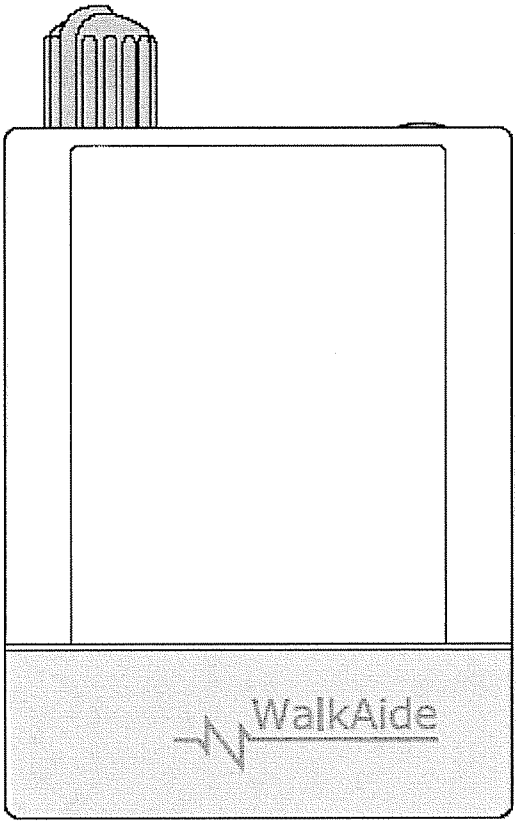
INNOVATIVE NEUROTRONICS

WALKAIDE CLINICIAN MANUAL



DRAFT

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

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1.0 Introduction

The WalkAide produces dorsiflexion of the ankle during the swing phase of gait. This small device attaches to the leg, just below the knee. During a gait cycle, the WalkAide stimulates the common peroneal nerve, which innervates the tibialis anterior and other muscles that produce dorsiflexion of the ankle. Users of the WalkAide are people who have lost the ability to voluntarily lift their foot, often as a result of damage to the central nervous system such as stroke, spinal cord injury, traumatic brain injury and multiple sclerosis. This type of stimulation will not work for people who have damage to the lower motor neurons/peripheral nerves.

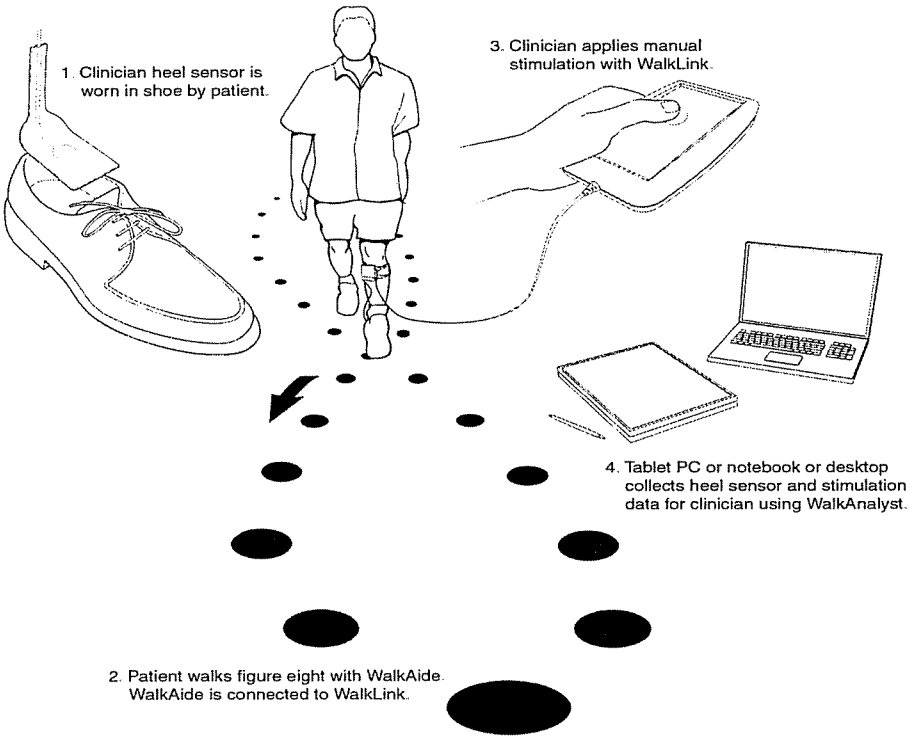


Figure 1 –Initial WalkAide Set-up Procedure using WalkLink, Heel Sensor, and WalkAnalyst

