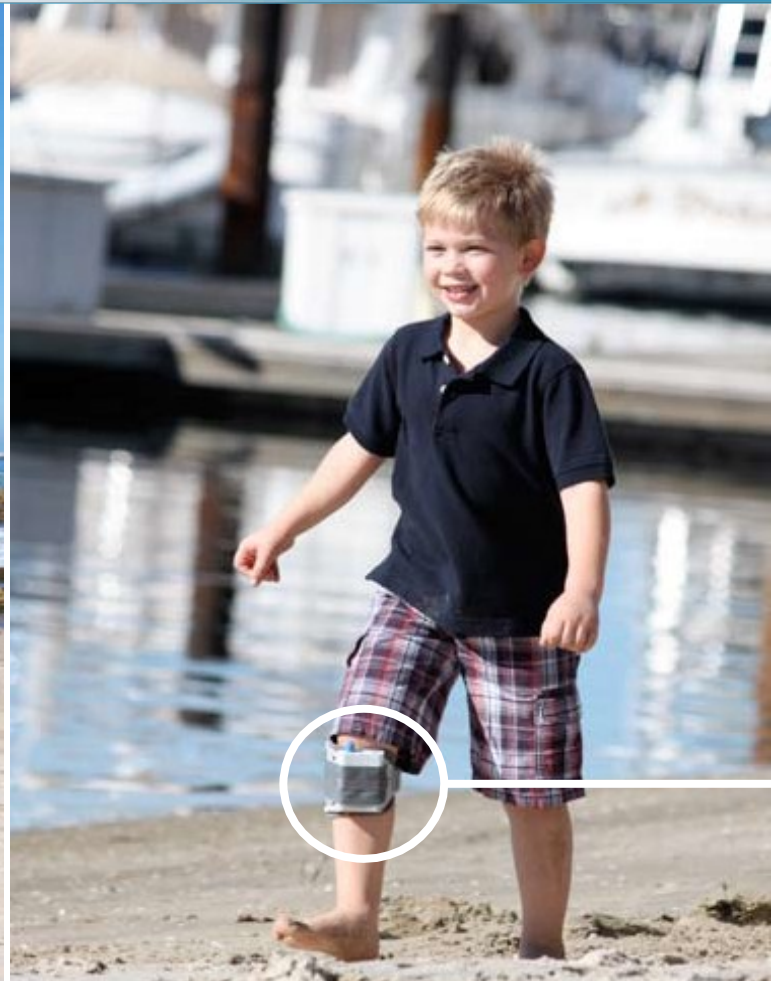


The WalkAide® System



Independence... One Step at a Time



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





The WalkAide[®] System



WalkAide Clinician User Manual

Issued 02.09.2017

Part No. LM06 Rev 12

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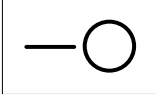




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SYMBOLS ON THE PRODUCT

Symbol	Used for	Symbol	Used for
	Prescriptive symbol		Type BF medical device per: IEC 60601
	Date of manufacture		Manufacturer
	Caution, consult accompanying documents		Caution, electrical precautions
	RF Emitting Device (wireless radio transmitter/ Bluetooth®)		Consult instructions for use
	Display power / standby		ON / OFF rocker switch
	Battery location / positioning		Error Signal
	Exercise button		Impulse / Stim button

INTRODUCTION AND PATIENT SELECTION

The WalkAide is a battery-operated, single-channel electrical stimulator that applies Functional Electrical Stimulation (FES) to the common peroneal nerve. It utilizes a tilt sensor with an inclinometer and accelerometer to control the timing and duration of the stimulation during walking.

The clinician uses the WalkAnalyst software on a laptop, computer or Windows based tablet to program the tilt sensor in the WalkAide. Use of the tilt sensor to trigger stimulation eliminates the need for additional components, heel (force) sensors or external wires.

The WalkAide electrical stimulation produces controlled dorsiflexion of the foot during walk. This small, class II medical device attaches to a molded cuff located just below the knee. Two electrodes are specifically placed over the motor nerve and corresponding 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. Candidates include 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.



INDICATIONS & CONTRAINDICATIONS

Indications

CAUTION: *Federal law restricts this device for sale or use by, or on the order of, a Practitioner licensed by the laws of the state in which he/she practices to use or order the use of the device.*

The Innovative Neurotronics WalkAide External Functional Neuromuscular Stimulator (WalkAide® System) is intended to address the lack of dorsiflexion in patients who have sustained damage to upper motor neurons or pathways to the spinal cord. During the swing phase of gait, the WalkAide System electrically stimulates the appropriate muscles that cause ankle dorsiflexion and may thus improve the gait in patients with chronic stroke. Medical benefits of Functional Electrical Stimulation (FES) may include prevention / retardation of disuse atrophy, increased local blood flow, muscle re-education, and maintained or increased joint range of motion.

Contraindications

Do not use on persons with implanted demand type cardiac pacemakers or defibrillators.

Do not use without medical clearance if a person has a history of seizure disorder.

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

Do not use WalkAide for people who experience dizziness or have difficulty maintaining balance. The WalkAide is not designed to prevent falling.

WARNINGS & PRECAUTIONS

Warnings

Do not 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.

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

Do not use the WalkAide while receiving any MRI scan.

Do not plug foot sensor into any electrical socket other than WalkAide.

Do not unplug foot sensor while sensor is in the shoe.

Do not use the WalkAide while operating potentially dangerous equipment such as automobiles, power lawn mowers or large machinery. Abrupt changes in stimulation level could create a hazard.

Do not use the WalkAide while sleeping or bathing.

Do not place electrodes over open wounds, broken skin or metal objects beneath the skin such as surgical staples.

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.

Do not use the WalkAide without electrodes.

Precautions

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.

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

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.

Use caution; the safety and efficacy of functional electrical stimulation (FES) may depend on the proper use and handling of the 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.

Use caution; the use of heat or cold producing devices; (i.e. electric blankets, heating pads, ice packs) may affect the electrodes, the patient's circulation, and/or may increase the risk of injury. A medical doctor and clinician should be consulted.

Use caution; 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.

Use caution; the use of electrodes not supplied by Innovative Neurotronics may diminish results or increase risk of burns or discomfort.

Use caution; the use of electrodes that are not approved by Innovative Neurotronics will invalidate the WalkAide warranty.

Use caution; the safety of FES for use during pregnancy has not been established.

Use caution; 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.

Use caution; 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.

Precautions (cont.)

Use caution; 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.

Use caution; effects of long term chronic stimulation are unknown in this particular application.

Use caution; 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.

Use caution; the user should not relocate the position of the electrodes within the cuff. Properly replace the electrodes as needed and wet the electrodes as instructed. Never use the WalkAide on any area of the body other than the leg.

Use caution; 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.

Use caution; WalkAide and WalkLink are not intended for use within flammable environments such as oxygen and anesthetics.

Use caution; 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.

Use caution; the user is cautioned that changes or modifications not expressly approved by the manufacturer could void the device warranty and the user's authority to operate the equipment.

FCC Precautions

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.

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 operated in conjunction with any other antenna or transmitter.

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) approval of device safety and the effectiveness of the device prior to marketing. Innovative Neurotronics submitted the 510(k) to the FDA which contained extensive testing and design data, and successfully received 510(k) approval on 09/21/05. A second FDA clearance was obtained specifically for use with chronic stroke on 8/8/14.

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 reddened skin under the electrodes due to increased circulation, 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 a medical doctor if these conditions persist and discontinue use of the WalkAide until the problem is resolved.

INTRODUCTION

Clinician Kit

The Clinician Kit consists of the WalkLink, WalkLink Cable, heel sensor, Bluetooth adapter, WalkAnalyst software and the WalkAnalyst System Clinician Manual. The WalkLink requires four (4) AA batteries.



Figure 1: The WalkLink Clinician Kit (Model Number 20-0300)

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

Minimum OS:	Windows 7, 8 or 10
Computer Type:	Laptop / Tablet
Processor:	1.2GHz or higher
LCD:	10.0inch (minimum) LED/LCD display
Memory:	2GB+ (Windows 7, 8 or 10)
Storage:	40GB (minimum, more is recommended)
WLAN:	802.11b/g/n
Webcam:	1megapixel+ webcam (optional)
Battery:	Rechargeable/ minimum 3 hours run time on full charge
USB Port	Optional for external blue tooth if needed
Video	XGA (1024 x 768)

Patient Kit

The Patient Kit consists of the WalkAide Control Module, WalkAide Electrode Lead Cable and WalkAide User Manual. An appropriately sized WalkAide Bi-Flex Cuff is ordered separately and the full-length foot sensor is an optional item. 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 2: The WalkAide Patient Kit (Model Number 20-1000)

Demo Kit

The Clinician Demo Kit (Model Number 20-1002) 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 is used for evaluation and treatment of any number of patients, but cannot be sold to a patient as it becomes a used medical device.

WalkAide / WalkLink Controls, Indicators & Alarms

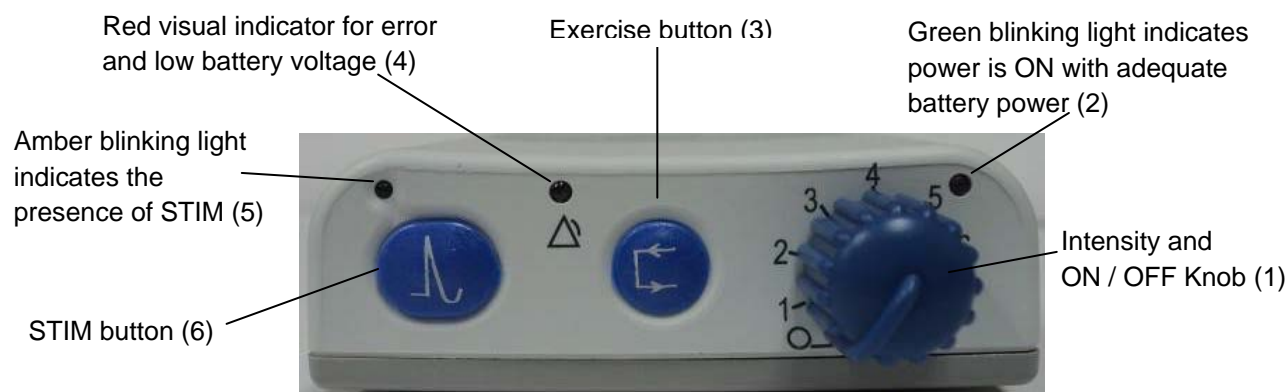


Figure 3: Top View of WalkAide Unit (Controls & Indicators)

Alarms

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

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 the heel/foot sensor. Connect the heel sensor or change the mode in WalkAnalyst to Hand/Tilt.

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

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

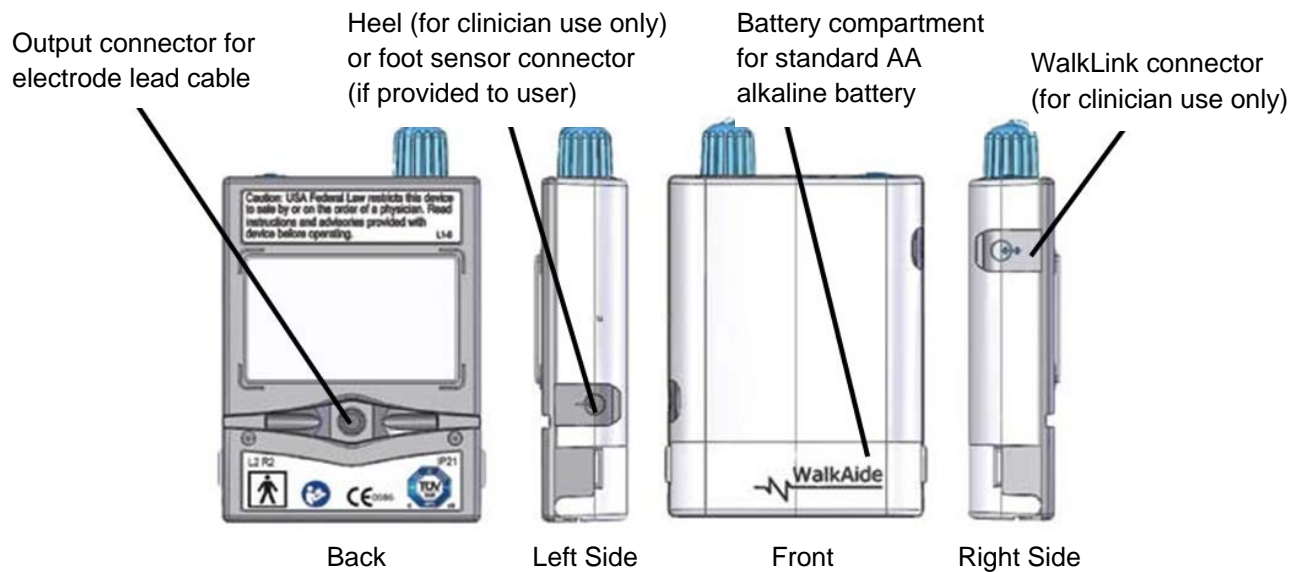


Figure 4: WalkAide Front, Side and Back

Rapid Beeping: Constant beeping with rapid green light flashing indicates the unit was turned on and to high intensity level too quickly, or a new battery was installed without turning off the device. Turn the device OFF and back ON slowly. This is a built in jolt protector alarm for the patient.

Hibernation Mode: A non-audible alarm with only a red blinking light indicates hibernation mode. Establish a Bluetooth connection between WalkAide and WalkAnalyst to automatically clear hibernation mode.



Figure 5: Front and Side Views of WalkLink Unit (Controls & Indicators)

WalkAide Bi-Flex Cuff

The WalkAide Bi-Flex Cuff is designed for single-handed application and removal. It may take practice to develop a routine that works best for each person. The WalkAide Bi-Flex Cuff comes in four different sizes (extra-small, small, medium and large) based on the circumference of the calf. The cuff will fit most adult and pediatric patients. The WalkAide Bi-Flex Cuff 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 6: Lateral Side Cuff



Figure 7: Medial Side Cuff



Figure 8: Lateral Side Cuff



Figure 9: Medial Side Cuff

The cuff must be positioned on the leg correctly to achieve effective and efficient stimulation. Align the orange visual indicator with the tibial crest as a reference for accurate placement. The fabric strap should be adjusted so that the cuff fits snugly. Folding the black portion completely beneath the gray strap makes the cuff as small as possible. Use the gray Velcro rectangle to secure the strap to the outside of the cuff in this situation. The latch will secure or release the cuff.



Figure 10: Clasp Open



Figure 11: Clasp Closed

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.

Washing the Bi-Flex Cuff or Cuff Liner

The WalkAide control module and electrodes must be removed from the cuff before washing. DO NOT remove the electrode markers. HANDWASHING is recommended to extend the life of the material. The cuff should then be hung to dry and NOT placed in a dryer.

