside the user's shoe. Take care not to damage the embedded sensor or the attached wires, and make sure the small round disc of the Foot Sensor is properly positioned and located directly under the user's heel. Use of the Foot Sensor will restrict shoe wear to a closed heel shoe until the user is able to transition to use of the Tilt Sensor.

5.3 WalkAnalyst Login

Step 1: Open WalkAnalyst

Step 2: Enter username and password
- Default username: wasystem
- Default password: clinician

Figure 42: WalkAnalyst Login Page

Step 3: Select one of two Options:
- Create New Patient Profile
- Open Patient Profile

Step 4: Select Programming Option

- Standard Programming – Detailed programming option for advance clinicians
- Rapid Programming – Simple programming option
- Rapid Adjustment – Allows for simple adjustment in existing programs
- User Administration – Option to change password and add additional users.

Figure 43: WalkAnalyst Patient Profile Options

Note: When creating a New Patient Profile, upon clicking on any of the above options, a prompt will indicate when new file is saved.

5.4 Rapid Programming

Step 1: Pressing the Rapid Program button initiates Rapid Programming. Rapid Data Collection option defaults to collect data in hand mode.

Figure 44: Programming Options

You will be prompted to clear your usage log. If the WalkAide unit is brand new, clearing the log is recommended. This sets the timer of the WalkAide; Clears hibernation mode. If you are using a demo unit you can select no.

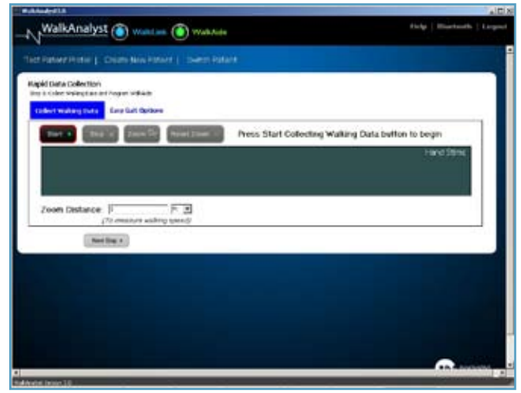


Figure 45: Rapid Programming Data Collection

Easy Gait Option: Option to change the Data Collection options from Hand default to Heel or to adjust stimulation Comfort level (Recommended for Pediatric or sensitive patients)

Step 2: Collect Walking Data. Click Start and begin collecting walking data. Upon completion, click Stop.

Zoom: Select your desired walking data by holding Left-click and dragging the mouse arrow. Upon releasing the Left-clicking you will hear 2 beeps signalling programming.

Enter zoom distance if the corresponding zoom distance is known; This will calculate patient's walking speed. Press Next Step button will send programmed parameter to WalkAide. WalkAide will operate in till stimulous.

Step 3: Turn on beep on stim and have patient walk with the newly programmed parameters. Adjust the control parameters based on clinical observation and patient feedback.

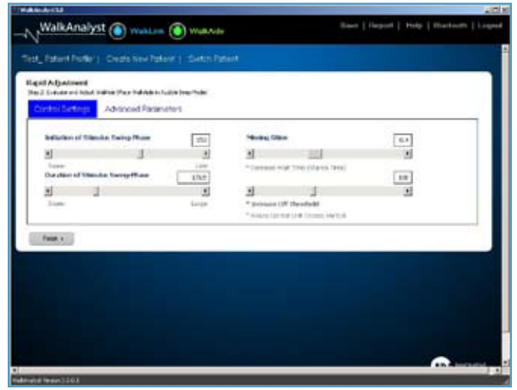


Figure 46: Rapid Adjustment page

Advanced Parameters: Click on advance parameters if you want to adjust the Comfort or Quality characteristics of the stimulation. (Figure 47)

If you are satisfied with your settings, click on Finish to finalize your program.

This saves data under the archive file in Standard Programming. Data collected in Rapid Programming is indicated with (R) prefix.

5.5 Rapid Adjustment

Rapid Adjustment page, adjust stimulation parameters to manually fine tune the programming. These adjustments are transferred to the WalkAide instantaneously. Every adjustment made will configure by audible beeps.

To adjust an existing program (patient profile)

1. Open Patient Profile
2. In Patient Profile page, click on Rapid Adjustment
3. Rapid Adjustment
   a. Turn on beep on stim and have patient walk. Adjust Initiation, Duration or Missing stims in Control Setting view based on clinical observation and patient feedback (Figure 46)
   b. Click on Advanced Parameter to adjust Stimulation Comfort and Quality (Figure 47)
4. Click Finish to Finalize the program

Figure 47: Advanced Parameters

5.6 Standard Programming

Press Stanard Program button (Figure 44) to start Standard Programming.

Step 1: Enter Patient Information

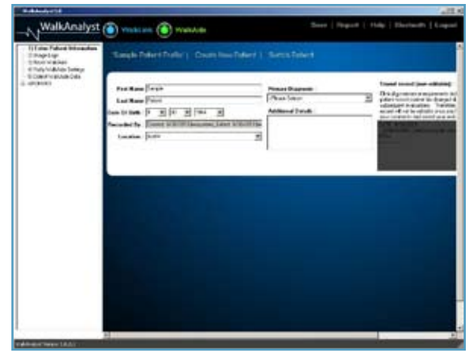


Figure 48: Enter Patient Information

Step 2: Clear Usage Logs

- The WalkAide collects walking data for the **most recent 72 days** of gait activity. (The usage log will not record hours of usage or number of stims that occur in exercise mode.) The log includes Hours Per Day and Stims Per Day.
- Select Clear WalkAide Logs (option). **Required for a New Patient Kit WalkAide.** Click on Clear WalkAide Log to set the internal date and time stamp. This will also set a new 72-day tracking sequence.
- For an **existing user**, click on the Retrieve WalkAide Log to download the most recent walking activity data. This Usage Log will be saved with a date and timestamped entry under Collected Logs.

Figure 49: Usage Logs

Step 3: Reset WalkAide

Reset WalkAide. Default Parameters must always be sent to the WalkAide before collecting walking data for a new user. Parameters provide basic reference information to the software and set the Stimulation Mode to Hand; activating the hand switch button on the WalkLink; allows the clinician to initiate swing, and stance duration; driving patient best walking data collection. These settings cannot be altered on this page.

- Click on **Send to WalkAide** icon located above the Stimulation Mode box. 2 'beeps' will sound from the WalkAide and a message window will appear indicating the default parameters have been successfully sent to the WalkAide.

Figure 50: Reset WalkAide

Step 4: Verify WalkAide Settings

- **Verify WalkAide Settings.** This screen presents the current WalkAide unit programming. For most users, these parameter settings provide the best starting point for data collection, however, adjustments can be made here to accommodate specific clinical needs of a patient. (i.e, Reduce pulse duration for a sensitive patient; or modify Exercise Settings to pre-set the exercise program). Always send the adjusted parameters by selecting the sent to WalkAide button.

Step 5: Collect WalkAide Data

Collect Walking Data: (Assure the cuff and WalkAide are properly positioned and there are no dangling cables that might impede walking. Ask the user to stand, balance and prepare to walk).

Click the **'Start'** icon ; this begins to collect a live data stream and will appear on the screen. Stand shoulder to shoulder on the same side of the user's affected limb, provide support assistance as needed. Prompt the patient to begin walking with their unaffected side.

Provide manual stimulation with the Hand Switch on the WalkLink. Simulate swing pushing the stim button from heel OFF through heel strike.