The WalkAide is a battery-operated, single channel electrical stimulator that can be used for functional electrical stimulation. It utilizes a tilt sensor to control stimulation during walking. A Hand Switch on the WalkLink is used by the clinician during set-up to trigger stimulation (Figure 1). A Heel Sensor or Foot Sensor is also used to collect walking information. The clinician uses WalkAnalyst software on a laptop computer to set up the Tilt Sensor in the WalkAide. Stimulation during normal usage will then be triggered appropriately from the Tilt Sensor. Use of the Tilt Sensor to trigger stimulation eliminates the need for wires from a heel switch during regular use.

Indications of Use

The Innovative Neurotronics WalkAide External Functional Neuromuscular Stimulator (WalkAide System) is intended to address the lack of ankle 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 patient's gait. 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** place the electrodes in the carotid sinus region (throat). Laryngeal or pharyngeal spasms may occur when the electrodes are placed across the throat or in the mouth.
- **Do not** place the electrodes over malignant tumors.
- **Do not** place the electrodes over areas in which symptoms of existing thrombosis are present.
- **Do not** use if person has a history of seizure disorder.

⚠ Warnings About FES

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

Electrodes - The use of electrodes not supplied by Innovative Neurotronics may result in less than adequate results or increased risk of burns or discomfort. Do not place electrodes over open wounds, broken skin or metal objects beneath the skin such as surgical staples.

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

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

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

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

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

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

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

⚠ WalkAide Specific Warnings

Walking - Care should be taken when using the WalkAide for clients who experience dizziness or have difficulty maintaining balance. The WalkAide is not designed to prevent falling. Assess patient's condition for inability to walk or balance.
Electrodes - The client should not relocate the position of the electrodes within the cuff. Do not use the WalkAide without electrodes.
Placement - Never use the WalkAide in any area of the body other than the leg.
Stimulation - Stop using the WalkAide if stimulation does not come on at the appropriate time when walking and/or there is a change in the sensation perceived while the stimulation is on.

⚠ Precautions

Heart Disease - Use caution in applying electrical stimulation to persons suspected of having heart disease. More clinical data is needed to show that such persons will not experience adverse results.
Sensory Deprivation - Use caution when placing electrodes on areas of the skin with reduced response to normal sensory stimuli, due to the risk of skin burns.
Children - FES devices should be kept out of the reach of children.
Hemorrhage - Use caution when applying electrical stimulation on persons with history of, or potential for hemorrhage.
Epilepsy - Use caution in applying electrical stimulation to persons suspected of having epilepsy. More clinical data is needed to show that such a person will not experience adverse events.
Recent Surgery - Do not use FES following recent surgery where muscle contraction may disrupt the healing process.
Electrodes - Do not use lotion or oil in the area that the electrodes make contact with the skin. Stimulation may not be effective.
Proper Use - The safety and efficacy of FES depends on the proper use and handling of the FES system. Improper use of the device or electrodes can result in injury to the patient. Regularly check accessories for wear and replace as needed. Electrodes should be firmly secured to the skin. Never use the WalkAide if it appears to be malfunctioning. If there is a change in the way it usually works (i.e. change in sensation, surging of stimulation, intermittent stimulation) do not use the WalkAide and contact Innovative Neurotronics immediately.
Operating Equipment - The stimulator should not be used while operating potentially dangerous equipment such as automobiles, power lawn mowers or large machinery. Abrupt changes in stimulation level could create a hazard.
Sleeping - The WalkAide should not be worn or used while sleeping or bathing.
Heat and Cold - The use of heat or cold producing devices such as electric blankets, heating pads or ice packs may affect the electrodes or the person's circulation and increase the risk of injury. A medical doctor and clinician should be consulted before using with FES.