Electrode Replacement

Disconnect the black and red leads between the WalkAide and the electrodes then remove the electrodes from the electrode locators. 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 into the strap pouch as indicated in the image below.



Figure: 12 Electrode lead cable inner



Figure: 13 Electrode lead cable outer

WalkAide Cuff Disposable Liner

The purpose of the WalkAide Cuff Disposable Liner is to provide a hygienic barrier between the patient and the cuff. Additionally, it can shorten preparation time in follow up visits. Each Disposable Liner must be cut to fit the patients' cuffs. The electrode placement remains on the liner for return visits. Remember to place protective plastic sheets over the electrodes to prevent drying.

1. Write the patient's name/info on the liner.
2. Cut along the cut lines for the desired size (medium or small). The default size is large.
3. Align the notch in the disposable liner with the orange visual indicator on the cuff's fabric liner.
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 electrode positions are determined, cut small holes in the disposable liner to pass the electrode wires through.



Figure 14: WalkAide Cuff Disposable Liner (Model Number: 20-090)

WalkAnalyst Software Initial Setup

WalkAnalyst is the software used by the clinician to interface with the WalkAide unit. It is used to collect and analyze the patient's walking data and program/personalize the WalkAide to the patient's gait. The gait analysis data are saved in the protected patient file. WalkAnalyst features Rapid+, Express Adult and Express Pediatric options for easy programming. It also allows clinicians to evaluate and report WalkAide performance compared with the patient wearing a brace or no assistive device. This software allows the clinician to customize clinical preferences suitable to a specific patient population or his/her fitting processes. The software is available for download from www.walkaide.com or can be ordered in CD format as Reference code 2-0-0603.

Installation

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

1. Once WalkAnalyst software is installed, software updates are available at www.WalkAide.com (Download link available on the Support page). Updating the software will back up and not erase existing patient files. (Backup page 23).
2. The installer should automatically start. Follow the set up instructions that appear.
3. If the installer does not start automatically, find the appropriate drive icon and open the folder. For Windows 7, 8 or 10 right click on Setup.exe and choose "Run as Administrator". Follow the set up instructions that appear.
4. The WalkAnalyst software will be installed in the Program Files/Innovative Neurotronics directory unless another directory is selected.
5. You will automatically be asked the preferred default language.
6. 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 instructions, refer to WalkAnalyst Installation & Bluetooth Configuration Guide provided with the WalkAnalyst software.

Note: The WalkAnalyst installer will detect if Microsoft.NET framework 3.5 Service Pack 1 (or better) is installed on your computer. If the appropriate framework is not installed, it can be found in the WalkAnalyst installation CD/flashdrive or Microsoft Download Center. After framework is installed, restart WalkAnalyst installation (step 3 above). For Windows version 7, 8 and 10 there is no need to do this step.

WalkAnalyst Upgrades

WalkAnalyst software, when connected to the internet, prompts the user whenever a new upgrade is available. Download the software from www.WalkAide.com (Support > Download) or contact the information technology department to download and upgrade the software.

Administration

If you are a WalkAnalyst user with Administrator level access you can select the Administration link to open the Administration screen.

User Administration:

- To Add a New User: Check/uncheck Administrator checkbox, type in the User ID, password (twice), a security question specific to the user, a security answer and press the Add User button. The user will use the security answer to change the password and/or change the security question/answer.
- To Edit a User: Select a user and press the Edit User button. To edit user information, check/uncheck Administrator checkbox and edit.
- To Remove a User: Select a user and press the Remove User button.

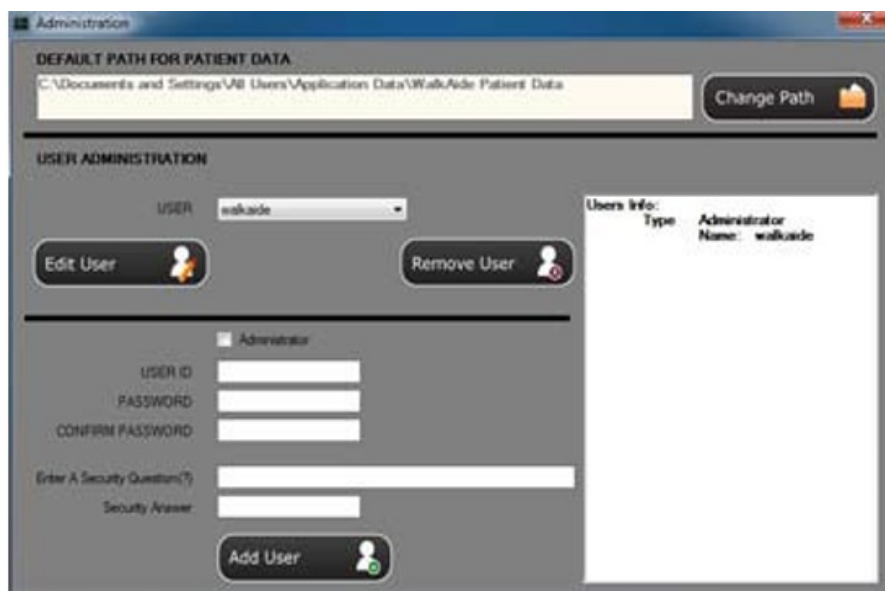


Figure 15: Administration

Patient File Storage Administration:

- The current location for WalkAide patient data is displayed in the Default Path for Patient Data field. Press the Change Path button to change this default path.

Changing Clinical Preferences

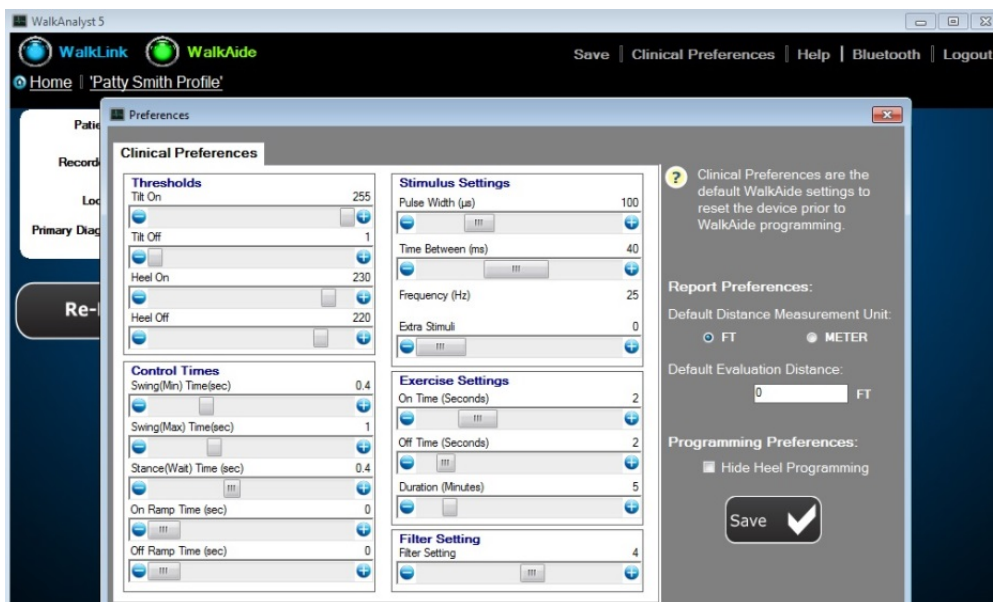


Figure 16: Clinical Preferences

WalkAnalyst software allows the clinician to modify default preferences.

Clinical Preferences: The WalkAide unit default preset values can be changed to individual preferences. For example, a pediatric center may decide to set the default Pulse Width value to a lower, more comfortable level suitable for pediatric patients.

Report Preferences: WalkAnalyst provides an option to compare a patient's gait performance with the WalkAide to the gait of the patient wearing a brace (such as AFO) or no assistive device. A preset distance and units of measurement suitable to the clinical setting can be entered.

Backup

The WalkAnalyst software allows you to back up patient data in an external, internal or network drive. The clinician must have adequate access to save data to the drive.

1. Log on to WalkAnalyst
2. Select Backup Patient Data on the WalkAnalyst home screen
3. Select the backup drive and press the BACKUP button
4. Backed up patient files can be located in the <drive>:\ WalkAideBackupYYYY_Mon_DD folder. (example: e:\ WalkAideBackup2012_Nov_11).

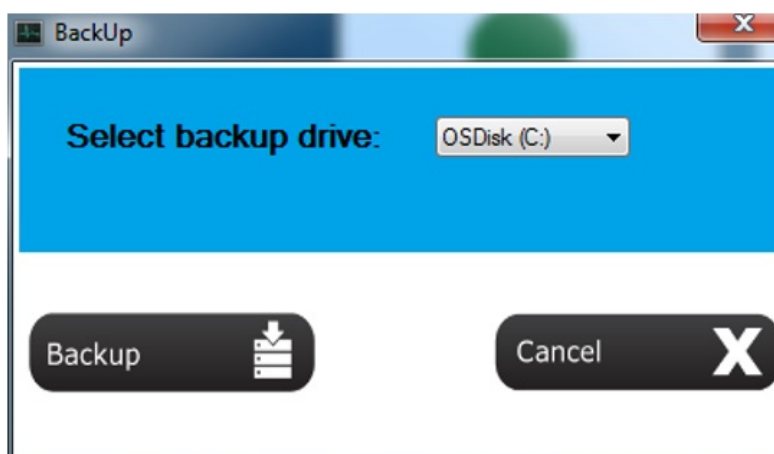


Figure 17: Backup

WalkLink Configuration and Bluetooth Pairing

Configuring Initial Set-up Process (Pairing)

A one-time link must be created from the computer to the WalkLink. This is called the “pairing process”. Follow the guidelines below to accomplish this process.

1. Plug in your USB Bluetooth adapter with the computer powered ON.
2. Start the WalkAnalyst application and log on.
3. Press the Bluetooth link on WalkAnalyst.

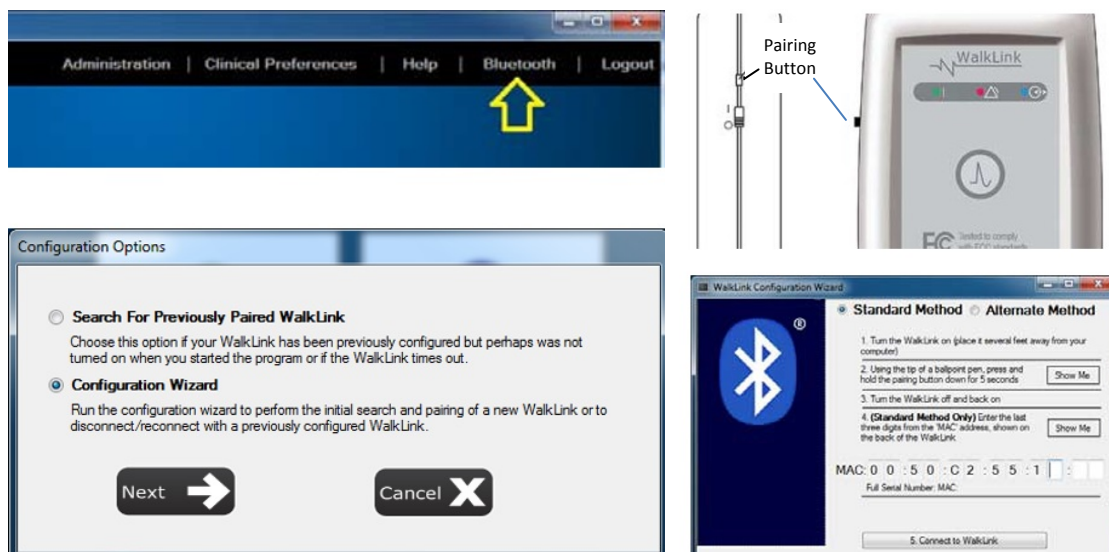


Figure 18: Pairing Process

4. Select Configuration Wizard and press the Next button. (Figure 18)
5. Turn ON the WalkLink: Green flashing light on the face of the WalkLink indicates the unit is ON. (Figure 18)

6. Reset the WalkLink: Using the tip of a pen or pencil, press and hold the Pairing Button (Figure 18) for 3 to 4 seconds. Turn the WalkLink OFF. Wait a few seconds and turn the power back ON.
7. Standard method will be applicable with most Windows based computers or tablets with Microsoft Bluetooth stack properly working. (See the troubleshooting section for pairing a WalkLink using the alternate method)
8. Enter the MAC Address and Connect: Read the last 3 digits of the MAC address from the back of the WalkLink device and enter them in the appropriate boxes on the WalkLink Configuration Wizard screen (Figure 18) then press the Connect to WalkLink button. Press the Connect to WalkLink button again if WalkAnalyst fails to find the WalkLink. It may take about a minute to establish a connection to the WalkLink. When finished, a confirmation message will appear. Press OK to complete the initial configuration. The WalkLink will show a blinking blue light. The indicators for WalkAide and WalkLink on the WalkAnalyst screen will turn Green and Blue, respectively.

Note: If the computer and the WalkLink were previously connected: Turn on the WalkLink and open the WalkAnalyst software. The blue light on the front of the WalkLink should begin to blink. The WalkAide can be connected 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.

WalkAnalyst Fitting Process

Electrode Placement and System Preparation

1. Turn the WalkAide OFF and attach the electrode lead cable to the back of the WalkAide. Direct the cable to the right to fit a right leg and to the left to fit a left leg. This allows appropriate 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. Run the lead wires up along the inside of the cuff. Position the cuff around the mid-calf region and secure it in place below the potential electrode sites. This positions the WalkAide in a convenient location to hook up the electrodes.
3. Moisten the electrodes with water. Place the back electrode overlapping the posterior and inferior borders of the fibular head and the front electrode on the upper 1/3 of the tibialis anterior muscle belly. (Figure 19)

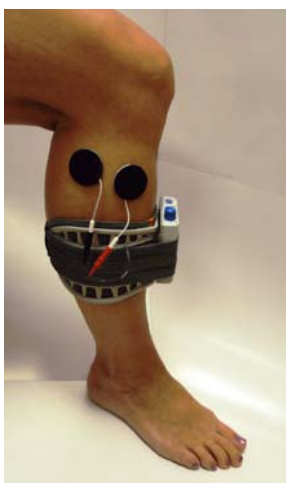


Figure 19
Placement of Electrodes



Figure 20
Exercise Mode Button

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 19).
5. Turn the WalkAide ON by turning the blue intensity knob in a clockwise direction to the 1 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, depress the STIM button on the WalkAide (labeled ✓) or on the WalkLink (if it is connected to the WalkAide and if Default Parameters have been previously sent), or use the Exercise Mode to initiate the stimulation (Figure 20). Observe the direction and amount of

foot lift that occurs in response to the stimulation and adjust either electrode position and/or stimulation intensity for the appropriate response.