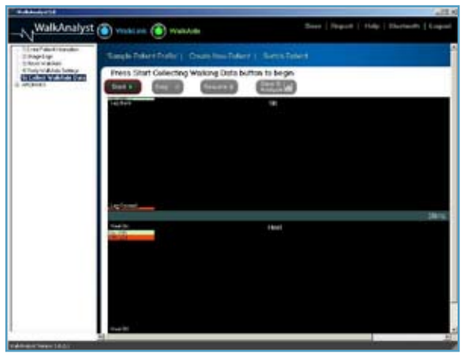


Figure 51: Start Collecting Walking Data

Step 6: Stop

Figure 52: Stop Collecting Walking Data

Step 6: Save and Analyze

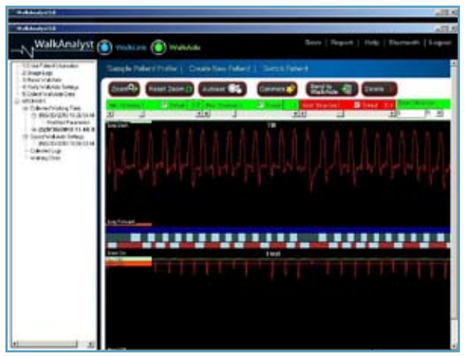


Figure 53: Save & Analyze button pressed

Step 7: Processing the Data

- Data processing involves following the sequence of the icons [from left to right) displayed above the Tilt data graph. 'Zoom,' 'Autoset' and 'Optimize' are the first three steps involved in processing the walking trial.

1. **'Zoom in to Highlight Steps'** - On the Tilt graph, place on the cursor to align with the lower point of the data to the **left** of the first step included in the data processing. (Initiation of Siwng). Press and hold the left mouse button and then drag the cursor to highlight the desired steps. Align the cursor with the lowest point of the data to the **right** of the last desired step and then release the left mouse button. (Termination of Swing). This 'Zoom' process will pull out the selected steps to allow the clinician to create the most effective walking program. The zoom process also allows the clinician to "leave out" periods of inconsistent steps. (Figure 54)

Figure 54: Zoom In

2. Click the 'Autoset WalkAide Parameters' button to automatically modify the parameter settings based on statistically calculated values from the recorded Tilt and Heel data. Click 'OK' to accept the statistical calculations and standard deviation once these parameter adjustments have been completed.

3. Click the 'Optimize Gait Program' button. The error rate for both the Hand and Heel are calculated. A final error of less than 20% is recommended. Choose the desired reference signal and associated error and then click on either the **Use Hand Data** or **Use Heel Data** icon. (Figure 55)

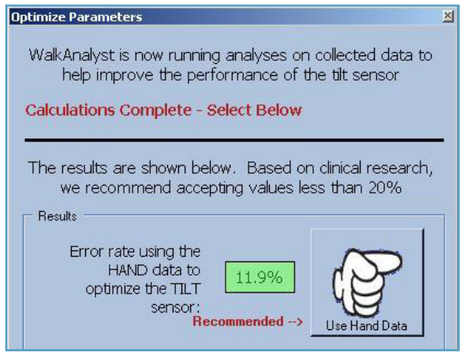


Figure 55: Optimize

- If the error associated with both the Hand and Heel is greater than 20%:
  - i. Click on **Reset Zoom to see all Data** and select a different sequence of steps for Optimization, or
  - ii. Collect a new walking trial for data processing. Repeat the Zoom, Autoset and Optimize procedure.

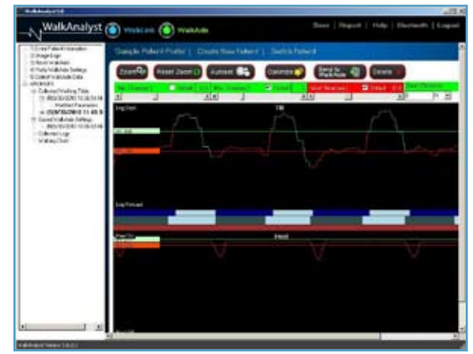


Figure 56: Optimized Parameters

- The timing of the initiation and termination of the stimulation is determined by the On and Off Thresholds, respectively. The WalkAnalyst software has calculated the settings for the Thresholds and Control Times based upon the data collected and referenced.

- The lower the On Threshold is set, the earlier the stimulation would be initiated for each step. The higher the On Threshold is set, the later the stimulation would be initiated for each step.

- The lower the Off Threshold is set, the later the stimulation would be terminated for each step. The higher the Off Threshold is set, the earlier the stimulation would be terminated for each step.

4. **'Send Parameters to WalkAide'.** Since most users are programmed to use the Tilt Sensor, the TILT MODE is highlighted in green in the message window (Figure 57).

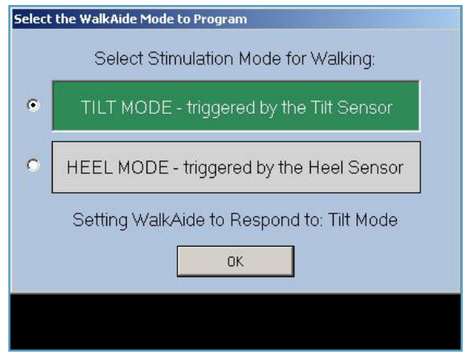


Figure 57: Tilt or Heel Mode

Click on 'OK' to send the parameters. The WalkAide will emit a beep and a message window will appear stating that the parameters have been successfully sent. (Figure 58)

Figure 58: Parameters Sent

- It is recommended to **Verify WalkAide Settings** after making any changes to the parameters. After creating a unique walking program for the individual, the WalkAide Parameters shown on the screen will no longer show Default Parameters but instead show the new On/Off Thresholds, Control Times and the Tilt Stimulation Mode.

- The WalkAide unit is now programmed for the individual. The WalkAnalyst software has determined the most effective pattern of stimulation based upon the Heel, Hand and Tilt data collected during the walking trial and has processed that data using the Zoom, Autoset and Optimize functions. Further assessment of the Heel and Tilt graphs reveal the timing of the stimulation relative to gait events.

- It is recommended to collect a **final walking trial** in Tilt Mode to verify effective and efficient programming of the WalkAide. Click on '5) Collect Walking Data' and repeat the data collection procedure for a walking trial with the WalkAide in Tilt Mode (click on Collect Walking Data, Stop Collecting Walking Data, Save and Analyze this Walking Data). Remember to instruct the user to always begin walking by advancing the unaffected leg first. This will create a sufficient amount of tilting of the affected leg to reach the On Threshold and trigger the stimulation with the very first step. The Heel Sensor may be removed or left in the shoe in case additional data collection is desired. (Figure 59)

Figure 59: Data Collection in Tilt-Saved

- The final walking trial in Tilt Mode should reveal an effective pattern of stimulation and produce a safe pattern of walking. If a stimulation was produced with each and every step, then no further adjustments are required and the clinician and user can discuss an appropriate wearing schedule and care of the WalkAide unit. If any missing stimulations were noted, then further manual adjustments to the walking program are needed. (refer to 5.4 Manual Adjustment of the Stimulation Parameters.)

- For reference, the WalkAide device serial number will be automatically logged and noted in the parameters screen.

An overview of the Patient Screening, System Preparation, Patient Preparation, and Data Collection and Processing is shown in Figure 60.

1	**Pre-Screening**	Clinically Qualify Ministim
2	**System Set-Up**	Insert Bluetooth adaptor; Connect WalkAide and WalkLink-turn on; Start WalkAnalyst Software
3	**Patient Set-Up**	Clean skin; black electrode to the back, red ahead
4	**Data Collection**	Select Rapid or Standard Program
5	**Program**	Start, stop, zoom (Pre-set into tilt mode)
6	**Refine Outcomes**	Place in Audible beep and adjust

Figure 60

5.7 Exercise Mode

The **Exercise Mode** can be programmed and used as a therapeutic modality, as an adjunct to therapy or as a way to condition the user's nerve or muscle. It is intended to be used only while the user is seated, with the leg and heel supported. (Figure 61)

Figure 61 Exercise Settings

Tips:

- The Exercise Mode may be helpful during or after the donning process to verify correct electrode placement.
- Some users may benefit from using the Exercise Mode to 'warm up' the neural pathways prior to walking.
- For some users, a lower intensity setting on the WalkAide is used for exercising than for walking. Users may occasionally assist the exercise stimulation by actively dorsiflexing the foot. Always have patient actively engaged in treatment session.

The Exercise Mode may be discontinued at any point in time by simply turning the WalkAide unit off, waiting 2-3 seconds, and then turning the WalkAide unit on again. It will now be ready to run the default walking program. It is important that the user remember to always turn the WalkAide unit off and then on again after any exercise session.

Adjusting the Exercise Settings

1. Click on **Verify WalkAide Settings** to retrieve the current settings.

2. 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 user.