⚠ Adverse Reactions

Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle stimulators. Do not leave the electrodes in place for long periods of time without checking or cleaning the skin underneath them. It is normal to observe somewhat reddened areas under the electrode placements. However, the redness should disappear within an hour. Signs of irritation are maintained redness, small pimple-like lesions or blisters. **DO NOT** continue stimulation over irritated skin.

Notify the medical doctor if these conditions persist and discontinue use of the WalkAide until the problem is resolved.

⚠ Caution

Functional electrical stimulation (FES) is the process of using electrical stimulation to activate muscles. Basic rules of FES use include:

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

WalkLink related statements:

1. FCC Part 15 notice:

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

2. FCC Radiation Exposure Statement for Portable Devices

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

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

Glossary

Term	Definition
Associated Parameters	Parameters that are associated or derived from the WalkAide control module during data collection and analysis.
Autoset Parameters	This process attempts to adjust the threshold settings to more closely match the actual data collected.
Cuff	Garment with plastic insert that attaches to the leg and is used to hold the electrodes and the WalkAide control module in the correct position.
Exercise Mode	Allows the client to repeatedly stimulate the dorsiflexors of the foot while resting (NOT ambulating) for a set period of time as determined by the clinician.
Functional Electrical Stimulation (FES)	Using small electrical impulses to activate dysfunctional muscles and produce intentional and useful movement.
Hand Switch	A function of the WalkLink whereby pressing the 'STIM' button on the WalkLink sends a command to the WalkAide control module to provide stimulation.
Heel and Foot Sensors	There are two types of load sensors: (1) The clinician Heel Sensor is used while testing a potential WalkAide client during data collection and analysis. (2) The optional patient Foot Sensor is sent home with those clients whose gait pattern does not provide sufficient tilt information to reliably trigger the stimulation.
Optimize Parameters	Function of the WalkAnalyst software that computes features of the collected data and attempts to configure the 'ON' and 'OFF' thresholds and other parameters to optimize the patient's gait.
Peripheral Nerve Stimulator	Allows accurate location of peripheral nerves, specifically the common peroneal nerve, for application of electrodes.
Retrieve Parameters	Allows the clinician to obtain parameters from the WalkAide control module using the WalkAnalyst software.
Send to WalkAide	Allows the clinician to send parameters to the WalkAide control module using the WalkAnalyst software.
STIM	Abbreviated form of stimulation.
Tilt Sensor	Onboard sensor in the WalkAide control module that measures tilt of the patient's leg during ambulation.
WalkAide	A battery-operated, single channel electrical stimulator that can be used for both therapeutic and functional electrical stimulation.
WalkAnalyst	Software used by the clinician to interface with the WalkAide control module. This allows data collection, analysis and parameter modification in order to correctly time applied stimulation to the client.
WalkLink	Provides wireless connection between WalkAide and computer, and also allows manual stimulation during walking trials via Hand Switch.
Zoom Feature	Allows clinician to focus on specific data by highlighting it with the stylus or mouse.

2.0 Equipment

2.1 Clinician Kit

The Clinician Kit consists of the WalkLink, WalkLink cable, Heel Sensor, and the WalkAnalyst software (Figure 2).

The clinician is recommended to have a computer with a minimum capacity:

- Windows XP Professional with SP2 or better
- 256 MB of RAM
- 1.5 GHz processor or better
- Bluetooth Connectivity Slot – USB Port
- Graphic display with minimum resolution of 1024 x 768 and video display setting set to 96 DPI
- 150 MB of free space