7. Once the optimal electrode positions have been found, place Black & Red electrode markers over the electrodes. Turn OFF the WalkAide, release the cuff strap and properly align the cuff to cover and maintain the electrode placement. (Figures 21 and 22).

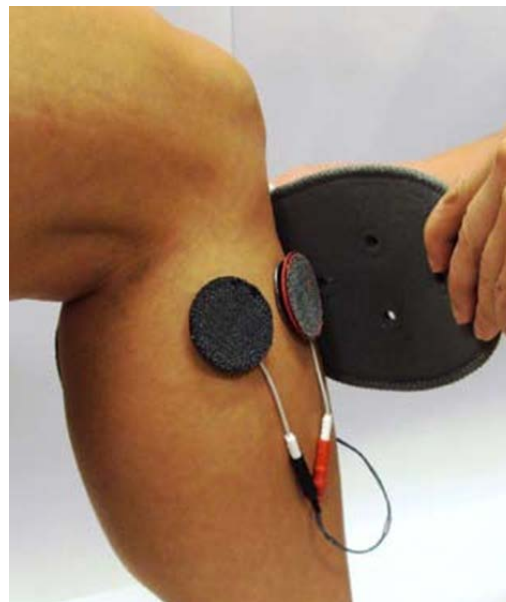


Figure 21 and 22: Carefully Align the Cuff Over the Electrodes and Secure to the Leg

TIPS:

- Electrode placement determines patient comfort and direction of foot movement.
- Always begin by identifying the placement of the Black electrode
- Generally, shifting the Black electrode more posterior and superior elicits more eversion and shifting the Black electrode more anterior and inferior elicits more dorsiflexion (Figure 23).
- Anatomical variations are common.

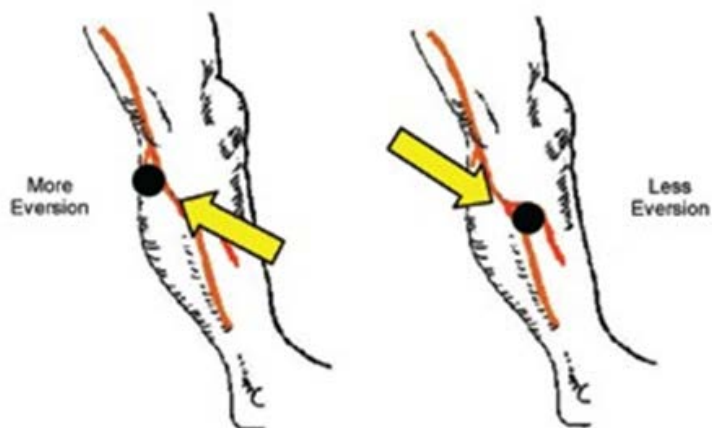


Figure 23: In General, the Posterior Black Electrode Determines the Direction of the Foot Lift

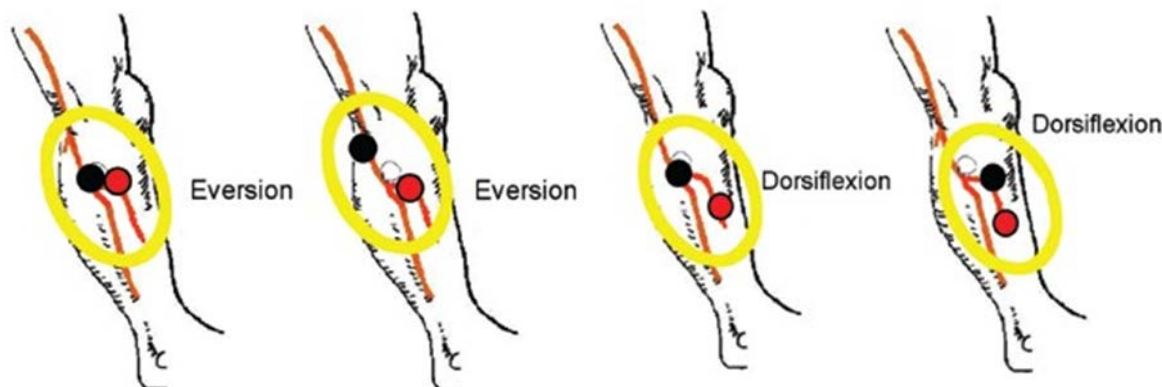


Figure 24: Final Placement of Electrodes Relates to Individual Anatomical Requirements

- Adjust the spacing between the Black and Red electrodes to achieve the desired functional foot lift.
- 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 positions 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.

Preparation for Data Collection:

1. Open WalkAnalyst and log on.
2. Complete the WalkLink and Bluetooth pairing process (page 25).
3. Connect WalkLink and WalkAide control unit using a WalkLink cable (Figure 25).
4. A blue light for WalkLink and green light for WalkAide on the WalkAnalyst software indicate the system is ready for data collection.



Figure 25: WalkLink Cable Connects WalkLink and WalkAide during data collection

Fitting a New Patient

Select Create Patient Profile. Add basic information (patient ID, location, primary diagnosis, etc.) and save the patient file. Select Program.

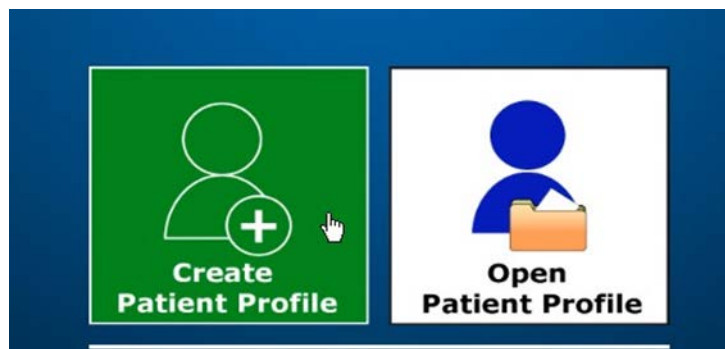


Figure 26: Creating a New Patient Profile

During the initial fitting, you have the following programming options:

- Rapid+ is a simple and easy programming option that can be used by all clinicians. See Rapid+ section for all the details of Rapid+ Programming.
- Express Adult and Express Pediatric are the fastest and easiest way to program the WalkAide used by novice and advanced clinicians. See Express section for all the details of Express Programming.
- Recover is used when the clinician supports a patient with a programmed WalkAide unit, but is missing the patient file. Connect the WalkAide to the WalkLink. Select Recover. Adjust as needed.
- When fitting a bi-lateral patient, set up two separate patient files. One for the left leg and another for the right leg, distinguish the leg in the patient file name. Fit the most involved leg first and then switch over to the other leg once the initial leg has been properly fitted and the WalkAide programmed. Then fit and program the second WalkAide for the second leg.

Fitting a Returning Patient



Figure 27: Open an Existing Patient Profile

Select Open Patient Profile and select one of the following options:

- Re-Program: Re-program the patient using Rapid+ Program or Express Program option.
- Adjustment: Make an adjustment to an existing WalkAide program.
- Transfer Program: Re-program a WalkAide with a preferred program or copy a WalkAide program from one unit to another.
- Evaluation & Report: Conduct a comparative evaluation of the patient's gait with and without the WalkAide or another assistive device.

Programming Options: Rapid+ and Express Programs

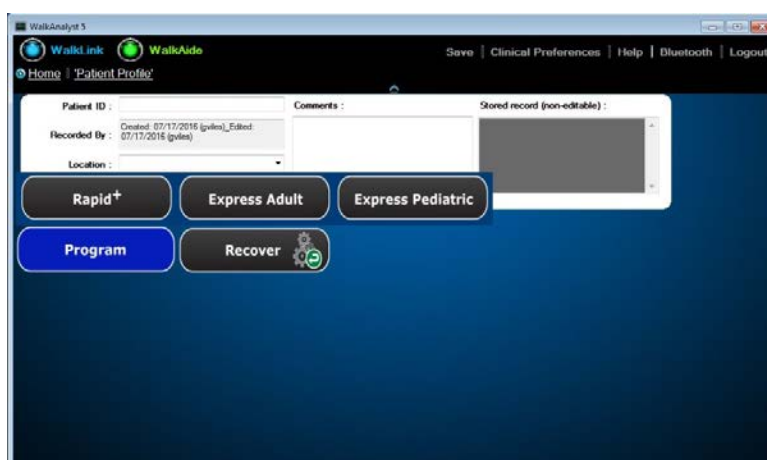


Figure 28: Programming Options

Start

Select the Rapid+, Express Adult or Express Pediatric option (Figure 28) to initiate programming and/or prepare the WalkAide device to operate by hand stimulation from the WalkLink. The software will ask if you want to save the file.

Note: Rapid+ programming is used when you want to manually collect gait data and to create an advanced customized program. Express programming is used when you want to automatically send a walking program to the WalkAide without collecting data. You can then customize the program. Express Pediatric is chosen when you have a patient that is under the height of 48 inches or the age of 14 years.

Adjust the cuff size to fit the patient with the WalkAide on the cuff. Position the cuff and electrodes following the instructions discussed previously, for system set up. Adjust the stimulus settings as appropriate for comfort and function. For example, decrease the Pulse Width and increase the Frequency for a pediatric patient. These can be adjusted immediately on the Stimulus Settings screen following selection of Rapid+ option. Use

the Advanced Settings screen to make these adjustments when using Express Pediatric or Express Adult. (Figure 29)

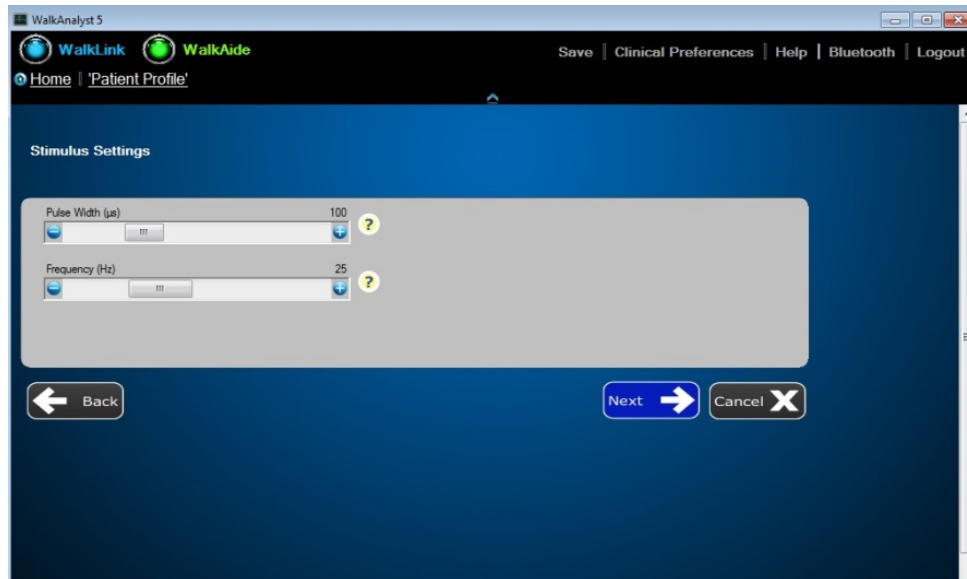


Figure 29: Stimulus Settings

WalkAnalyst allows you to change stimulus settings such as Pulse Width, Frequency, Extra Stimuli, On Ramp Time and Off Ramp Time. Press the Next button. When you select Next with Rapid+ programming it takes you to the Data Collection screen. When you select Next with Express programming it takes you to the Adjustment screen. Note: Hover over the ? next to any field to open a text window with descriptions of the stimulus settings and how they may be applied.

Rapid+

Click Start to begin collecting walking data. Walk at the patient's involved side and use the WalkLink hand trigger to synchronize the stimulation with the patient's gait. During each step with the involved leg, press and hold the WalkLink stimulation button from heel off, through the swing phase, until at least initial contact with the ground. Select Stop upon completion of data collection.

Ideally, select 8-10 evenly spaced bars to represent the patient's typical gait, by left clicking and dragging the cursor to highlight those steps. Upon releasing the mouse, the WalkAide settings are calculated and an Optimization Error is displayed. (An optimization error of less than 20% is recommended). Press Next to program the WalkAide unit in the Tilt stimulation mode and advance to the Adjustment screen.

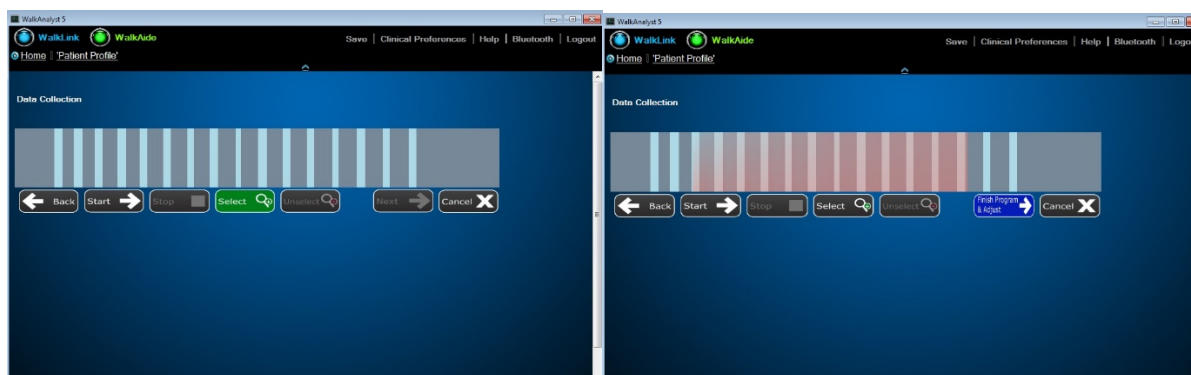


Figure 30: (Data Collection) Select Collected Data

Rapid+ or Step 2: Express

Customize the patient's walking program, stimulus settings, exercise program, etc. as explained in the next section: Adjustment.

Adjustment

Setting adjustments are transferred to the WalkAide instantly and are confirmed by 2 audible beeps from the device. Activate the Beep on Stim mode on the WalkAide and observe that patient walking to assess the value of the adjustments you make. Complete all of the adjustments to effectively customize the patient's walking program, then select Finish and Save Program. This will automatically save the program and the walking trial graph. The WalkAide unit is now programmed for the individual.