3. The parameter ranges are as follows: **On Time**: 1 – 5 seconds, **Off Time**: 1 – 10 seconds, exercise **Duration**: 1 – 30 minutes. A sample chart for Exercise Settings is shown below (Figure 62)

	User with Severe Atrophy (1:5)	User with Moderate Atrophy (1:3)	User with Minimal to No Atrophy (1:2)
On Time (Seconds)	1-2	1-3	1-5
Off Time (Seconds)	5-10	3-10	2-10
Duration (Minutes)	5-10; gradually increase	15; gradually increase	15-30
Number of sessions per day	Start with 1; gradually increase	Start with 1; gradually increase	1-2

Figure 62: Sample settings for the Exercise mode

4. Click the '**Send to WalkAide**' icon in order to store the new parameter changes for the Exercise Mode in the WalkAide unit.

5.8 Wearing Schedule

Gradual introduction into wearing of the WalkAide system is important. The Wearing Schedule below serves as a general guideline and can be modified by the clinician to meet the specific needs of the individual. Users should proceed through the daily wearing schedule and increase wearing time only if no skin irritation and/or muscle soreness is present. (Figure 63)

	ON Time	OFF Time
Days 1-3	15-60 minutes	30 minutes
Days 4-6	1-3 hours	30 minutes
Days 7-9	3-5 hours	30 minutes
Days 10-12	5-6 hours	1 hour
Days 13-14	6-8 hours	1 hour

Figure 63: General Wearing Schedule for New WalkAide User

Helpful hints to enhance the break-in period:

- If muscle soreness occurs, reduce the wearing time or discontinue use and contact your WalkAide clinician.
- If skin irritation or redness occurs under the electrodes, do not resume WalkAide stimulation until the redness disappears. If the redness has not disappeared by the end of the scheduled off period, do not reapply the WalkAide until the redness disappears and report this occurrence to your WalkAide clinician.
- Slowly work in to full-time wearing of the WalkAide system. How well the user tolerates the WalkAide during this break-in period will depend on each individual's daily regimen and overall activity level.
- Remove the cuff at regular intervals throughout the day and inspect the skin under the electrodes. These areas will be pink due to increased blood flow under the electrodes, but this redness should disappear quickly. If the redness persists, discontinue WalkAide wear until the redness completely disappears.
- DO NOT use moisturizing soaps, lotions or oils to soften the skin. Make sure the skin is clean and dry prior to applying the cuff.
- Make sure the WalkAide is applied correctly with appropriate electrode position each time to maximize function and minimize any potential discomfort.
- If shaving the leg is desired, this should be done in the evening after the WalkAide has been removed for the day to prevent potential irritation during daily wear.
- Wet the electrodes with water before applying the cuff. Rewet the electrodes occasionally throughout the course of the day to maximize conductivity.
- Make sure the electrodes are changed at least every 40 hours, and cover them each night with the plastic backing tabs. The on surface of the plastic tab should be placed 'on' the gel surface of the electrode so that the no surface of the plastic tab is readable to the user.
- Refer to the User Manual for additional information.

Precautions for WalkAide wear:

- Skin irritation under the electrodes does occur in a small percentage of FES users. Some of the common causes of irritation initially are use of lotions or perfumed soaps, recent shaving, non-compliance with break-in schedule, failure to properly wet electrodes, poor electrode placement that forces an excessively high intensity level, and failure to change the electrodes often enough. The best way to avoid skin irritation is to increase to all day wear slowly, maintain proper skin hygiene, practice proper electrode care and choose the placement that allows for the least amount of stimulus intensity. Once irritation has occurred, the WalkAide must be discontinued until the skin is 100% clear of irritation. Using the WalkAide over irritated skin will only exacerbate the condition.

5.9 Usage Log

1. Click on '**Collected Logs**' listed on the left side of the screen (Figure 64). Click on the '**Retrieve WalkAide Log**' icon to retrieve the information and then click 'OK' once the information has been retrieved.
2. The log will only collect data for up to 72 days. To reset the WalkAide unit Usage log file, click on

Figure 64: Collected Log Retrieval and Reset Screen

the '**Reset WalkAide Log**' icon to clear the file and begin the next collection period.

3. To see collected usage data, look under '**Collected Logs**' on the left of the screen. Click on the appropriate date/time of the most recent file downloaded.
4. In the Graphical View, two sections of bar graphs will appear (Figure 65). 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 NOT included. If desired, the vertical slider on the left of the graph may be used by dragging it up and down to change the scale of the graph. This would be useful in the event that scale of the graph was either too small to be readable or contained bar graphs that exceeded the scale at the top of the displayed information.

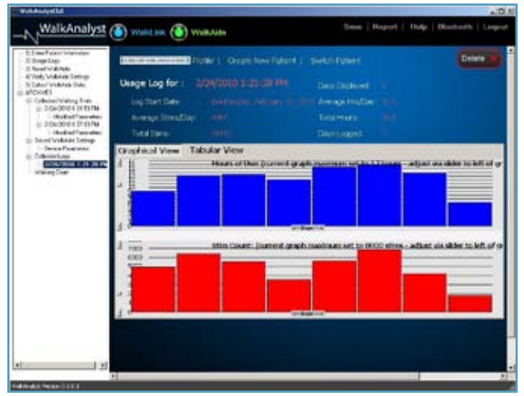


Figure 65: Graphical view of Usage Log

5. Tabular View, the days, hours and stimulation count are listed numerically in a table (Figure 66).

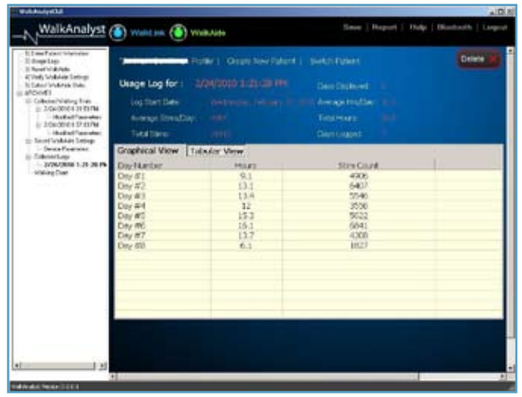


Figure 66: Tabular view of Usage Log

6. A report of the walking trial or Usage Log may be printed (Figure 67). 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 associated parameters. Select any one of the Usage Logs to print a report showing the graphical and tabular view screens. (Figure 67)