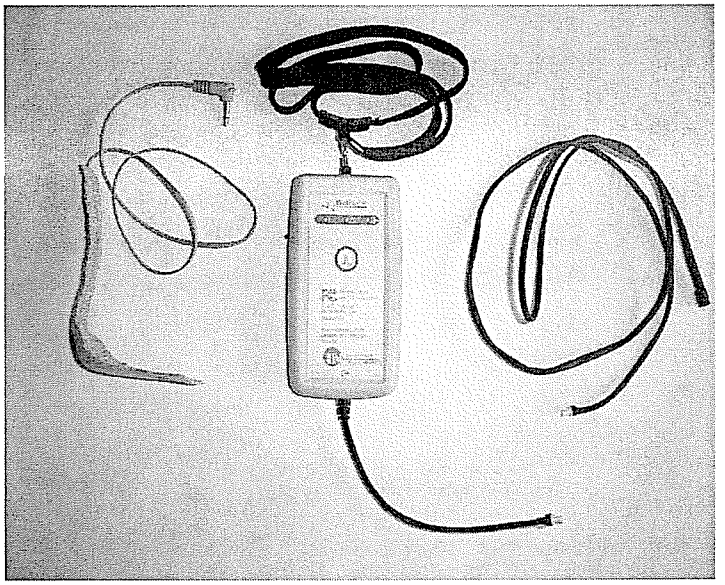


Figure 2 – Clinician Kit (excluding WalkAnalyst Software).

The WalkAide requires a single AA battery and the WalkLink requires four (4) AA batteries to operate. Only AA alkaline (1.5 V) batteries should be used and extra batteries should always be available during follow-up appointments.

2.2 Patient Kit

The Patient Kit consists of WalkAide Control Module, WalkAide Electrode Lead Cable, WalkAide Electrodes (pkg. of 4), and Foot Sensor (optional item). There is a cuff shown here – isn't that part of this kit?

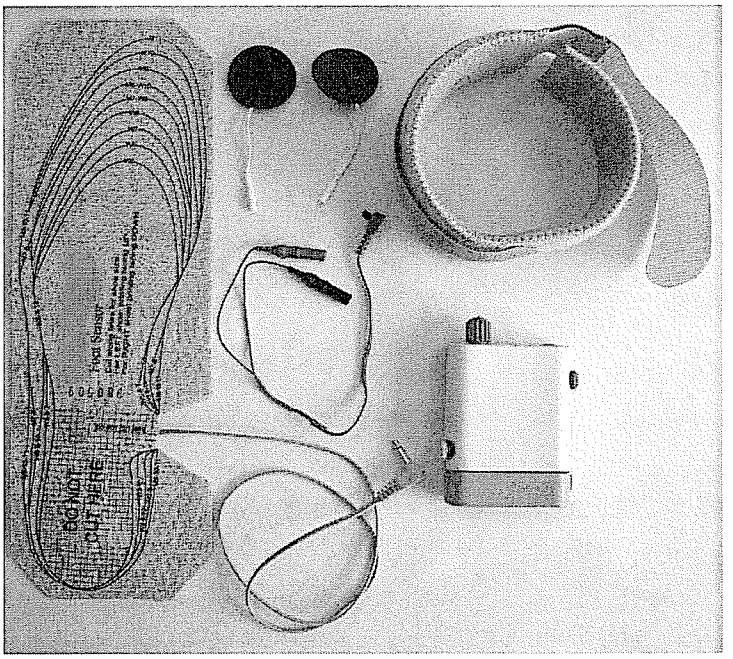


Figure 3 – WalkAide Client Kit

2.3 Symbols and Definitions

Meaning of Symbols

	Attention, consult accompanying documents
	Type BF Equipment
	Indicates Error Signal
	Indicates battery location and positioning
	Indicates impulse, STIM button
	Indicates location of Client and Clinician Heel Sensor
	Indicates input/output connector location for WalkLink
	Indicates exercise button