Control Settings: Activate Beep on Stim mode. Observe as the patient walks with the newly programmed settings. Adjust the Control Settings based on clinical observation and patient feedback. (Figure 31)

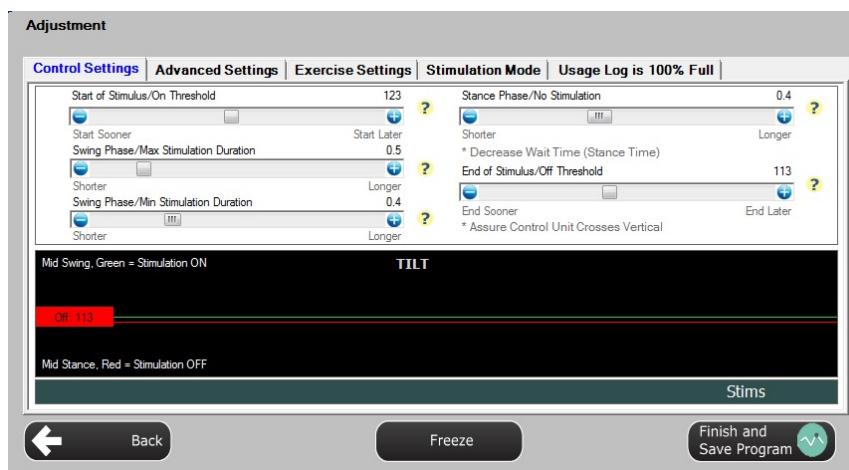


Figure 31: Control Settings

Advance Settings: Click on the Advance Settings tab to adjust the comfort or quality characteristics of the stimulation. (Figure 32)

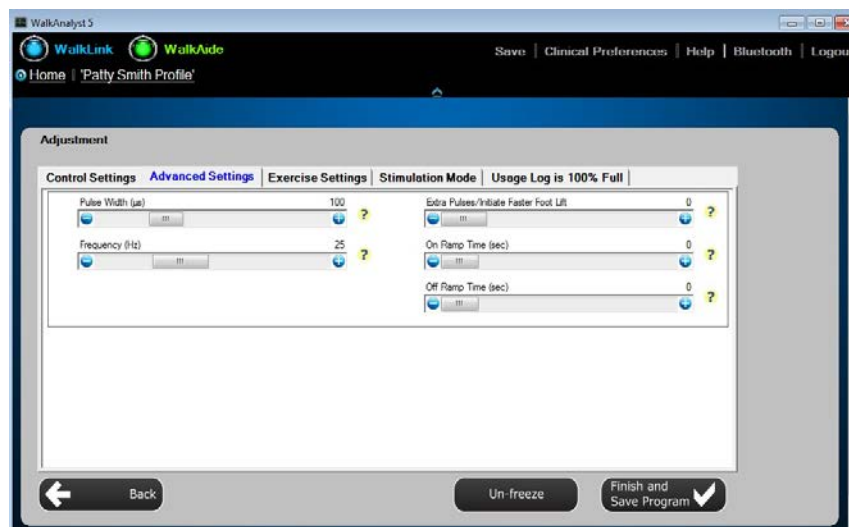
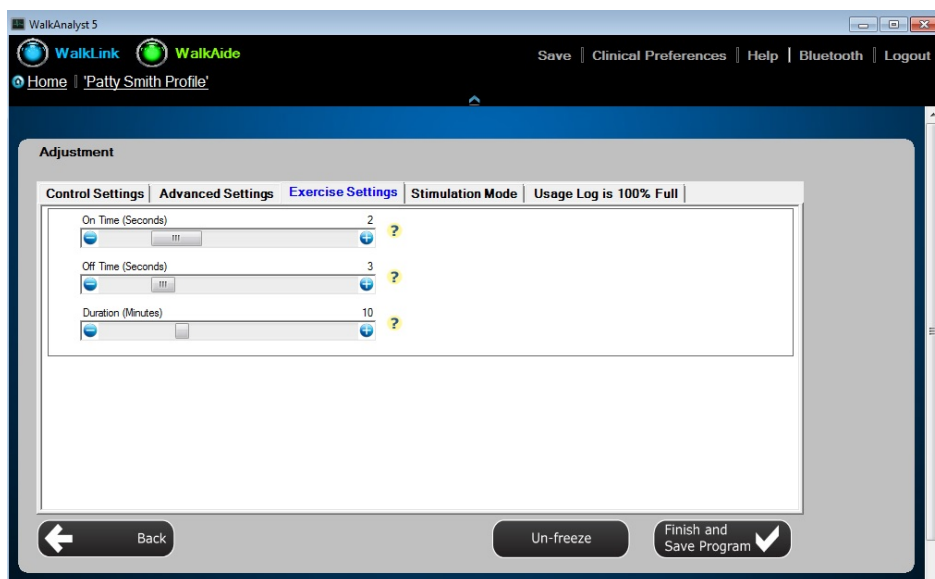


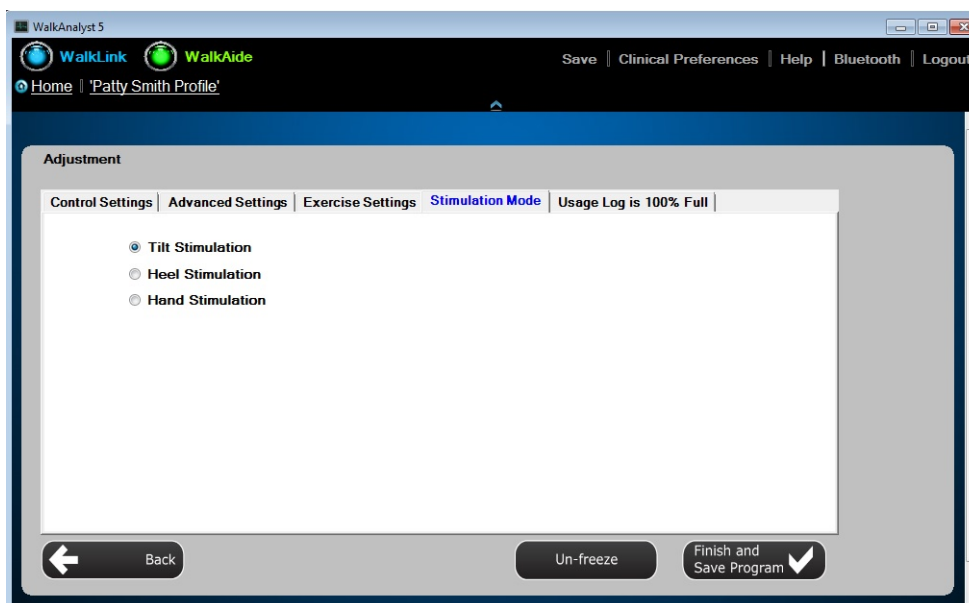
Figure 32: Advance Settings

Exercise Settings: Click on the Exercise Settings tab to adjust patient's exercise settings. (Figure 33)

*Page 36 discusses Exercise Settings and provides examples.

**Figure 33: Exercise Settings**

Stimulation Mode: Use this tab to toggle between Tilt, Heel and Hand stimulation modes. (Figure 34)

**Figure 34: Stimulation Mode**

The Tilt Mode produces the most natural, energy efficient gait for controlled walkers. The Heel Mode can be used when a patient cannot consistently trigger the tilt sensor for safe or effective walking. The Hand Mode can be used therapeutically, giving the Physical Therapist control of the stimulation timing during gait training and exercises.

Usage Logs: Click on the Usage Logs tab to save and/or clear usage data. (Figure 35)

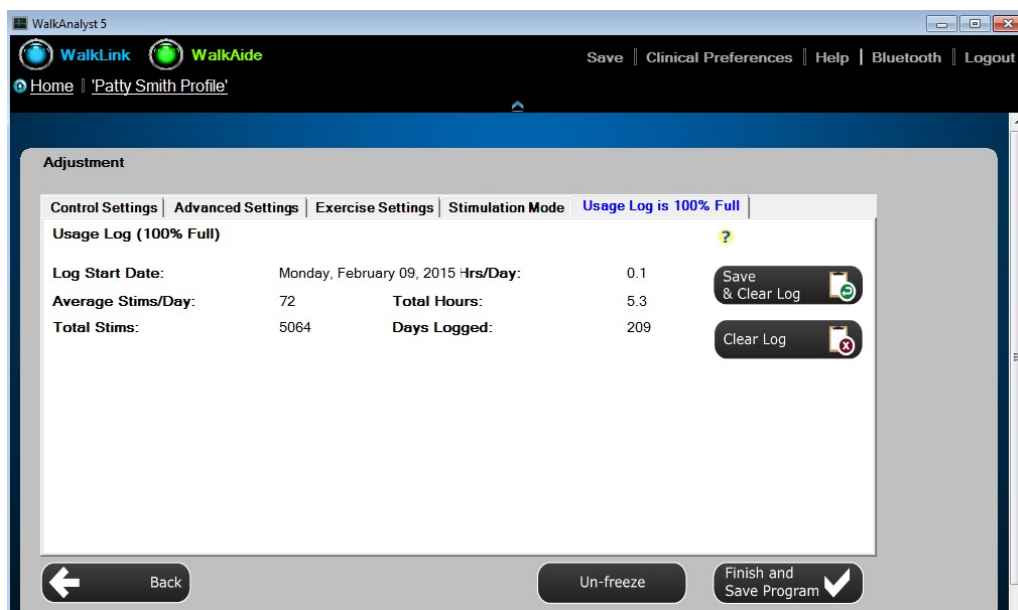


Figure 35: Usage Logs

- Save and Clear Log saves walking data stored in the WalkAide then clears it for further data collection. This option will save data, which can then be found under the Report Tab. (Figure 37)
- Clear Log clears walking data stored in the WalkAide to prepare for collection of future data.
- Usage data during WalkAide Exercise Mode operation are not recorded in the Usage Log.
- The WalkAide unit collects walking data for up to 69 days since the last date the Usage Log was cleared. At day 70, data from day 69 will be deleted from the log. To reset the Usage log when the % Full is high, select Save and Clear Log or Clear Log.
- Graphical view shows the Total Hours/Day and number of Stims/Day recorded during walking.
- Tabular view shows the Total Hours/Day and number of Stims/Day recorded during walking.

Exercise Settings

On Time: 1 - 5 seconds of stimulation for muscle contraction

Off Time: 1 - 10 seconds of relaxation between subsequent stimulations

Exercise Duration: 1 - 30 minutes

Sample Exercise Settings:

	User with Severe Atrophy (1:5)	User with Moderate Atrophy (1:3)	User with Minimal to
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

Figure 36: Exercise Setting Sample

Exercise Program Tips

- The Exercise Mode may be helpful during fitting to verify correct electrode placement.
- Some users may benefit from using the Exercise Mode to “warm up” the neural pathways prior to walking.
- The exercise program can also be used at home for therapeutic exercise approved by the patient’s clinician, especially if the patient walks only for limited durations.
- Always have the patient actively engaged in the treatment session.

Turn the WalkAide power ON. Activate Exercise Mode by pressing and holding down the middle button until the WalkAide beeps. Discontinue the Exercise Mode by turning the WalkAide unit OFF. Turn the WalkAide unit ON again to return the device to Walking Mode. Always turn the WalkAide unit OFF and then ON again prior to walking.

The WalkAide Exercise Mode can be 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. Change the exercise settings from the Exercise Settings tab of the Rapid+ or Express Adjustment screen. (Figure 33)

Evaluation & Reports

WalkAnalyst provides an option to compare a patient's gait performance with WalkAide versus wearing a brace and/or no assisted device. During this evaluation process, it is critical that you collect walking data for the same preset distance. Select the evaluation data and generate comparative reports to highlight the WalkAide performance improvement and justify medical necessity of WalkAide.

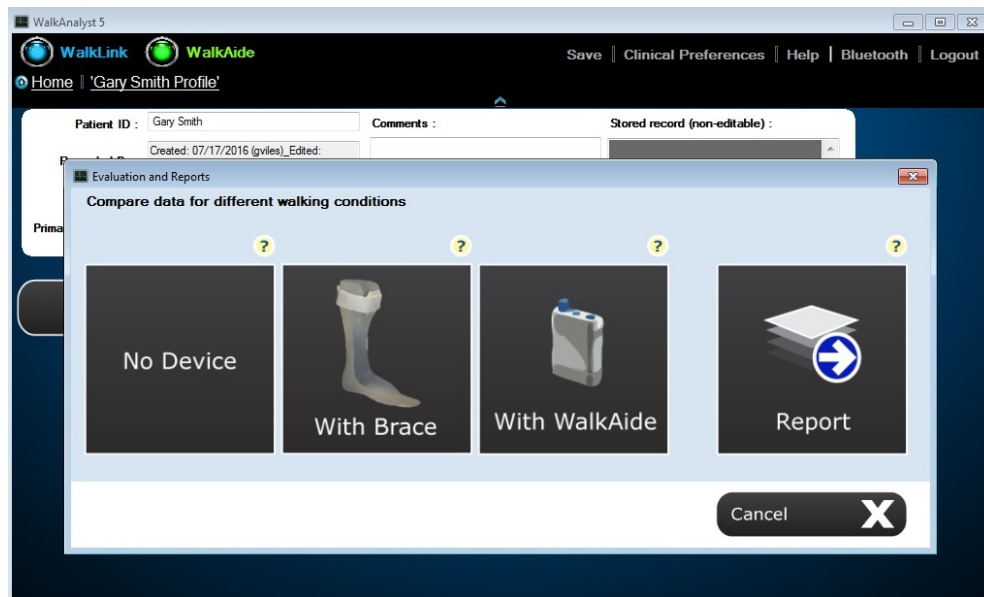


Figure 37: WalkAide Evaluation and Reports

Collect Walking Data - No Device:

With the WalkAide System on the patient, either disconnect the electrode lead wires from the electrodes or turn the stimulation intensity down below 1 so that the patient does not feel any stimulation. The WalkAide device should be turned ON and connected to the WalkLink. Select No Device to launch the data collection window. Select Start and ask the patient to walk. The patient's gait data is displayed on the screen. Monitor the start and end points of the preset distance the patient walks. Press Stop to end data collection. Use the mouse to highlight the section of the patient's gait occurring between the start and end points of the preset distance. When prompted, enter the evaluation distance and number of strides taken to travel this distance. Press Save to record this evaluation data.

Collect Walking Data With Brace:

With the WalkAide System on the patient, either disconnect the electrode lead wires from the electrodes or turn the stimulation intensity down below 1 so that the patient

does not feel any stimulation. The WalkAide device should be turned ON and connected to the WalkLink. Select 'With Brace' to launch the data collection window. Select Start and ask the patient to walk. The patient's gait data is displayed on the screen. Monitor the start and end points of the preset distance the patient walks. Press Stop to end data collection. Use the mouse to highlight the section of the patient's gait occurring between the start and end points of the preset distance. When prompted, enter the evaluation distance and number of strides taken to travel this distance. Press Save to record this evaluation data.

Collect Walking Data With WalkAide:

With the WalkAide System on the patient, adjust the intensity to obtain a functional foot lift. The WalkAide device should be turned ON and connected to the WalkLink. Select 'With WalkAide' to launch the data collection window. Select 'Start' and ask the patient to walk. The patient's gait data is displayed on the screen. Monitor the start and end points of the preset distance the patient walks. Press 'Stop' to end data collection. Use the mouse to highlight the section of the patient's gait occurring between the start and end points of the preset distance. When prompted, enter the evaluation distance and number of strides taken to travel this distance. This data will be generated by the software, if you entered a specific evaluation distance in Clinical Preferences. Press 'Save' to record this evaluation data.