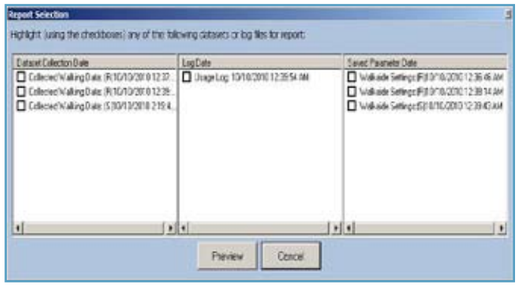


Figure 67: Reporting Options

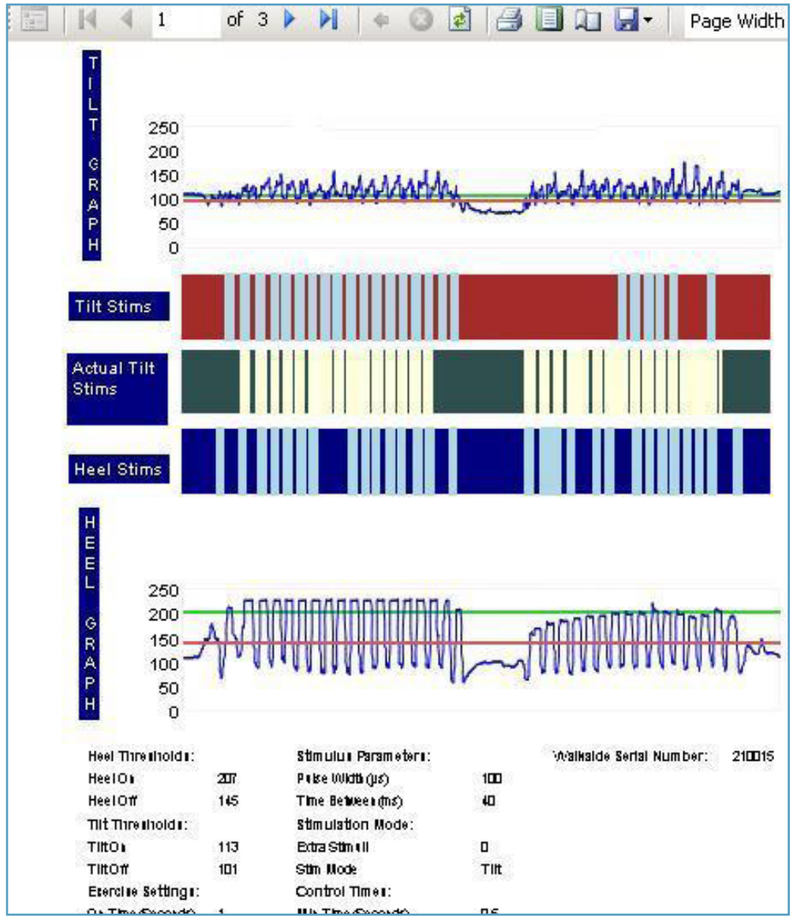


Figure 68: Collected Data Graph and Parameter Listing

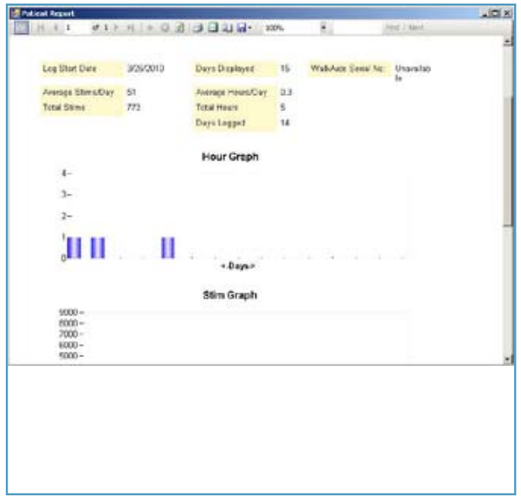


Figure 69: Usage Log Summary Reports

6.0 Use and Care of the WalkAide and Accessories

Cleaning the WalkAide—The user 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 before washing. 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.

Cleaning the Electrode Locators—The user should use a mild detergent to clean the electrode locators during each electrode change event.

Storage—When not being worn, the WalkAide system (cuff, electrodes and WalkAide unit) should be stored in a resealable plastic bag in an area where temperatures do not exceed 120 degrees F (48.8 degrees Celsius) or fall below 40 degrees F (4.4 degrees Celsius). This will keep the electrodes from drying out. The WalkAide should be turned off when not in use and overnight to preserve the batteries and to allow the internal clock to function optimally.

Battery—If the WalkAide is to be stored for an extended period of time and not used, remove the battery from the battery compartment. When the alkaline batteries become depleted, please dispose of properly, in accordance with all local and national regulations. Do not use Lithium, disposable, or "bargain brand" batteries – regular AA batteries from a major manufacturer (e.g., Ray-o-vac, Eveready or Energizer brand batteries).

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

Disposal—When the device has reached the end of its useful life, please dispose of properly, in accordance with all local and national regulations.

6.1 Care and Use of WalkAide Electrodes

Electrode efficiency and durability depends entirely on the application, storage and care of the electrodes by the well-informed WalkAide user. The durability of the electrodes is dependent upon keeping the adhesive gel clean, hydrated and free from foreign debris. Other factors relating to electrode durability are skin condition, wearing environment, usage and climate. **In all cases, the electrodes must be changed every ~40 hours of wear to maximize function and minimize the potential for skin irritation.**

To obtain the most use from the electrodes, the following tips should be discussed and reviewed with the WalkAide user.

- Before applying the WalkAide system, the skin must be clean, dry and free from lotions or oils. Any debris on the skin will be transferred to the electrode compromising the adhesiveness and effectiveness of the electrode.
- When applying new electrodes, always lift the electrodes from the plastic backing at the edge. Never pull on the lead wire.
- When removing the WalkAide from the leg, gently pull the cuff down and away from the leg in the same direction the hair lies. Never grasp the cuff and roughly pull away from the leg. Using a dab of wate rto separate the electrode from the skin can prolong electrode wear.
- Always cover the electrodes with the plastic backing when not in use. Be sure the 'on' side of the plastic piece is covering the gel.
- Always store and seal the unit in the provided storage bag and keep in a cool dry place when not in use. (Electrodes should be stored at temperatures of 41˚ to 80˚ F. Do not store in the freezer/refrigerator, or leave in extreme heat.)
- Never submerge the electrodes in water.
- Re-hydrate the gel with a drop of water several times during daily wear.
- Electrodes are to be used for **a single user**; Never share electrodes or re-use on a second person.
- **Never** apply the electrodes to or use the stimulation on broken, blistered or irritated skin.
- If a rash or skin irritation occurs, discontinue use and contact the WalkAide clinician. It is not appropriate to restart WalkAide wear until the skin is **100%** clear of irritation or redness.

6.2 Additional Information

1. A stimulus may be produced when connecting or disconnecting the Hand Switch or the Heel/Foot Sensor from the WalkAide unit. **Always turn the WalkAide OFF**.

2. Zoom feature: When in the Graphs screen, place cursor at the beginning of the desired data, press and hold the left mouse button 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 to see all Data**' 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 user returns for follow-up. This allows the parameters to be easily restored if needed and documents the usage of the WalkAide.
   - Click on 'Save WalkAide Settings' and then click on the 'Save WalkAide Parameters' icon at the beginning of each visit.
   - Click on 'Collected Logs' and then click on 'Retrieve WalkAide Log' at the beginning of each visit.

4. It may be necessary to modify the parameters each time the user 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.

7.0 Troubleshooting

7.1 WalkAide Control Unit Troubleshooting

1. The blue light for the WalkLink shows black in WalkAnalyst program despite the cable connections at both the laptop and the WalkAide unit.

Possibilities:

- There is a loose or damaged cable connection with either the WalkAide or WalkLink .
- The WalkAide battery needs replacing if pressing down on the STIM button on the unit does not show an amber light.
- The WalkLink batteries are not sufficiently charged.
- The USB Bluetooth Adapter is not properly seated.
- Bluetooth connection: Re-establish

2. No stimulation despite the amber light when pressing the STIM button on the WalkAide unit.

Possibilities:

- Check the electrode leads to ensure they are not broken.
- Check to make sure the electrode lead cable is firmly connected to the back of the WalkAide.
- 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.
- The electrodes and/or skin need to be re-wet to improve conduction.
- The cables may have been reversed (ie: Red to back)

4. Occasional sharp stimuli.

Possibilities:

- The electrodes are old and need to be changed.
- The electrodes are not wet enough.
- The cuff is not adequately tightened causing it to shift with motion and thereby compromising electrode/skin connection. Ensure proper positioning of cuff and tighten the strap. Avoid tight, slim-fitting pants that can cause a pull on the cuff.
- Check skin under electrodes for irritation or open areas.
- 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 is 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 seconds.

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. Check device parameters and make changes to 'Stimulation Mode' if necessary.

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.
- Internal time clock battery needs replacing. Contact 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.

7.2 The ABC's of Electrode Placement

Accuracy of electrode placement is the key to the efficient, comfort and functional control of foot lift. 'Balanced' placement of the electrodes promotes a safe and symmetrical gait while preserving muscle endurance. The closer the black (posterior) electrode is to a position directly over the motor nerve, the more comfortable the stimulation is for the user precise positioning of the electrodes lessens the sensory response to the stimulation. The more precise the electrode placement, the stronger the muscle contraction at lower levels of intensity. The goal of electrode placement is to produce the most functional movement at the lowest intensity level so that the risks of muscle fatigue or skin irritation are minimized.

`Black to the back and red ahead' is the key phrase to remember when connecting the electrodes. The black electrode is negative and sends the stimulation into the leg. The red electrode is positive and forms a complete circuit to pull the stimulation out of the leg. The stimulation is optimized if it enters at the motor nerve and exits after traveling in the direction of the muscle.