2.4 WalkAide Controls and Indicators

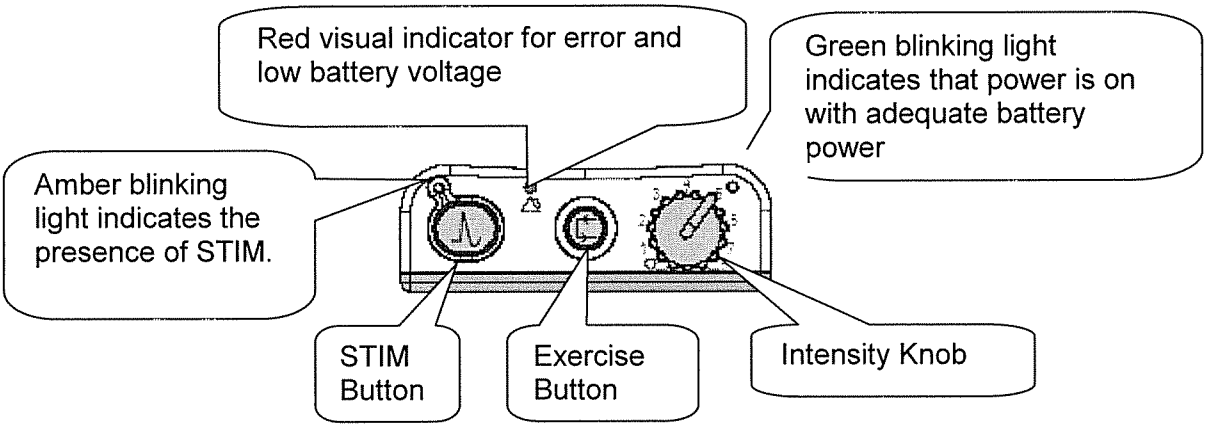


Fig 4 – Top view of WalkAide

Audible Alarms:

1. Low Battery:	An audible alarm every minute with red blinking light.
2. Heel/Foot Sensor:	An audible alarm of two beeps every two seconds indicates that Heel/Foot Sensor is not connected, if it is configured for the Heel/Foot Sensor.
3. Device Error:	An audible alarm of 4 times every 2 second.