Evaluation Report:

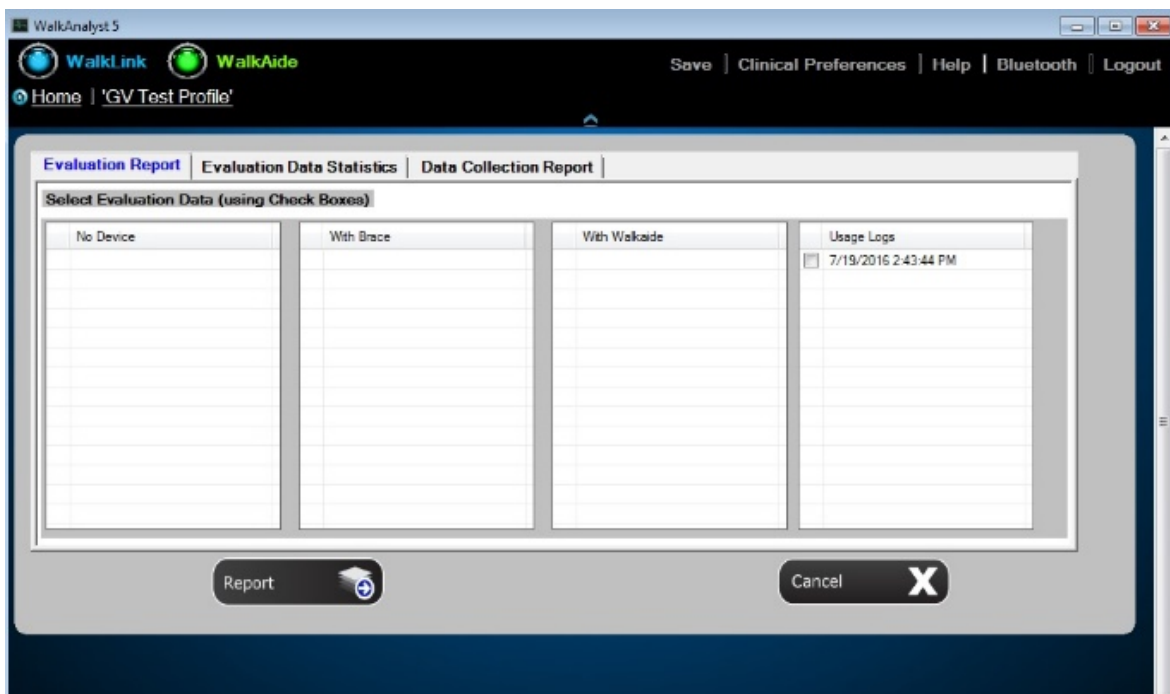


Figure 38: Evaluation Report

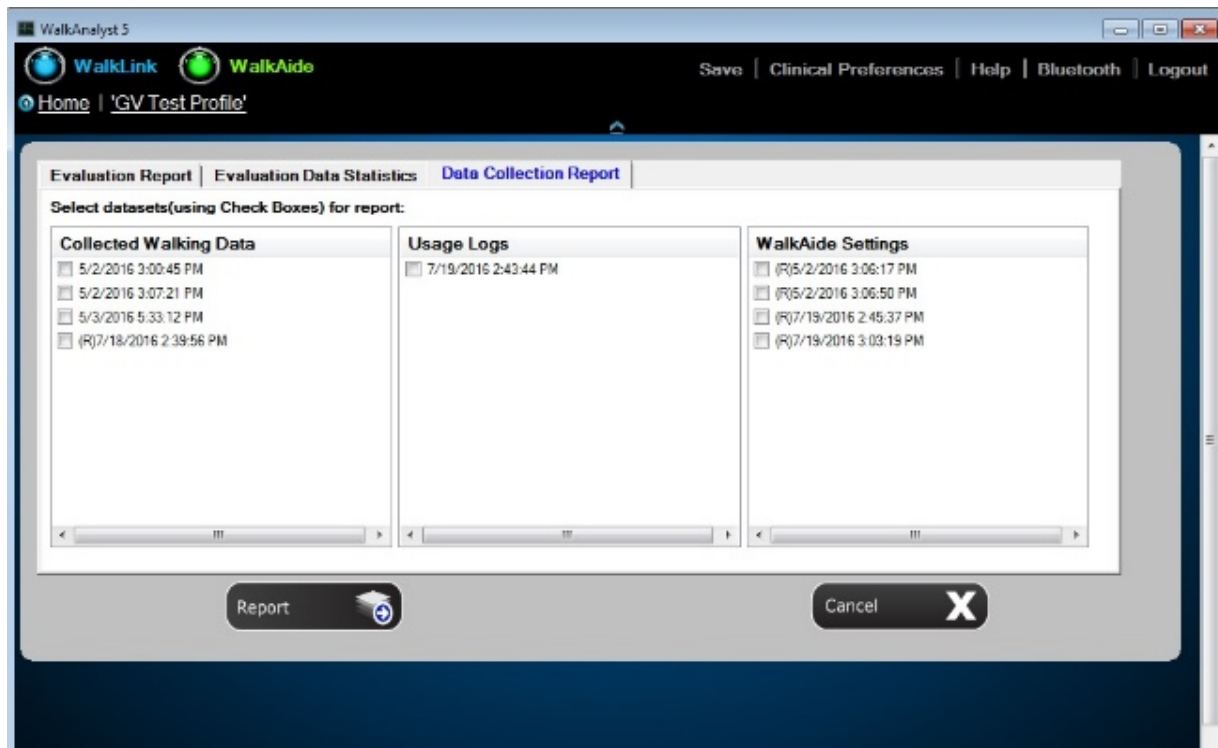


Figure 39: Data Collection Report

Select Report to show the data collection lists for different walking scenarios and different evaluation dates. Select the checkboxes next to data you wish to include in the report.

Press the Report button to select Report Options, then press Next to generate the report.

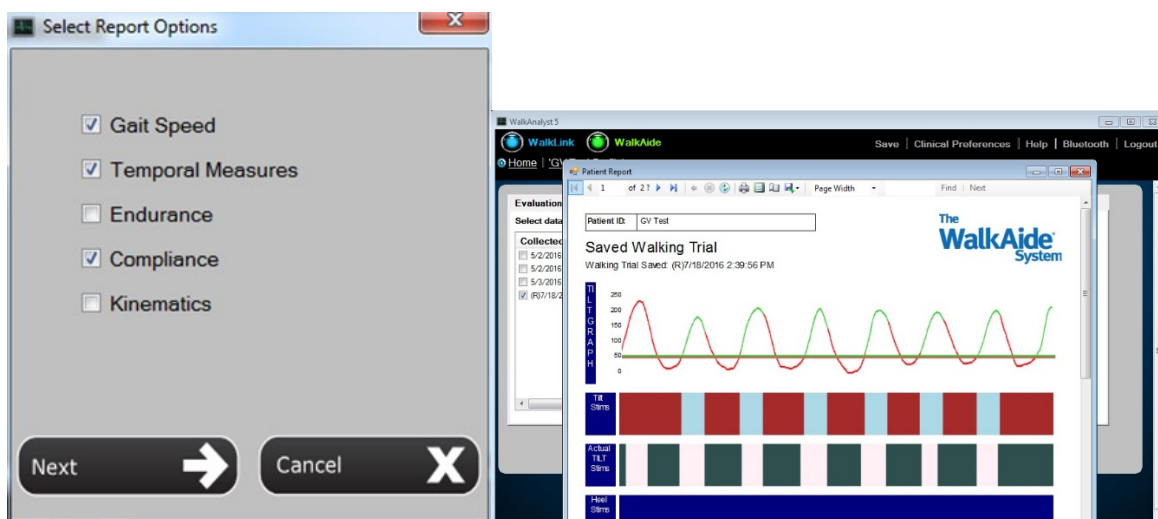


Figure 40: Report Options and Corresponding Printable Reports (PDF)

Use the right or left arrows at the top to browse between different pages of the report. Use the down arrow next to the Export option to save the report in Word or PDF formats. You can include additional clinical notes on the printed PDF report or type them into the Word version.

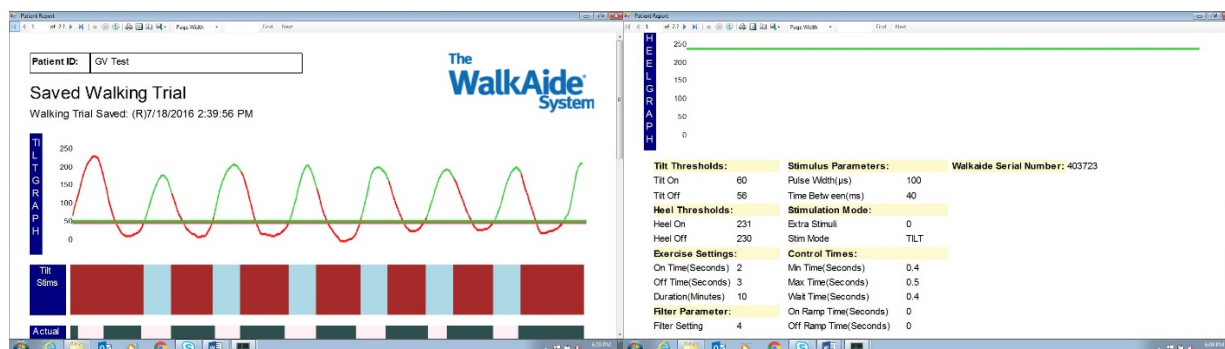


Figure 41: Evaluation Report

Transfer Program

Send Preferred Setting: Quickly identify a patient's walking program, view and/or transfer it to the WalkAide. Use this feature at follow-up visits, WalkAide fittings and therapy sessions. Make adjustments on the Adjustment screen as needed. (Figure 42)

Copy a WalkAide: Copy WalkAide settings from one WalkAide to another. Make adjustments on the Adjustment screen as needed. (Figure 42)

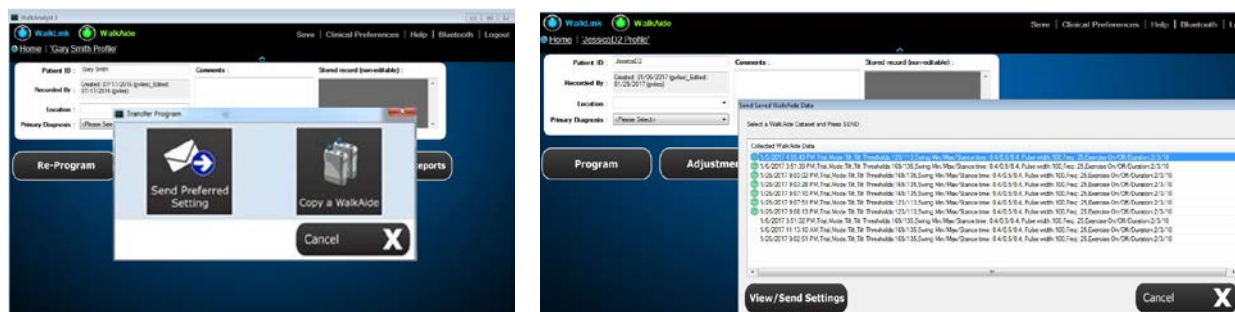


Figure 42: Transfer Program

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.

	ON Time	OFF Time
--	---------	----------

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

Figure 43: Sample Wearing Schedule

- If muscle soreness occurs, the patient should reduce the wearing time or discontinue use and contact the WalkAide clinician.
- If skin irritation or redness occurs under the electrodes, the patient should not resume WalkAide stimulation until the redness disappears. If the redness has not disappeared by the end of the scheduled OFF period, the WalkAide should not be reapplied until the redness disappears and the occurrence should be reported to the WalkAide clinician.
- The patient will slowly work up 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.
- Instruct the patient to remove the cuff at regular intervals throughout the day and inspect the skin under the electrodes. These areas may be pink due to increased blood flow under the electrodes, but this redness should disappear quickly. If the redness persists, the user should 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 recommended medium before applying the cuff. Rewet the electrodes occasionally throughout the course of the day to assure good conduction and maximize conductivity.

Use and Care of the WalkAide

Cleaning the WalkAide

The user should use a damp cloth and a mild detergent to wipe any stains off the WalkAide unit. The WalkAide CANNOT BE SUBMERGED in water. The WalkAide System Silicone Cover (model number: 20-0800) may enhance the water resistant properties of the WalkAide but the WalkAide is never water proof.

Storage: When not being worn, the WalkAide System (cuff, electrodes and WalkAide unit) should be stored in a re-sealable plastic bag in an area where temperatures do not exceed 120° F (48.8° Celsius) or fall below 40° F (4.4° Celsius). 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 rechargeable, Lithium, disposable, or “bargain brand” batteries. Use regular AA batteries from a major manufacturer (e.g., Duracell, 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.

Use and Care 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.

TIPS:

Review this with WalkAide users, when delivering a WalkAide for a home trial or permanent delivery:

- 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 gel 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 water to separate the electrode from the skin can prolong electrode wear.
- Always cover the gel electrodes with the plastic backing when not in use.
- 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 electrodes 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 broken, blistered or irritated skin.
- If a rash or skin irritation occurs, discontinue use. The patient should contact the WalkAide clinician. It is not appropriate to restart WalkAide wear until the skin is 100% clear of irritation or redness.
- The electrodes must be replaced at least every 1 – 2 weeks, or sooner if the gel surface is disrupted, appears to be dirty or if the quality or strength of the stimulation changes during use.

TROUBLESHOOTING

Electrode Placement Best Practice

Accuracy of electrode placement is the key to the efficiency, comfort and functional control of the 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. Electrode position varies with each patient.

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

1. The closer the electrodes, the more superficial the current → more eversion
2. The farther apart the electrodes, the deeper the current → more dorsiflexion

Manual Adjustment of the Stimulation Settings

Manual adjustment of the stimulation settings can fine-tuning the swing and stance durations to better accommodate the patient's gait. This process relies on the clinical judgment of the clinician and can be completed using options on the Adjustment screen.

ON and OFF Thresholds: ON and OFF Thresholds trigger the initiation and termination of the stimulus. They are represented as green and red horizontal lines on the gait graph, respectively. (Figure 44)

With regard to the tilt sensor, the numerical values listed as the ON and OFF Thresholds relate to the range of tibial tilt from the vertical starting position of the leg with the WalkAide on it. 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.

ON Threshold: Stimulation initiates when the tilt/heel sensor value reaches the ON Threshold.