Conductivity is enhanced by a complete circuit. Assuring a uniform electrode-skin interface. Apply water to the electrodes (and the skin if desired); make sure that there is no water between the electrodes. Spacing of the electrodes will also affect conduction of the stimulus signal:

1) The closer the electrodes, the more superficial the current = more eversion

2) The farther apart the electrodes, the deeper the current = more dorsiflexion

7.3 Manual Adjustment of the Stimulation Parameters

Manual adjustment can always be performed by adjusting parameters to control swing and stance duration. This process relies on the clinical judgment of the treating clinician.

ONLY use the manual adjustment feature if the gait pattern of stimulation is NOT completely satisfactory after applying the **Zoom in to Select Steps**, **Autoset WalkAide Parameters** and **Optimize Gait Program** options.

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 swing and stance (Figure 70).

Figure 70: Adjusting the On and Off Thresholds

a. Stimulation occurs when the sensor value reaches the **On** threshold.
   - The **On** threshold (horizontal solid green line) may be too high and the sensor value never reaches it. If this is the problem, the "mountains" on the graph will not cross the green line. To correct this, lower the **On** threshold by clicking and holding on the green bar to the left of the graph screen area and dragging it lower. When the button is released, the modified pattern of stimulation is calculated and displayed.
   - Top graph: Tilt On = angle △'s
   - Lower graph: Heel On = heel unloading

b. Stimulation terminates when the sensor value reaches the **Off** threshold.
   - The **Off** threshold (solid horizontal 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. To correct this, raise the **Off** threshold by clicking on the orange bar to the left of the graph screen area and dragging it higher.
   - Top graph: Tilt Off = angle ☆'s
   - Lower graph: Heel Off = heel loading

c. The **On** and **Off** Thresholds may be adjusted over time as changes occur in walking speed, step length, symmetry, ease of swing, amount of hip and knee flexion, degree of hypertonicity, etc, or to achieve specific therapeutic modalities.

d. The numerical values listed as the **On** and **Off** thresholds relate to the range of tilt (angle or heel line) available for measurement within the WalkAide unit itself. The numerical values are not a report of hip, knee or ankle alignment angles. The clinical significance of the numerical values is that a change in the numerical value of the threshold by a value of three is approximately one degree of tilt. So, if the **On** threshold is lowered by a numerical value of nine, then it will take three fewer degrees of tilting of the tibia to reach the **On** threshold.

Examples of Threshold Adjustments

- Example 1 – **Tilt On** Threshold is too high (Figure 71). Steps occur on the Tilt graph during which the peak does not reach the **On** Threshold and therefore stimulation does not occur. Lower the **On** Threshold to better match the Tilt data in the graph.

Figure 71: The On Threshold is set too high, creating missed stims

- Example 2 – **Tilt On** Threshold is too high (Figure 72). A stimulation occurs with each step but the user reports a late stimulation or the clinician hears (with '**Beep on Stim**') and/or observes a delay in the foot lift. Lower the **On** Threshold to initiate the stimulation earlier.

Figure 72: The On Threshold is set too high, producing a delayed pattern of stimulation

- Example 3 – **Tilt Off** Threshold is too low (Figure 73). Steps occur on the Tilt graph during which the valley does not reach the **Off** Threshold and therefore stimulation is not retriggered in preparation for the next step. Raise the **Off** Threshold to better match the Tilt data in the graph.

Figure 73: The Off Threshold is set too low, below the Tilt graph data

2. The **Min Time** sets the minimum period of stimulation that is allowed. The range is from 0 to 1.5 seconds and increases (or decreases) in increments of 0.1 sec. (The **Min Time** always overrides the **Max Time** and the **Off** Threshold.) The **Min Time** ensures that stimulation continues for a sufficient duration to assure that the toe clears the ground during swing phase. The **Min Time** also assures that the swing phase occurs for a specified amount of time, this prevents poorly timed on and off cycles that may occur with abnormal tibial motion during swing (usually from ataxia). Adjustment to the **Min Time** also addresses periods of faster walking or faster steps when the user spends less time in swing. The value increases (or decreases) in increments of 0.1 sec. (Figure 74)

Figure 74: The Min and Max Times have been set too low, providing only a brief period of stimulation.

3. The **Max Time** sets the maximum period of stimulation that is allowed. The range is from 0.2 to 3 seconds and increases (or decreases) in increments of 0.1 sec. The **Max Time** allows for periods of slower walking or slower steps when the user needs to spend more time in swing. The **Max Time** also prevents extended periods of stimulation. For example, if the user sits down and tilts the leg forwards, the stimulus will be discontinued after the value set in **Max Time** has been reached. Together, the Min and Max time allow for variations in walking speed from step to step, morning to afternoon or gradual increases in walking speed over time. A correctly adjusted Min Time allows for faster walking if necessary (for example, speeding up to cross the street) while a sufficiently long Max Time allows the user the necessary increase in stim time needed to take a slower step if the situation requires it (for example walking slowly across a rough surface). The Off threshold overrides the Max Time during walking to ensure that the stimulation is appropriately terminated at initial contact.

4. The **Wait Time** is the minimum amount of time after each stimulus that must elapse before a new stimulus can be initiated. The range of the **Wait Time** is from 0 to 1 second and increases (or decreases) in increments of 0.1 sec. The **Wait Time** prevents the user from getting stimulated before stance phase can be completed (this may be necessary if the user is ataxic or flexes the stance knee excessively during stance). The **Wait Time** prevents unwanted or inadvertent stimulation during stance phase. As user's increase their walking speed and spend less time in stance, a lower **Wait Time** will be necessary.

Figure 75: Lower the Wait Time allows for increases in walking speeds

In general, the **Min**, **Max** and **Wait Time** values will be higher for slower walkers as they spend more time in swing and more time in stance. The Min, Max and Wait time values will be lower for faster walkers as they spend less time in swing and less time in stance.

<u>From the 'Modified Parameters' screens:</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 gait data timing of the stimuli. The threshold values will be automatically transferred to the Modified Parameters and Params as Collected screens. (Figure 76)
   a. Heel On
   b. Heel Off
   c. Tilt On
   d. Tilt Off

Figure 76: On and Off Thresholds for the Heel and the Tilt Sensors are best adjusted from the date and time stamped graph screens

2. **Control Times** – The **Min Time**, **Max Time** and **Wait Time** are best adjusted on the Graphs screen by moving the appropriate sliders to produce a consistent pattern of stimulation. The values of these Times are automatically transferred to the Modified Parameters. (Figure 77)

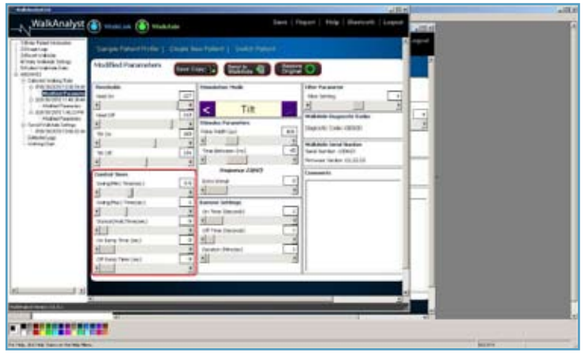


Figure 77: Control Times control the duration, cessation, introduction and termination of the stimulation (swing & stance duration)

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 (Figure 78). Use this to modify the introduction of the stimulus when the On Threshold is reached. Increasing the On Ramp essentially decreases the rate of dorsiflexion of the foot once the stimulation comes on after terminal stance. Increasing the On Ramp Time will result in more gradual dorsiflexion and may be helpful in decreasing clonus or spasticity, or to increase comfort for those who are more sensitive to the stimulation. The range of the On Ramp Time is from 0 to .5 seconds.

e. The **Off Ramp Time (sec)** controls the rate of the fall of the stimulation from its set value to zero (Figure 78). Use this to modify the termination of the stimulation after the Off Threshold is reached. Increasing the Off Ramp Time will help to control foot slap or decrease the rate of plantarflexion during initial contact. Increasing the Off Ramp Time will result in more gradual plantarflexion and create a slower eccentric lengthening of the tibialis anterior muscle function during initial loading. The range of the Off Ramp Time is from 0 to .5 seconds.

- Note: increasing the Off Ramp Time will **add length** to the duration of the stimulus and may require an adjustment to Wait Time to prevent a missed stim.