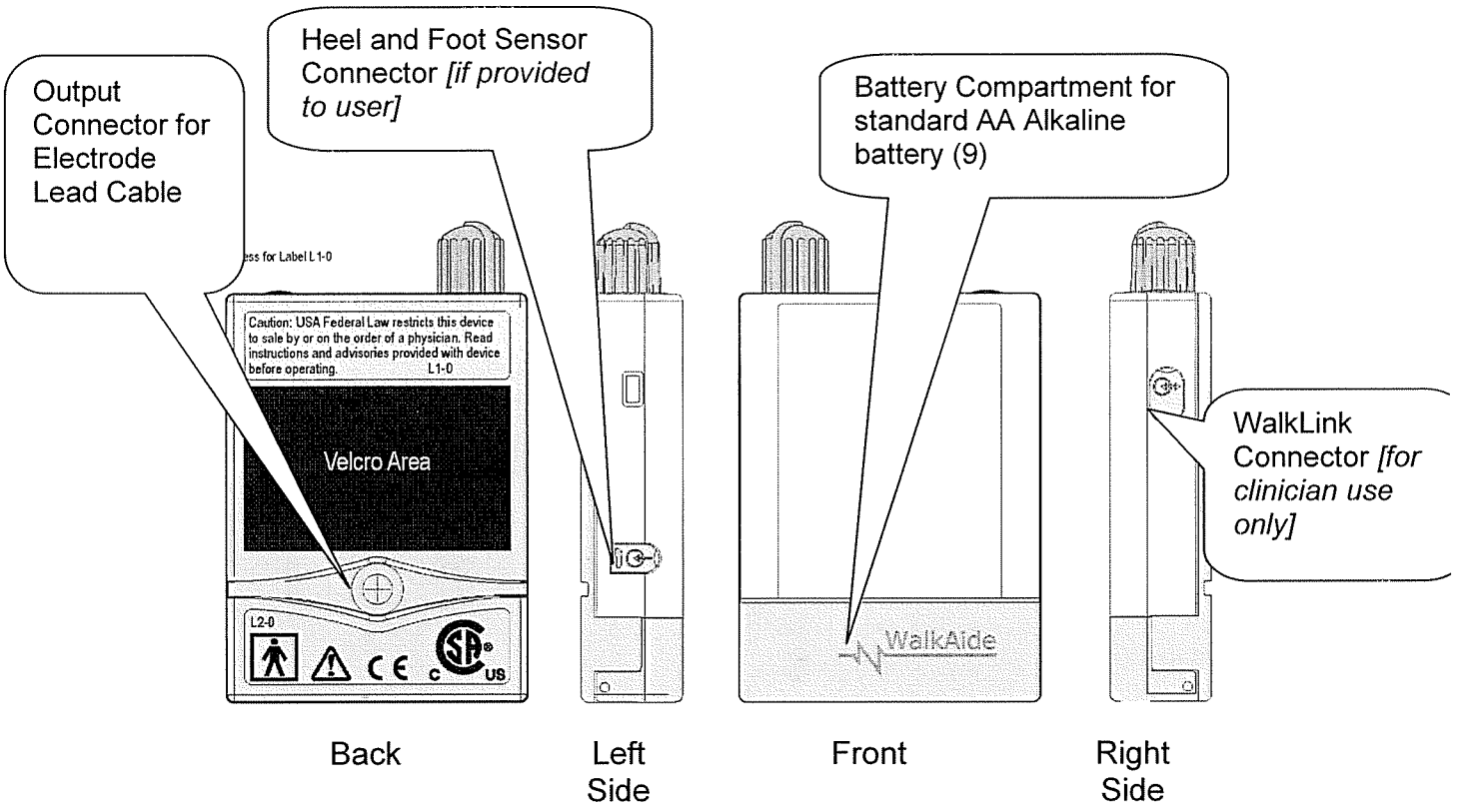


Figure 5 – Back, side(s), and front views of WalkAide unit.

2.5 WalkLink Controls and Indicators

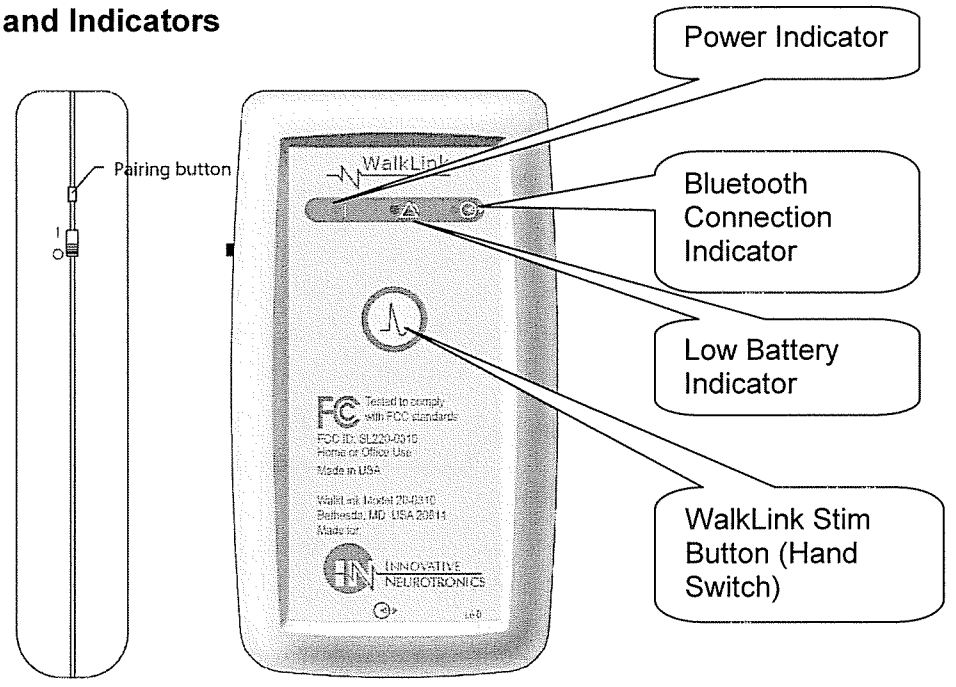


Figure 6 – Front and side views of WalkAide unit

3.0 Installation of the WalkAnalyst Program from CD

(This only needs to be installed once – the first time in order to run this program.)

1. Insert the CD WalkAnalyst Program in the appropriate drive. The tablet PC may have an external CD drive. Make sure it is properly connected and operating correctly prior to inserting the WalkAnalyst CD.

2. The CD should automatically start the installation program. Follow the set up instructions that will appear.

3. If the CD does not automatically start the installation program, find the appropriate drive icon and open the folder. Double click on the "Setup.exe" file. Follow the set up instructions that will appear.

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

5. Once the program has been installed, an icon will be created on the desktop for quick access. WalkAnalyst can also be accessed from the Windows 'start' menu.

4.0 Set-Up Procedures for WalkLink

The WalkAide device sends real time data to and receives parameter changes from the WalkAnalyst program. In order to avoid connecting a physical cable to the patient, a wireless solution has been created employing Bluetooth radio technology.