- If the ON Threshold is too high, the tibia does not tilt far enough forward or the heel does not unload enough for the sensor value to reach the threshold. The stimulation doesn't start. Lowering the ON Threshold can resolve this problem and/or can trigger the stimulation to start sooner.
- Raising the ON Threshold delays the stimulation so that it starts later. The tibia must progress farther or the heel must unload more to initiate the stimulation.

OFF Threshold: Stimulation terminates when the sensor value reaches the OFF Threshold.

- If the OFF Threshold is too low, the tibia doesn't extend far enough or the heel doesn't load enough for the sensor value to reach it. The stimulation doesn't stop until it reaches the maximum duration (Max Time). This can delay or prevent the initiation of the next stimulation. To correct this, raise the OFF Threshold.

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.

Examples of Threshold Adjustments:

Example 1: The green ON Threshold is too high (Figure 44). 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 so that each step in the graph crosses it.

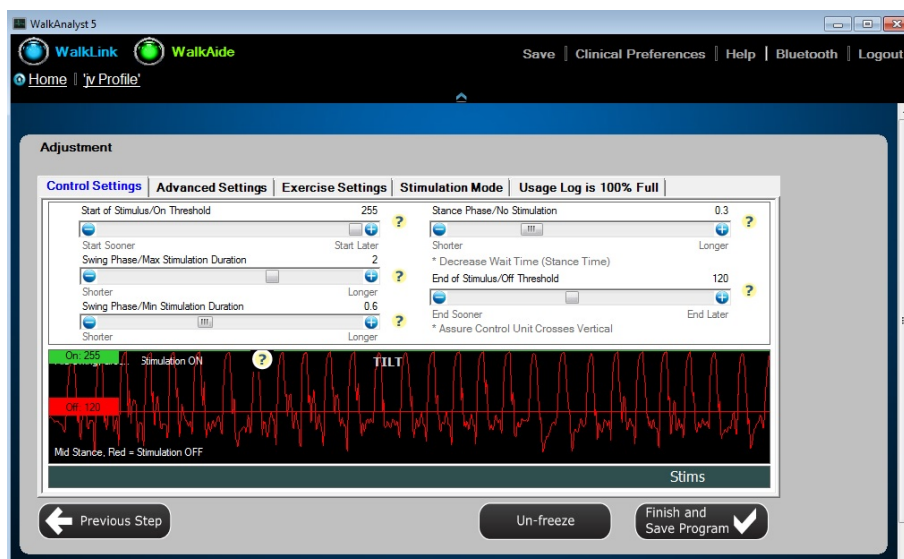


Figure 44: Tilt ON Threshold Too High

Example 2: Tilt ON Threshold is too high (Figure 45). 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.

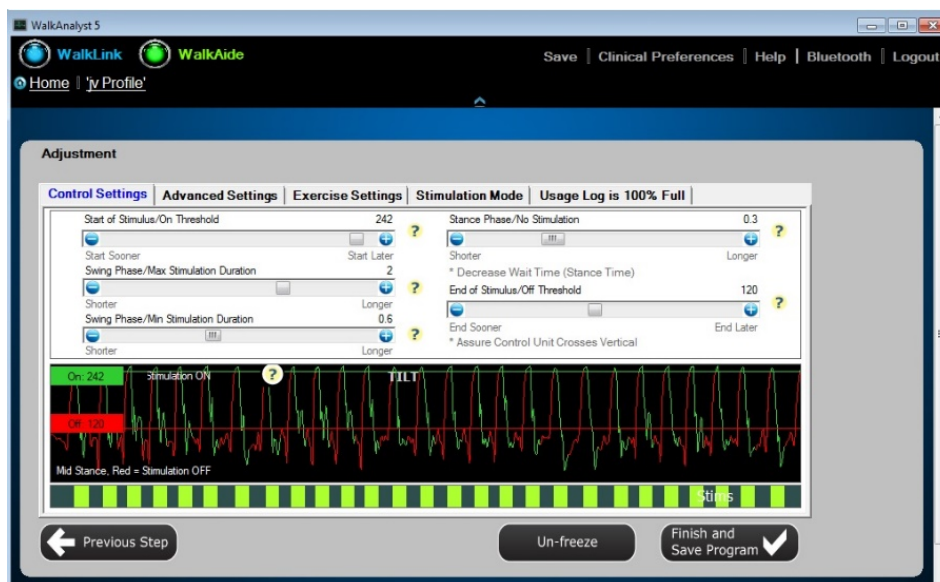


Figure 45: Tilt ON Threshold Too High

Example 3: Tilt OFF Threshold is too low (Figure 46). Steps occur on the Tilt graph during which the valleys do not reach the OFF Threshold and therefore stimulation isn't terminated by the tibial motion. Raise the OFF Threshold to capture all steps so stimulation starts and stops appropriately (Figure 47).

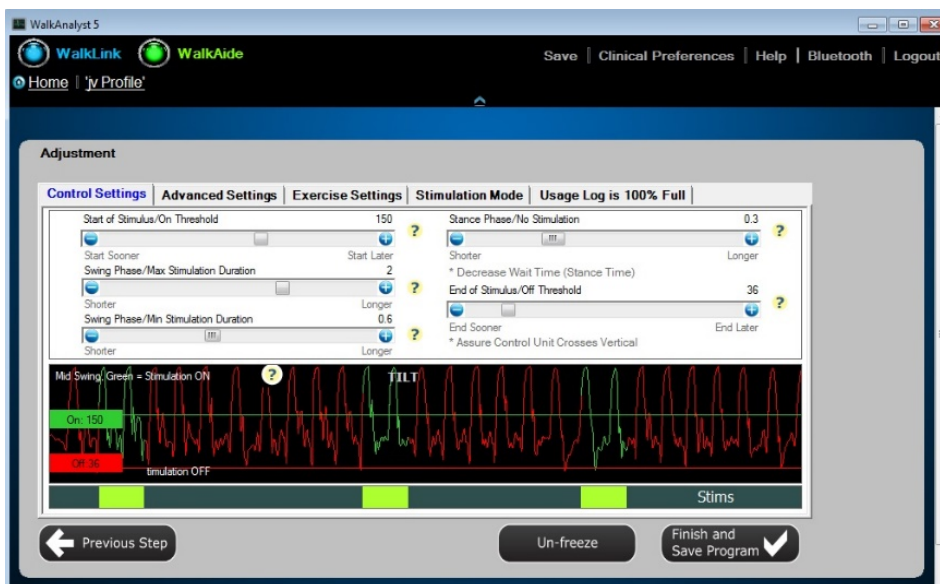
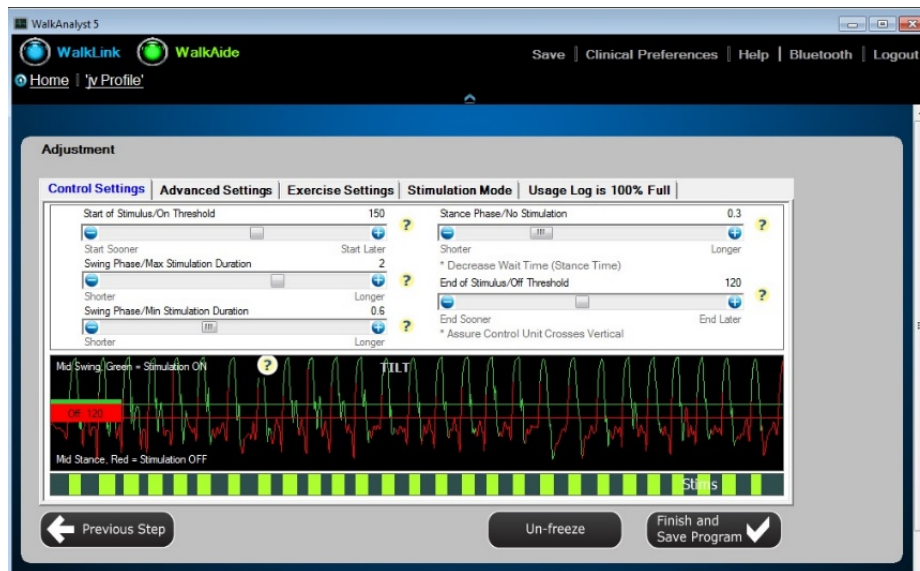


Figure 46: Tilt OFF Threshold Too Low



Figures 47: Tilt OFF Threshold Correctly Adjusted

Control Settings (Swing Phase/Min Stimulation, Max Stimulation and Stance Phase):

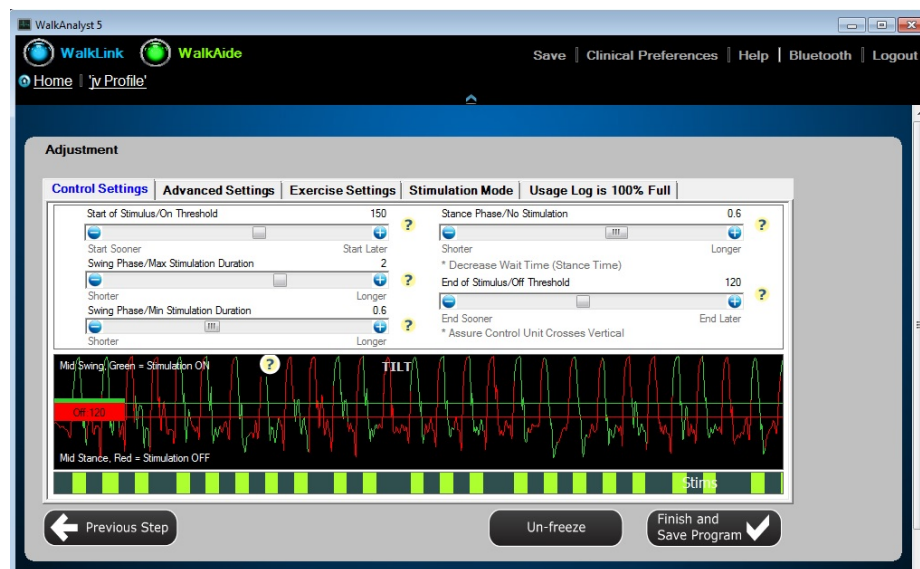


Figure 48: Control Times Adjustment

Swing Phase/Min Stimulation Duration: This is the minimum duration of stimulation that occurs each time it is initiated. The range is from 0 to 1.5 seconds and it can be adjusted in increments of 0.1 second.

The Min Stimulation Duration always overrides the OFF Threshold. It ensures that the stimulation lifts the foot throughout the Swing Phase and that the foot is stable at Initial Contact with the ground. The Min Stimulation Duration can be increased to promote

more control with an ataxic gait, an unstable knee or a hypertonic ankle, for example. The Min Stimulation Duration may need to be decreased for a faster walker that has a shorter Swing Phase.

Swing Phase/Max Stimulation Duration: This is the maximum duration of stimulation that could occur, if the patient does not hit the OFF Threshold to terminate it. The range is from 0.2 to 3 seconds and it can be adjusted in increments of 0.1 second.

The Max Stimulation Duration allows for periods of slower walking speeds, when the user needs to spend more time in swing. It can be increased to keep the foot lifted when walking up or down stairs, navigating obstacles or if a patient has difficulty completing a step once it is started. The Max Stimulation Duration also prevents extended periods of stimulation. For example, if the user sits down and tilts the leg forwards, the stimulus will be discontinued once the Max Stimulation Duration has been reached.

The OFF Threshold overrides the Swing Phase/Max Stimulation Duration during walking to ensure that the stimulation is appropriately terminated at Initial Contact.

The Min Stimulation Duration cannot be longer than the Max Stimulation Duration.

Stance Phase/No Stimulation: This is the minimum amount of time that must elapse after one stimulus ends, before a new stimulus can be initiated. Generally, this is the duration of the Stance Phase. It ranges from 0 to 1 second and can be adjusted in increments of 0.1 second.

The Stance Phase/No Stimulation prevents unwanted or inadvertent stimulation during stance phase (i.e. uncontrolled knee flexion, hyperextension leading into Swing Phase, ataxia). As users increase their walking speed and spend less time in stance, lower the Stance Phase. Figure 48 is an example where the stance time is too long.

In general, the Swing/Min Stimulation Duration, Swing/Max Stimulation Duration and Stance Phase/No Stimulation values will be longer for slower walkers who spend more time in the Swing and Stance phases. These values will be shorter for faster walkers as they spend less time in Swing and Stance.

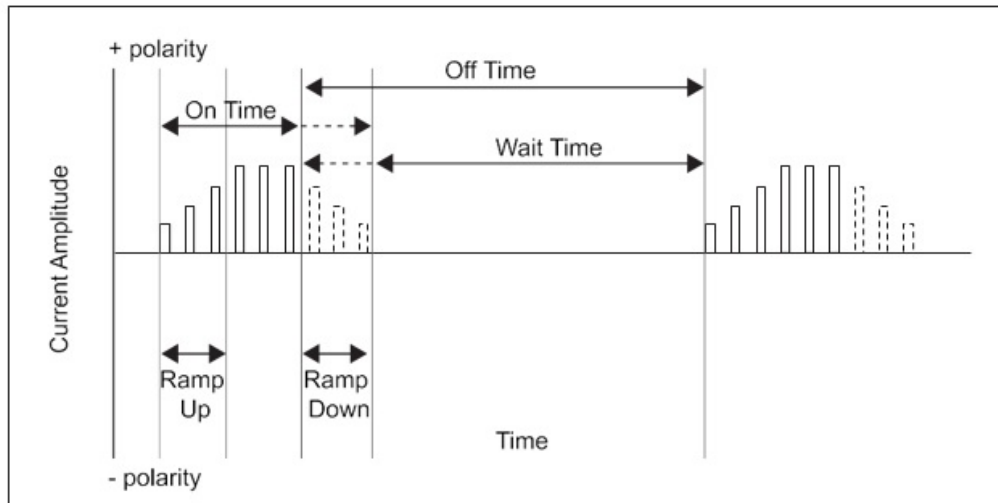


Figure 49: Control Times, Ramp ON and Ramp OFF Times

ON Ramp Time: The rate at which the stimulation intensity rises from zero to its set value. Increasing the On Ramp Time results in a more gradual dorsiflexion. ON Ramp 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 second.

OFF Ramp Time: The rate at which the stimulation intensity decreases from its set value to zero. Increasing the OFF Ramp Time helps control foot slap by decreasing the rate of plantarflexion at Initial Contact. It can also control tibial progression to prevent knee hyperextension. The range of the OFF Ramp Time is from 0 to .5 second.