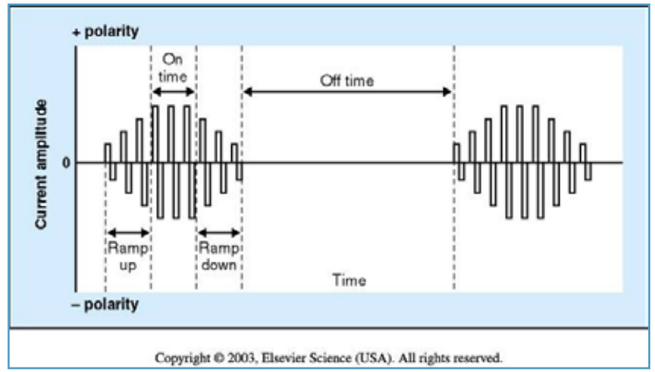


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Figure 78: The On Ramp Time modifies the introduction of the stimulation

3. **Stimulation Mode** – Identifies the mechanism for triggering the stimulation, specifically **Hand**, **Tilt**, or **Heel**. (Figure 79)

a. The **Hand Mode** is used during initial data collection procedures when the clinician is required to use the Hand Switch on the WalkLink to provide an effective pattern of stimulation allowing clinician to override patients walking pattern. The Hand Mode is the set function of the Default Parameters.

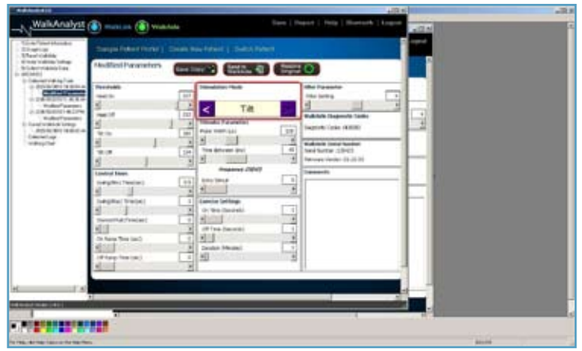

Figure 79: Stimulation Mode

b. The **Tilt Mode** is the preferred stimulation mode for most users. The tilt function operates by tracking the movement and speed of the lower leg during walking. An effective walking program will trigger the stimulation during each step. Use of the Tilt Mode minimizes additional wires and components for the user.

c. The **Heel Mode** is used during initial data collection procedures to provide another set of data for programming. The Heel Mode is also used as an ongoing method of stimulus generation in some cases, often as a transitional modality for user's with a sustained step-to gait or erratic pattern of walking. Continued use, therapy and gait training often allow the user to transition to the Tilt Sensor once a more efficient and consistent pattern of walking has been obtained.

4. **Stimulus Parameters** – These adjust the characteristics of the pulses within the stimulus train. (Figure 80)

Figure 80: Stimulus Parameters

a. The **Pulse Width** is the duration of each individual stimuli within the stimulus train and can be increased or decreased. (The range of the Pulse Width is adjustable from 25 to 300.) The wider the pulse width, the more motor units are recruited leading to a more robust contraction. Increasing the Pulse Width may provide a more forceful stimulation, and allow for a greater contraction at an equal or lower intensity. (If the **Pulse Width** has been raised, lower the intensity level of the WalkAide unit before testing to prevent possible overstimulation of the user). It may be helpful to increase the pulse width if the user's foot is not dorsiflexing quickly or strongly enough. Decreasing the **Pulse Width** may provide a less forceful stimulation, and allow for a softer contraction. It may be helpful to decrease the **Pulse Width**, if the stimulation is uncomfortable even at lower stimulation intensity levels. (recommended for pediatric or more sensitive patients).

i. For example, when testing the WalkAide system on a user with a smaller leg or a child, the **Pulse Width** should be lowered to 25 prior to testing the system. (Figure 81)

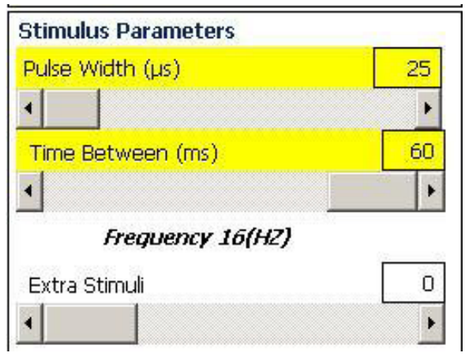

Figure 81: Decreasing the Pulse Width and increasing the Time Between for a less forceful stimulation

ii. Conversely, if the intensity setting on the WalkAide must be turned all the way up to 8 in order to achieve an effective stimulation, a limitation to the range of adjustment is available to the user. The Pulse Width should be increased so the intensity adjustment on the WalkAide can be decreased and allow some adjustability by the user. (Figure 82)

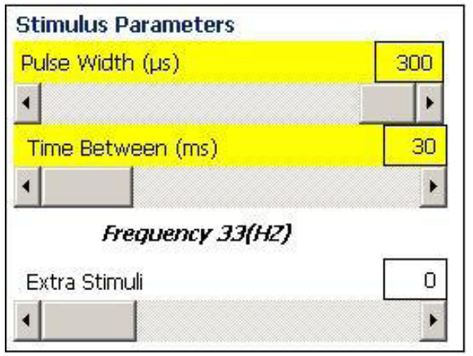

Figure 82: Increasing the Pulse Width and decreasing the Time Between for a more forceful stimulation

b. The **Time Between** (ms) stimuli is inversely proportional to the stimulus rate (frequency) and is adjustable from 30 to 60. A time of 50 ms represents a rate of 1 stimulus every 0.05 seconds, or 20 stimuli per second. For example, **Time Between** pulses of 30ms, 40ms, 50ms, and 60ms would equate to 33.33Hz, 25Hz, 20Hz, and 16.67Hz, respectively.. The longer the time in between, the lower the rate or frequency of the stimuli. (Figures 81-82)

c. The **Extra Stimuli** feature is essential and can be helpful 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 users with faster walking speeds or may be considered if a delayed response to the stimulation is noted. The range is from 0 to 3. (Figure 81-82)

5. **Exercise Settings** – discussed in detail in section 5.7.

6. **Filter Parameter**

a. If the sensor signal is quite "noisy" (i.e., variable steps, leading to very jagged graphs) it may be difficult to develop a clear program that assures that stimulation will be reliable. If this is the case, the Filter Setting can be increased and new data collected. This will smooth the appearance of the graphs in any new data collected but will have no impact on any previously collected data. Increasing the filtering (smoothing) may introduce some delays in the onset of stimulation. Alternatively, if an earlier stimulus is desired and the data are not very noisy, the filtering may be decreased. The default filter setting is 4, and the range is from 0 to 7. (Figure 83)

Figure 83: Filter Parameter

7. **WalkAide Diagnostic Codes** –Six digit readout indicating WalkAide System hardware's internal status / fault. This diagnostic code should be communicated to ININC technical staff as requested. (Figure 84)

Figure 84: WalkAide Diagnostic Codes

8. **WalkAide Serial Number** – For reference, the WalkAide unit serial number will be automatically logged and noted. (Figure 85)

Figure 85: WalkAide Serial Number

9. **Comments** – Use this section to add pertinent information about the user, their walking experience, parameter settings and/or adjustments, intensity level, etc. (Figure 86)