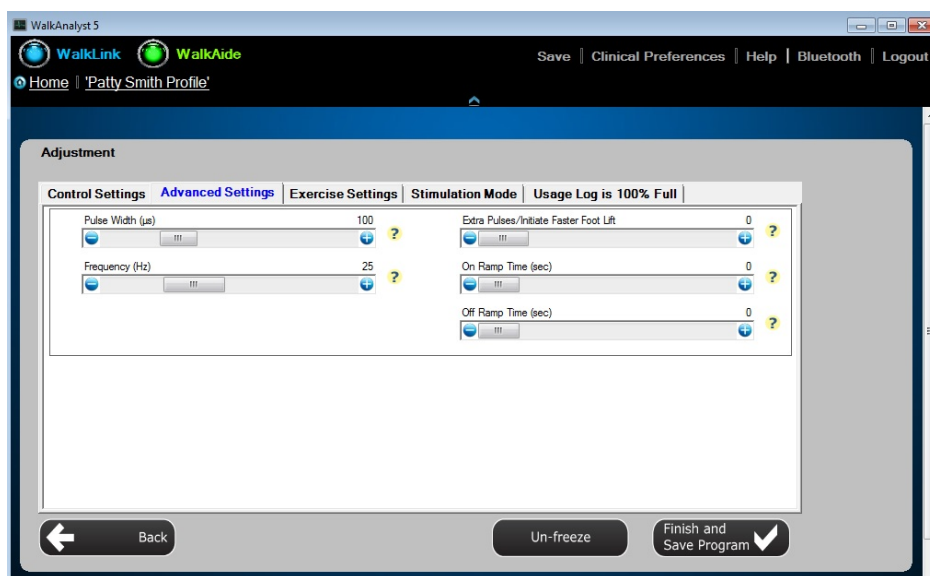


Figure 50: Control Times, Ramp ON and Ramp OFF Time

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 stimulation.

Stimulus Settings:

Pulse Width: This is the duration of each individual pulse within the stimulus train. Its range can be adjusted from 25 to 300 microseconds.

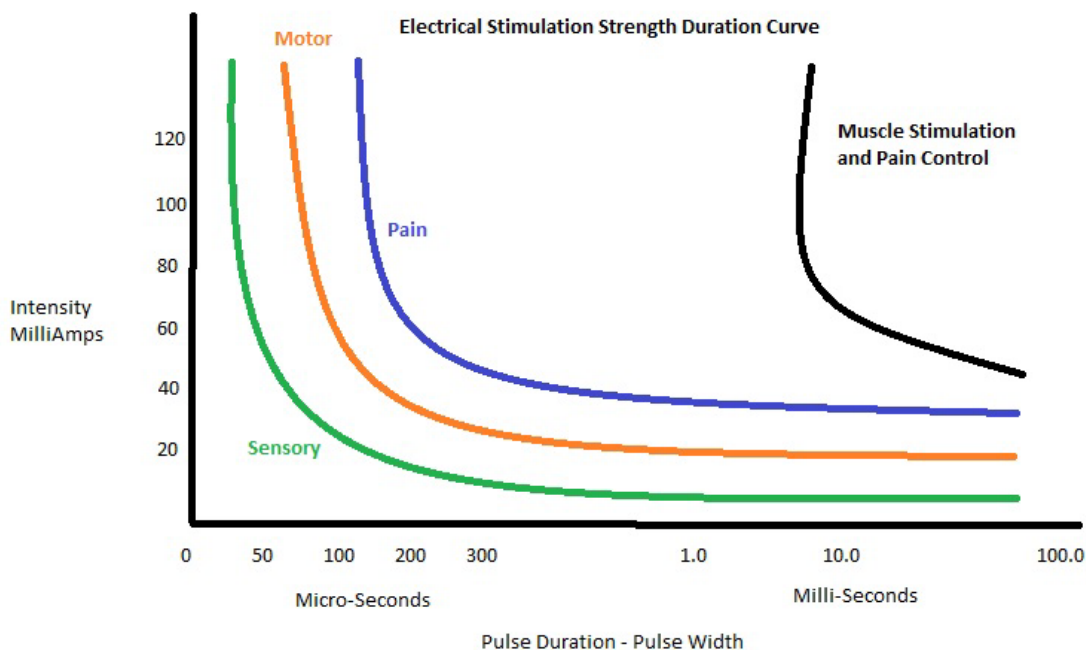


Figure 51: Strength Duration Curve

The longer 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). Decreasing the Pulse Width may make the stimulation less powerful for a more comfortable sensation and contraction.

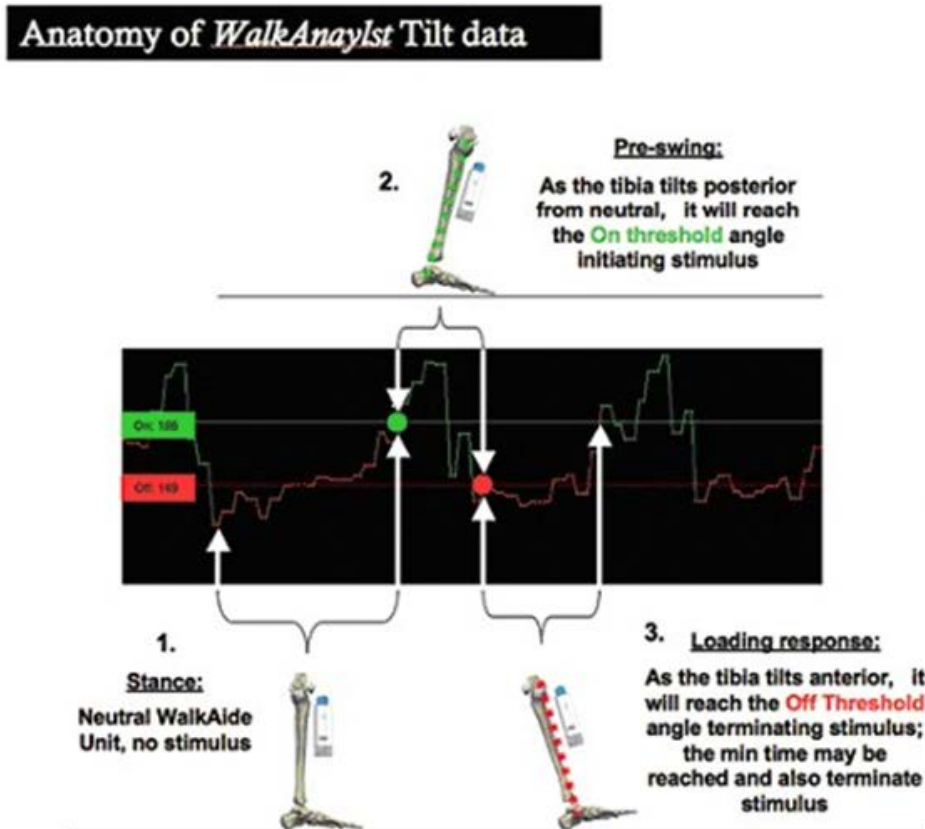
TIPS:

- When testing the WalkAide System on a child or user with a smaller leg, the Pulse Width should be lowered to 25 microseconds prior to testing the system.
- If the intensity setting on the WalkAide must be increased to its highest levels in order to achieve an effective stimulation, increase the Pulse Width. The intensity can then be lowered. This will promote a functional response at a lower intensity and allow some adjustability by the user.

Frequency: The Frequency is the rate at which the pulses occur per second of stimulation. It is adjustable from 16.7 to 33Hz. In general, stimulation at a higher frequency is more comfortable.

Extra Pulses: Adding Extra Pulses to the beginning of the stimulus train promotes a quicker response to the stimulation and potentially a faster muscle contraction. This may be helpful for faster walking speeds or may be considered if a delayed response to the stimulation is noted. The range is from 0 to 3.

Graph Analysis



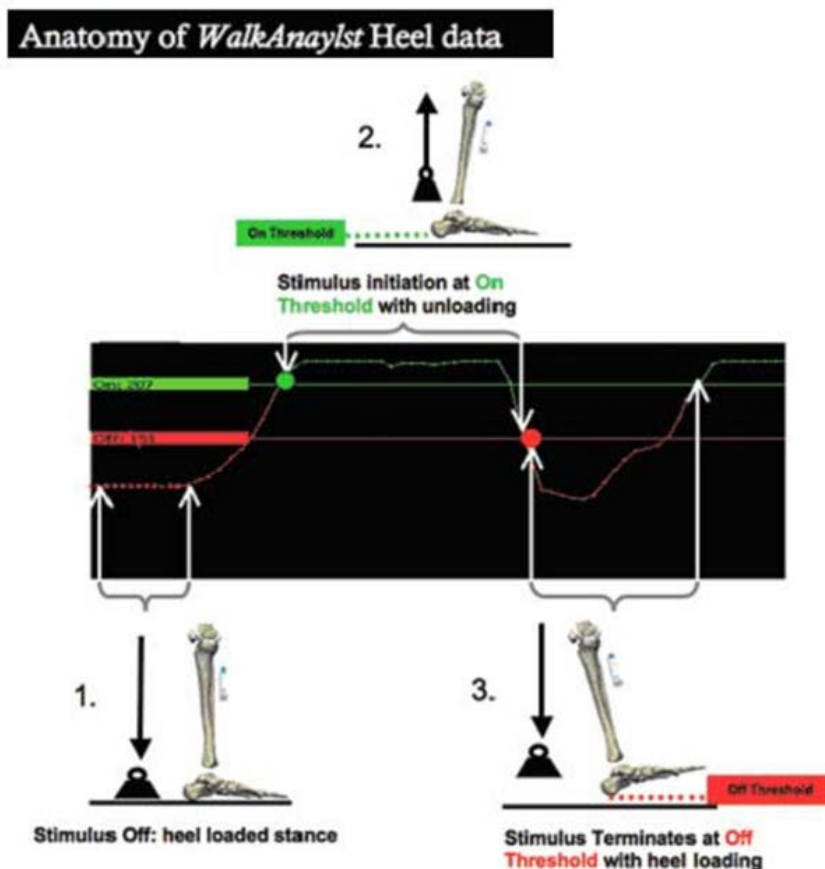


Figure 52: Graph Analysis

Follow-Up and Re-Optimization

The WalkAide System is designed to be part of a progressive rehabilitation program. 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.

~~To Re-optimize The User's Walking Program:~~

Rapid+ or Express Adjustment: Adjust stimulation parameters to manually fine tune the programming. Adjustments are transferred to the WalkAide instantly and are signaled by audible beeps on the device.

To adjust an existing program:

1. Open Patient Profile
2. Select Adjustment
3. Make necessary adjustments
 - a. Activate Beep on Stim and have the patient walk. Adjust initiation, duration or termination of stimulation in Control Settings view based on clinical observation and patient feedback.
 - b. Click on Advanced Settings to adjust stimulation comfort and quality.
 - c. Click Finish to finalize the program.

WalkAide Troubleshooting

The green light for the WalkAide is not lit in the WalkAnalyst program despite the cable connections at both the laptop and the WalkAide unit.

Possibilities:

- There is a loose or damaged cable connection between WalkAide and WalkLink.
- The WalkAide battery needs replacing.
- The WalkLink batteries are depleted.
- The USB Bluetooth adapter is not properly seated.
- Bluetooth connection: Re-establish

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

Possibilities:

- Check the electrode leads to ensure that they are not broken.
- 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.

Intensity of the stimulation is weaker at the same setting.

Possibilities:

- 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.

An occasional sharp stimuli is reported.

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 pull on the cuff.
- Check skin under electrodes for irritation or open areas.
- Ensure complete electrode contact with skin.

Red light is flashing with 4 beeps every two seconds.

Possibilities:

- Indicates a fault has occurred in the control module. Turn OFF the WalkAide by turning the light blue intensity knob counter-clockwise to 0. Wait 5 seconds and then turn it 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.

Red light is flashing with 2 audible beeps every minute.

Possibilities:

- Low battery condition. Change the battery.

Red light flashing with audible 2 beeps every two seconds.

Possibilities:

- If the unit beeps two times every two seconds, it 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.

Red light is flashing with no audible alarm.

Possibilities:

- Time clock in the WalkAide unit for Usage Log has stopped working. Reconnect to WalkAnalyst to select Save and Clear Log or Clear Log.
- Internal time clock battery needs replacing. Contact Innovative Neurotronics.

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 an audible beep when the knob is turned from 0 to ON.
- A new battery may be needed.

WalkLink Troubleshooting

The left-most LED light does not flash a green light every two seconds.

Possibilities:

- The flashing green light is a power indicator. If it is not flashing, the device may have timed out after approximately 10 minutes of non-use. Turn the WalkLink OFF for a few seconds and then turn it ON again. Select Bluetooth in the upper right corner of the WalkAnalyst screen and choose Search for Previously Connected WalkLink.
- Ensure that the four AA alkaline 1.5V batteries in the WalkLink are new. Do not use rechargeable batteries in the WalkLink.

The WalkLink device did not appear during the WalkAnalyst Bluetooth configuration process.

Possibilities:

- Turn the WalkLink OFF for ten seconds. Turn it back ON, press search again.
- Confirm laptop is using Windows XP Service Pack 2 or better, Windows 7, 8 or 10.
- WalkLink device may need to be unpaired and re-paired with the laptop. Follow these steps:
 1. Turn ON the WalkLink device and confirm the flashing green power light.
 2. Use a ballpoint pen or pencil to press and hold the small recessed Pairing Button located above the ON/OFF switch. Depress and hold for one second.
 3. Turn OFF the WalkLink, wait 10 seconds and turn ON the WalkLink to try the search process again.

4. 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 Configuration 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.

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.

Possibilities:

- Turn the WalkLink OFF and back ON, and either choose the first option in the Bluetooth Configuration Wizard (i.e. Search for Previously Connected WalkLink) or simply exit and restart the WalkAnalyst software application while the 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 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.

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

Possibilities:

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

Alternate Pairing Method

Alternate pairing method should be used to pair WalkLink with the computer using vendor provided software, such as Bluetooth Device, My Bluetooth Place, BlueSoleil, etc.

When using Alternate Method of Pairing: Prior to running the WalkLink Configuration Wizard, establish a serial port communication (please note the COM port number) with WalkLink using software provided by the Bluetooth vendor (i.e. My Bluetooth Places, IVT/BlueSoleil software, Bluetooth Device/Microsoft, etc.). On the WalkLink Configuration Wizard screen, select the COM port number from the dropdown list that matches the COM port number from the Bluetooth software and press Save. The WalkLink will show a blinking blue LED in addition to the blinking green LED and the WalkAnalyst WalkLink indicator will turn blue.

Bluetooth USB Troubleshooting

There is a conflict with an internal Bluetooth or another Bluetooth driver installed on the computer.

- Disable the 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 the internal Bluetooth. If another Bluetooth driver/software is causing the conflict, get help from your IT support team. Call Innovative Neurotronics Technical Support if you have trouble resolving this problem.

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 received, follow the installation instructions that accompany the Bluetooth USB device. Vendor provided software may be needed. Use the Alternate Method for Pairing. Call Innovative Neurotronics Technical Support for assistance.

The Bluetooth device is not displaying a blue light.