Figure 86: Comments

7.4 Anatomy of Tilt and Heel Data

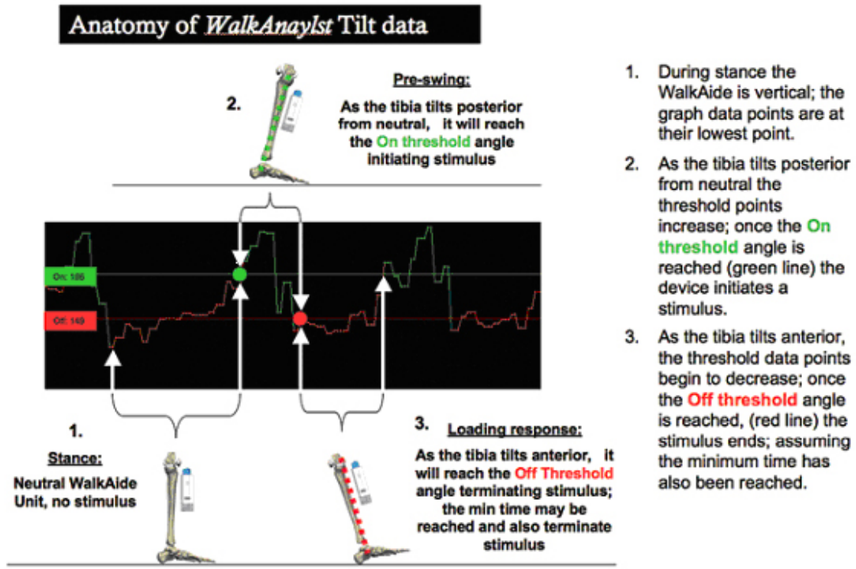

Figure 87: Anatomy of WalkAnalyst Tilt Data

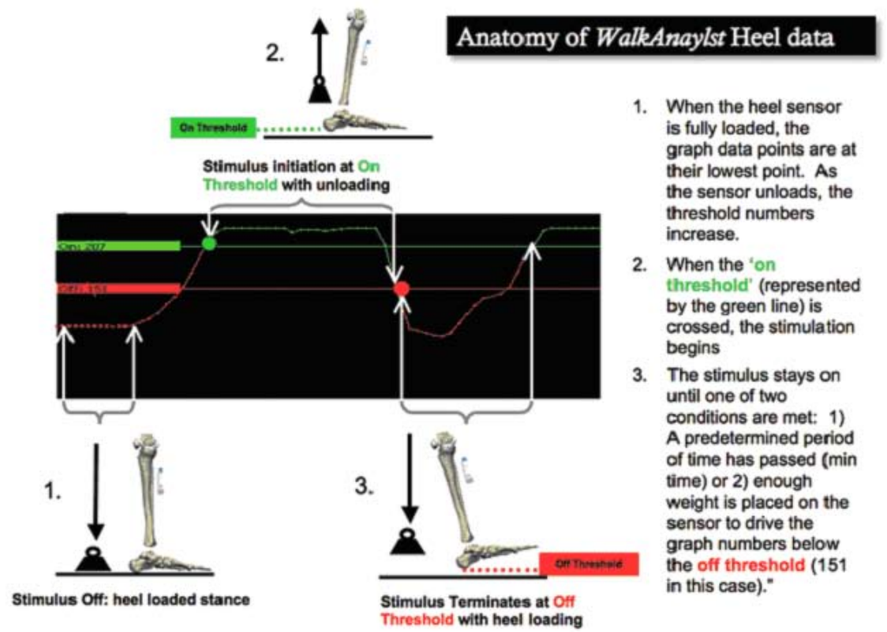

Figure 88: Anatomy of WalkAnalyst Heel Data

7.5 Follow-Up and Re-Optimization

The WalkAide system is designed to be part of a progressive rehabilitation program. Notably, many users increase walking speed over time with consistent use of functional electrical stimulation. Other changes in the walking pattern include decreased effort with gait, changes in step and stride length, improved symmetry of stance and swing phases, decreased need for external support (i.e. canes, walkers, crutches), and improved swing phase dynamics. Other functional changes include increased ankle range of motion, increased muscle strength and increased voluntary control of dorsiflexion. As a result, it will be necessary to re-optimize each user's walking program from time to time to promote continued improvements. It's likely that a user with a more recent walking dysfunction will require more frequent changes to the programming than a user with a more chronic involvement. Often as a patient's function and mobility improve, there emerges potential for other gains in mobility, motor control and quality of gait. A referral to Physical Therapy for further rehabilitation and gait training is often appropriate even in users many years post the initial CNS event.

There are four methods to re-optimize the user's walking program. These are outlined below with clinical descriptors of when each method may be most indicated.

Option 1: **Rapid Adjustment:** Adjust stimulation parameters to manually fine tune the programming. These adjustments are transferred to the WalkAide instantaneously. Every adjustment made will configure by audible beeps.

To adjust an existing program (patient profile)

1. Open Patient Profile
2. In Patient Profile page, click on Rapid Adjustment
3. Rapid Adjustment
   a. Turn on beep on stim and have patient walk. Adjust Initiation, Duration or Missing stims in Control Setting view based on clinical observation and patient feedback
   b. Click on Advanced Parameter to adjust Stimulation Comfort and Quality
4. Click Finish to finalize the program

Option 2: Send Default Parameters: If the new or experienced user has made significant changes in their walking program since the last adjustments were made, proceed through set-up as if a new user.

- Connect all equipment (including the Heel Sensor) and establish Bluetooth connection.
- Click on 'Save WalkAide Settings' and then click on the icon labeled 'Save WalkAide Settings'.
- Click on the date and time-stamped trial listed below 'Save WalkAide Settings' and make any clinical comments relevant to this walking program.
- Follow steps 2 – 5 to Reset WalkAide, Clear Usage Logs, Verify WalkAide Settings, and Collect Walking Data.
- Process the best walking trial by using the Zoom, Autoset and Optimize functions.
- Send the new walking program to the WalkAide and collect a final walking trial in Tilt Mode for verification.

Option 3: Standard Programming, Manual Adjustments: If the user has made moderate changes in their walking ability or if the clinician is planning ahead for changes, then manual adjustments can be made.

- Connect all equipment (including the Heel Sensor) and establish Bluetooth connection.
- Click on 'Save WalkAide Settings' and then click on the icon labeled 'Save WalkAide Settings'.
- Click on the date and time-stamped trial listed below 'Save WalkAide Settings' and make any clinical comments relevant to this walking program.
- Click on 5) 'Collect Walking Data' and collect a walking trial with the user's current settings.
- Critically evaluate the graph data and relate the thresholds to gait events such as heel off, swing and initial contact. It may be helpful to use the Beep on Stim feature here to listen to the timing of the stimulation during data collection and also to elicit feedback from the user.
- Make minor adjustments as needed to the On/Off thresholds and/or Control Times.
- Send the new walking program to the WalkAide and collect a final walking trial in Tilt Mode for verification.

Option 4: Re-Optimize Existing Walking Program: If subtle changes are noted and both the user and clinician are relatively satisfied with the existing walking program, then re-optimizing the data is most indicated.

- Connect all equipment (including the Heel Sensor) and establish Bluetooth connection.
- Click on **'Save WalkAide Settings'** and then click on the icon labeled 'Save WalkAide Parameters'.
- Click on the date and time-stamped trial listed below 'Save WalkAide Settings' and make any clinical comments relevant to this walking program.
- Click on 4) **'Verify WalkAide Settings'** and change the Stimulation Mode to Hand. Send Parameters to WalkAide.
- Collect a new walking trial (or trials) pressing the Hand stim button on the WalkLink to control the timing and duration of the stimulation.
- Select the best walking trial that is most representative of the user's current, consistent gait pattern.
- Use the Zoom function to highlight 6 – 8 consecutive steps.
- Click on **'Optimize Gait Program'** and use the Hand or Heel data to optimize the parameters. (Since this walking data was collected over the user's existing walking program, the Autoset function is NOT used.)
- Send the new walking program to the WalkAide and collect a final walking trial in Tilt Mode for verification.

7.6 WalkLink and Bluetooth Troubleshooting

Section 1: Hardware: Bluetooth USB Device

Problem 1: Conflict with internal Bluetooth or another Bluetooth driver installed on the computer

- Turn off internal Bluetooth of the computer. Internal Bluetooth adapters are FCC class 2 devices with very limited range. Check your computer manual on how to disable internal Bluetooth. If another Bluetooth driver/software is causing the conflict, you may need help from your IT support team. Call the Innovative Neurotronics technical support team if you have trouble resolving this problem.

Problem 2: An error occurred while installing the device.

- After inserting the Bluetooth USB adapter, if a confirmation message that the new hardware is installed and ready to use was not recieved, follow the installation instructions that accompany the Bluetooth USB device. Vendor provided software may be necessary to have Bluetooth working properly. Use Alternate Method for pairing. Call Innovative Neurotronics technical support for additional support.

Problem 3: The Bluetooth device is not displaying a blue light

- A properly functioning Bluetooth device will display a blue light to indicate it is working properly. If not, try the Bluetooth device in a different USB port.

- During the search process, the blue light will blink rapidly this is another indicaton that the hardware is functioning properly

If problems persist; check the function of the USB port. If another USB device is available and functional, such as a mouse or keyboard, temporarily swap out the functional devices with the Bluetooth USB device to see if the mouse or keyboard begins to function.

Section 2: Hardware: WalkLink device

Problem 1: The left-most LED light does not flash a green light every two seconds

- The flashing green light is a power indicator. If it is not flashing, the device may have simply timed out after approximately 10 minutes of non-use. Turn the WalkLink off for a few seconds and then turn it on again. Click on the Bluetooth icon in the upper right corner of the screen and 'Search for Previously Connected WalkLinks'.

- Check and make sure the four AA alkaline 1.5V batteries in the WalkLink are new. Do not rely on rechargeable batteries for the WalkLink.

Problem 2 : The WalkLink device did not appear during the WalkAnalyst Bluetooth configuration process

- Turn the WalkLink off for ten seconds, turn it back on and press search again.

- Confirm that the laptop is using Windows XP Service Pack 2 or better, Windows 7 or Vista.

- The WalkLink device may need to be unpaired and re-paired with the laptop. Follow these steps:

  - Turn on the WalkLink device and confirm the flashing green power light.
  - Use a ballpoint pen or something similar to press and hold the small recessed unpair button located above the on/off switch. Depress and hold for one second.
  - Turn off the WalkLink, wait 10 seconds, turn on the WalkLink and try the search process again.

- Make sure that the WalkLink is on and search for the WalkLink at least five times. Sometimes the WalkLink is recognized on later searches.

- If you are having difficulty pairing the WalkLink using the Bluetooth Wizard, please refer to the Alternate Bluetooth Pairing section of the WalkAnalyst Installation & Bluetooth Configuration guide provided with the WalkAnalyst Software; it is also located in the help portal of the WalkAnalyst software.

Problem 3: A connection has been established with the WalkLink device during installation but now messages from WalkAnalyst appear that WalkAnalyst could not find a configured WalkLink.

- Turn the WalkLink off and back on, and either choose the first option in the Bluetooth configuration wizard (i.e. Search for Previously Connected WalkLinks) or simply exit and restart the WalkAnalyst software application while WalkLink is still ON.

- Make sure the green light on the WalkLink is blinking every two seconds. The WalkLink will timeout after approximately 10 minutes if the WalkAnalyst software is not running, even if the blue light is blinking on the WalkLink initially. Turn the WalkLink off for a few seconds, then turn it back on and restart the WalkAnalyst application.

One thing to recognize in this situation is that unless something has changed in the computer configuration, there is no need to run the full Bluetooth configuration wizard again. Once the WalkAnalyst has successfully connected one time, the program should start over and over again without any changes to the hardware settings. It is important to understand that the 'pairing' and hardware recognition process is unique to a specific: (1) computer, (2) USB port, (3) Bluetooth device and (4) WalkLink. If any of these items change, then the Bluetooth connection must be reestablished.

Problem 4: When the WalkAnalyst software program opens with the start-up screen, a message appears stating that the software is opening in offline mode.

- Turn off WalkLink and turn it back ON. If this WalkLink was previously connected, link will re-establish within 15-45 seconds. If link does not re-establish or this WalkLink was not connected previously, click on the Bluetooth link and follow the pairing process.

8.0 WalkAide User Manual

Additional information on safety considerations, skin care, operational manual, changing electrodes and changing batteries is included in the WalkAide User Instructions. **Please read this information and go over it with each user as needed.**

Information regarding air travel with the WalkAide is also provided in the User Manual along with a WalkAide Medical Device ID card (Figure 86). The Transportation Security Administration (TSA) has established a program for screening persons with disabilities and their associated equipment, mobility aids and devices. Their program covers all categories of disabilities (mobility, hearing, visual, and hidden). A medical device identification card for the WalkAide is provided in the User Manual. WalkAide users must identify themselves as wearing an external medical device prior to walking through the metal detector and request a visual and physical inspection of the WalkAide. Further information can be found on the TSA website:
http://www.tsa.gov/travelers/airtravel/specialneeds.

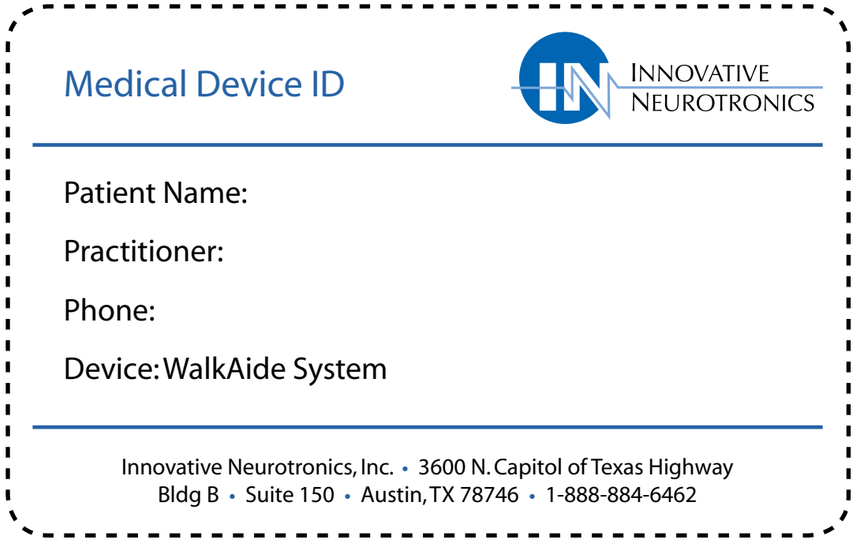

Figure 89: WalkAide Medical Device ID card

9.0 Technical Information

WalkAide

Size	8.2cm(H) x 6.1cm(W) x 2.1cm(T)
Weight	87.9 g
Power Source	One 1.5 volt Alkaline AA battery (LR6)
Maximum Current	200 mA at 500 ohm; 121 mA at 1 K ohm
Maximum Voltage	121 V at 1 K ohm; <150 V at 1 M ohm
Operation Modes	2 - Walking, Exercise
Number of Channels	1
Pulse Type	Asymmetrical Biphasic
Pulse Width	25-300 microseconds (Adjustable)
Frequency Range	16.7 – 33 Pulses Per Second (Adjustable)
Maximum Stimulation Period	3 seconds
Stimulation Trigger Source	Tilt or Heel Sensor
Controls and Indicators	• ON/OFF/Intensity; Stimulation, Exercise • Error
Shipping and Storage Conditions:	Device (Long Term) Temperature: -4° – 140°F (-20° – +60° C) Relative Humidity: 95% max., non-condensing Electrodes (Long Term) Temperature: 41° – 80.6°F (5° – +27° C) Humidity: 35 – 50% Electrodes (Short Term - less than 1 month) Temperature: 32° – 104° F (0° – +40° C) Humidity: 35 – 50%

WalkLink

Size	14.3cm(H) x 70cm(W) x 2.5cm(T)
Weight	113 g
Power Source	Four 1.5 volt Alkaline AA batteries (LR6)
Communication Standard	Bluetooth 1.2 (slave mode)
Operating Frequency	2.402 – 2.480 GHz
Transmitted Power	Class 1
Wireless Technology	Frequency Hopping Spread Spectrum
Controls and Indicators	• ON/OFF slide switch • Unpair, recessed push button • Green, power indicator • Red, low battery indicator • Blue, wireless link indicator
Shipping and Storage Conditions:	Temperature: -4° – 158°F (-20° – +70° C) Relative Humidity: 95% max., non-condensing

10.0 Contact Information

If further assistance is required, please contact:

Innovative Neurotronics, Inc.
3600 North Capital of Texas Hwy.
Bldg. B, Suite 150
Austin, TX 78746
Toll Free (888) 884-6462
Local (512) 721-1900
www.walkaide.com / support@ininc.us

Operations Center	Customer Support	Clinical Support	Technical Support
888-884-6462	888-884-6462 Ext. 2	888-884-6462 Ext. 3	888-884-6462 Ext. 4