- A properly functioning Bluetooth device will display a blue light. If not, try the Bluetooth device in a different USB port.
- During the search process, the USB blue light will blink rapidly as an indication of proper function.

If problems persist, use another USB device, such as for a mouse or keyboard, to test the USB port. If the mouse or keyboard works with their corresponding USB device in that same USB port, the port is not the problem.

WalkAide User Manual

Additional information on safety considerations, skin care, operation and use of the WalkAide, etc. is included in the WalkAide User Manual. Please read this information and review it with each user prior to distribution of the technology for independent use.

Information regarding air travel with the WalkAide is also provided in the User Manual along with a WalkAide Medical Device ID card. 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). 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>.

TECHNICAL INFORMATION

WalkAide		
Size	Height Width: Thickness: Weight:	8.2 cm 6.1 cm 2.1 cm 87.9 g
Medical Device Class	FDA	Class II
Power Source	Volt	One 1.5 Alkaline AA battery
Maximum Current	mA	200 mA at 500 ohm 121 mA at 1 K ohm
Maximum Voltage	Volts	121 V at 1 K ohm <150 V at 1 M ohm
Operation Modes	Exercise	2 Walking, Exercise
Number of Channels	Channels	1
Pulse Type Pulse Width Frequency Range	Pulse	Asymmetrical Biphasic 25-300 microseconds (Adjustable) 16.7-33 Pulse per second (Adjustable)
Maximum Stimulation Period Stimulation Trigger Source	Stimulation	3 seconds Tilt or Heel Sensor
Controls and Indicators	Indicators	ON/OFF; Intensity; Stimulation, Exercise Error
Shipping and Storage Conditions	Device Temperature	Long Term -4°F to 140°F -20°C to +6°C
	Device Relative Humidity	95% max, noncondensing
Shipping and Storage Conditions	Electrode Temperature	Long Term 41°F to 80.6°F 5°C to +27°C
	Electrode Relative Humidity	35 – 50%
Shipping and Storage Conditions	Electrode Temperature	Short Term (less than 1 month) 32° to 104° F 0°C to +40° C
	Electrode Relative Humidity	35 – 50%
Operating Condition	Device	32° to 104° F 0°C to +40° C
Altitude	Feet	Less than 8000ft 2400 meters
IEC 60529 Rating	Device	IP22

Technical Information (continued)

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

Proper Disposal

Proper disposal procedures shall be observed as required by specific state and/or local regulations. It is the responsibility of the owner of the device to follow applicable laws and regulation on disposal guidelines.

Contact Information

If further assistance is required, please contact:
 Innovative Neurotronics, Inc.
 4999 Aircenter Circle, Suite 103, Reno, NV 89502
 Email: cs@ininc.us or international@ininc.us
 Phone 1-888-884-6462, Fax 512-329-5097
www.walkaide.com

WALKAIDE STANDARD AND OPTIONAL ACCESSORIES

Part No.	Description
WalkAide Patient Kit	
20-1000	WalkAide Patient Kit – includes electrode lead cable and carrying case
20-1000R	WalkAide Patient Kit Replacement Unit - 90 day warranty, purchased within 5 years of original
09-100	WalkAide Carrying Case
WalkAide BiFlex Cuffs	
20-0240	Bi-Flex Cuff, Pediatric
20-0250	Bi-Flex Cuff, Small
20-0260	Bi-Flex Cuff, Medium
20-0270	Bi-Flex Cuff, Large
WalkAide Patient Accessories	
20-0800	WalkAide System Silicone Cover
09-100	WalkAide Carrying Case (when ordered separately)
20-0120	Battery Door
Bi-Flex Cuff Spare Parts	
20-0200	Cuff Buckle/Latch
20-0201	Electrode Locator - 1.25" (Black)
20-0202	Electrode Locator - 1.25" (Red)
20-0205	Electrode Locator - 1.875" (Black)
20-0206	Electrode Locator - 1.875" (Red)
20-0241	Bi-Flex Cuff Liner, Pediatric
20-0242	Cuff Strap, Pediatric
20-0251	Bi-Flex Cuff Liner, Small
20-0252	Cuff Strap, Small
20-0261	Bi-Flex Cuff Liner, Medium
20-0262	Cuff Strap, Medium
20-0271	Bi-Flex Cuff Liner, Large
20-0272	Cuff Strap, Large
WalkAide Clinician Screening Tools	
20-1002	WalkAide Demo Kit - WalkAide Demo Kit includes 1 - 20-0110 Electrode Cable
20-0300	WalkLink Clinician Kit - WalkLink kit includes 1 - 20-0315 WalkLink Right Angle Cable Kit
WalkAide Clinician Accessories	
09-100	WalkAide Carrying Case
20-0110	Electrode Lead Cable
20-0290	Cuff Disposable Liners
20-0311	WalkLink Cable
20-0313	WalkLink Clinician Tool Case
20-0315	WalkLink Right Angle Cable Kit
20-0320	Heel Sensor
20-0350	Bluetake USB Bluetooth Adapter

WalkAnalyst Software	
20-0603	WalkAnalyst Software - CD version
20-0603	Software available via download – www.walkaide.com – support - downloads
Computer Special Order – based on available inventory	
20-0314	Netbook Computer, with WalkAnalyst & Bluetooth Installed
WalkAide Electrodes	
20-0500	1.25" Electrodes, 1 package, 4 electrodes each package
20-0510	1.25" Electrodes, 1 case – 10 packages, 4 electrodes each package
20-0521	1.25" Premium Electrodes, 1 package, 4 electrodes each package
20-0531	1.25" Premium Electrodes, 1 case – 10 packages, 4 electrodes each package
20-0540	1.875" Premium Electrodes, 1 package, 4 electrodes each package
20-0550	1.875" Premium Electrodes, 1 case – 10 packages, 4 electrodes each package
20-0571	1.875" Cloth Electrodes, 1 package, 2 electrodes each package
20-0570	1.875" Cloth Electrodes, 1 case – 10 packages, 2 electrodes each package

SAMPLE WALKAIDE SCREENING QUESTIONNAIRE

Patient Name:		Phone:	
		Date:	
What is your medical diagnosis or cause of your foot drop? (Check the appropriate box below)			
UPPER MOTOR NEURON – Indicated		LOWER MOTOR NEURON – Contraindicated	
<input type="checkbox"/>	Stroke	<input type="checkbox"/>	Spinal disc injury or surgery to Lumbar/Lower spine
Upper Motor Neuron Lesion/Injury/Disease(s):		<input type="checkbox"/>	Foot drop after total knee or hip replacement
<input type="checkbox"/>	Transverse Myelitis	<input type="checkbox"/>	Sciatica
<input type="checkbox"/>	Multiple sclerosis	<input type="checkbox"/>	Lumbar/Lower spinal stenosis
<input type="checkbox"/>	Traumatic brain injury	<input type="checkbox"/>	Polio
<input type="checkbox"/>	Cerebral palsy	<input type="checkbox"/>	Guillain-Barre
<input type="checkbox"/>	Incomplete spinal cord injury (T-12 or higher)	<input type="checkbox"/>	Muscle trauma or Disease
<input type="checkbox"/>	Hereditary spastic paraplegia (HSP)	<input type="checkbox"/>	Charcot-Marie Tooth
<input type="checkbox"/>		<input type="checkbox"/>	Neuropathy / diabetic neuropathy
Other:		Other:	
If your Diagnosis puts you in the “Indicated” side, please proceed to the questions below			
			YES
			NO
Do you have a cardiac pacemaker or defibrillator? <i>(If answer is YES, patient needs physician clearance before coming in for trial)</i>			
Do you have a history of seizures? <i>(If answer is YES, patient needs physician clearance before coming in for trial)</i>			
Are you pregnant? <i>(If answer is YES– not able to evaluate at this time)</i>			
Have you been diagnosed with regional Cancer in the involved lower leg <i>(If answer is YES, not able to evaluate at this time)</i>			
Do you have any open wounds or an existing symptomatic thrombosis in the involved lower leg? <i>(If answer is YES – not able to evaluate at this time)</i>			
Are you able to walk at least 20 consecutive steps with or without an assistive device (e.g. cane)? <i>(If answer is NO or is mostly wheelchair bound – not able to evaluate at this time)</i>			

Terms and Conditions of Sale

Thank you for your interest in Innovative Neurotronics, Inc. ("ININC") products. The following provisions set forth the terms and conditions on which ININC sells its products.

Terms of Sale; Orders

Purchase of any products sold by ININC shall be subject to and expressly limited by the terms and conditions contained herein. No orders shall be binding upon ININC until accepted in writing by an authorized official of ININC at its home office in Reno, Nevada; and acceptance of an order by ININC is expressly conditioned on Buyer's assent to these terms and conditions. ININC hereby objects to any additional or different terms or conditions, whether contained in any purchase order or other communication from Buyer. No order accepted by ININC may be cancelled, altered or modified unless in writing signed by an authorized agent of ININC in pen and ink.

Minimum Order Quantity

Wholesalers and distributors are subject to a handling charge of \$75 for orders less than \$1,000.

Prices: All pricing quotes must be documented in writing and signed by ININC to be valid. All prices are firm for 30 days from the date quoted. ININC reserves the right to change the prices and specifications of its products at any time without notice. Products purchased from distributors will be at the prices set by those distributors and subject to the terms and conditions of sale of the distributor.

Tax Information

Any tax, duty, custom or other fee of any nature imposed upon the products, their sale, transportation, delivery, use or consumption shall be paid by Buyer in addition to the price quoted or invoiced. If ININC is required to prepay any such tax or fee, Buyer will reimburse ININC. Buyer must provide ININC with a resale/exemption certificate in order to avoid the withholding of applicable taxes. No refund or adjustment to previously withheld taxes will be made by ININC after the expiration of sixty (60) days from the invoice date. Proof of certification should be mailed to:

Innovative Neurotronics, Inc.
4999 Aircenter Circle, Suite 103
Reno, NV 89502
or fax to (800) 350-1102.

Payment

Unless ININC specifies otherwise, payment terms are net 30 days from date of invoice. Buyer's obligation to pay outstanding invoices and all other amounts is absolute and unconditional and is not subject to any abatement, reduction, set-off, defense, counterclaim, deferment or recoupment for any reason whatsoever. Balances remaining unpaid at due date are subject to an interest charge of 1.5% per month or the highest rate permitted by law, whichever is lower, until paid.

Any discounts, rebates, administrative fees credits, or other fees due or owed to Buyer will be applied against delinquent balances before payment or reimbursement is made. Any disputed amounts should be reported immediately and remitted with the undisputed amount by the payment due date. If ININC agrees with the billing dispute, ININC will credit Buyer accordingly. All billing disputes must be reported to ININC in writing within six (6) months of the applicable invoice date, or will be deemed to be waived.

ININC reserves the right in its sole discretion to require prepayment from any Buyer at any time and may refuse to sell and/or withhold further shipment until all overdue balances are made current. [Except as otherwise provided in the arbitration clause below,] Buyer shall be liable for, and shall reimburse ININC for all costs and expenses it may incur in connection with collection of any amounts owed to ININC or enforcement of its rights, including without limitation, reasonable attorneys' fees and expenses, costs of dispute resolution, and cost of collection agencies.

Returned Goods Policy

Non-warranty product returns are subject to the following conditions:

All returns are subject to the prior authorization of ININC, in its discretion. Buyer must notify Customer Support at (888) 884-6462 and complete a Returned Goods Authorization "RGA" Form. The RGA Form requires product number, product description, quantities and along with a specific reason for return. Customer Support will either authorize or deny the request for return. Only items appearing on an approved RGA Form are acceptable for return. Unauthorized returns will be destroyed and no credit issued. All authorized returned goods must be shipped Freight prepaid to the ININC location indicated on the RGA Form, except ININC will pay freight costs for Product shipped-in-error. Returns that are authorized for Product ordered-in-error or shipped-in-error will not be accepted unless returned within 30 days of delivery.

Glossary

Term	Definition
Adjustment	Allows the clinician to fine tune WalkAide parameters to meet specific patient needs
Audible Beep	Optional Biofeedback Feature; Audible signal can be activated to indicate when the stimulus is on. Hold the middle button down and turn the WalkAide on by turning the blue knob
Bi-Flex Cuff	A pretibial shell that attaches to the leg and is used to hold the electrodes and the WalkAide control module in the correct position
Clear Usage Log	Clears walking data stored in the WalkAide to prepare for collection of future data
Collect Walking Data	Collects patient 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-
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 (Stance Time); and initiation and termination of the stimulation (Ramp On, Ramp Off).
Create Patient Profile	Creates a new file for a new patient.
Default Settings	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 or other specified data
Exercise Mode	Allows the user to repeatedly stimulate the lower leg while sitting for a set period of time as determined by the clinician
Exercise Settings	Allows the clinician to adjust the ON Time, OFF Time and Duration of the Exercise Mode for the individual user
Express Adult and Express Pediatric	Send generic walking programs to the WalkAide.
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	When the WalkAide is programmed in Hand Mode, pressing the STIM button on the WalkLink sends a command to the WalkAide unit to provide stimulation

Term	Definition
Heel Sensor	The clinician heel sensor is used during data collection and analysis while testing a potential WalkAide user. It is also used as a gait training tool in a rehabilitation setting
Open a Patient Profile	Opens an existing file for an existing patient
Rapid+	Sends default settings to the WalkAide and allows custom programming through data collection.
Reset Zoom/Unselect	Reverses the Select function during programming, returning the original walking sequence so that a new data set can be selected to represent the patient's typical gait pattern.
Save and Clear Usage Log	Saves walking data stored in the WalkAide then clears it for further data collection.
STIM	Abbreviated form of the word stimulation.
Stimulation Mode	Allows the clinician to select from Heel, Hand or Tilt modes to trigger the stimulation during walking.
Stimulus Setting	Allows the clinician to adjust the characteristics of the pulses within the stimulus train. Adjustments include Pulse Width, Time Between and Extra Stimuli.
Usage Log	Collects WalkAide usage information during walking, specifically Hours per Day and Stims per Day. The Usage Log collects 69 days of walking activity since it was last cleared.
WalkAide	A battery-operated, single channel electrical stimulator using FES as a therapeutic tool and/or a neuroprosthesis
WalkAide Diagnostic Codes	Six digit readout indicating the internal status/fault of the WalkAide® System hardware.
WalkAide Serial Number	The serial number can be found inside the battery compartment of the WalkAide.
WalkAide Settings	Walking parameters currently programmed into the WalkAide unit.
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 stimulation applied to the user. Comfort and functional response related to the stimulation can also be
Walking Data Thresholds	Determine the timing of the initiation and termination of the stimulation by either the heel or tilt sensors.
WalkLink	Provides a wireless connection between the WalkAide and a computer. It also allows manual stimulation during walking trials, gait training and/or therapeutic exercise via the hand switch.