Setting up this connection requires two primary steps: (1) installing a Bluetooth adapter for the personal computer and (2) establishing the link from that adapter to the WalkLink device.

- After the initial set up process is complete, turn on the WalkLink prior to starting WalkAnalyst. The blue light on the front of the WalkLink should begin to blink and the program should start normally. The WalkAide can be attached to the WalkLink at any time and the yellow light bulb indicating connection will appear when the WalkAide is turned 'ON'.

- If WalkAnalyst is opened and messages appear stating that connection was not possible, simply follow the onscreen connection assistance (Figure 7).

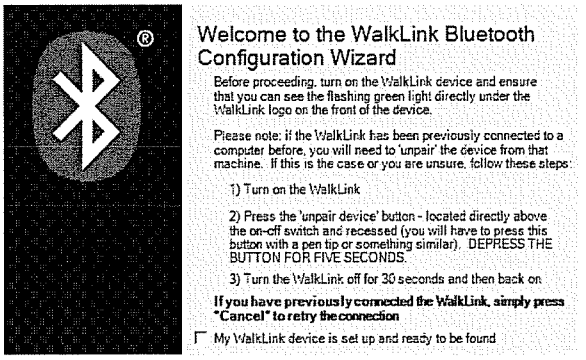


Figure 7: Bluetooth Connection Wizard

5.0 Overview of Data Collection Process

Figure 9 outlines the process used to provide the WalkAide for a new user.

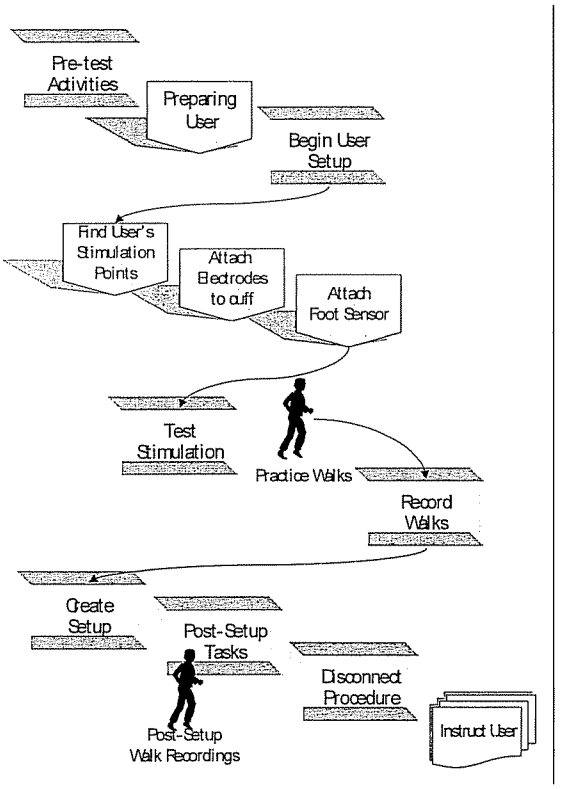


Figure 8 – Set up process for WalkAide.

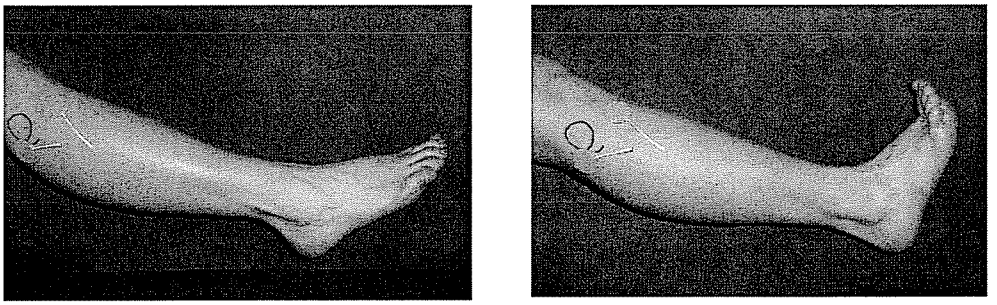
5.1 Set-Up Procedures for a New Client

- Insert previously installed Belkin USB Bluetooth adapter into the personal computer.
- Prior to the client's arrival, turn on the WalkLink, start the WalkAnalyst program and verify that the wireless connectivity (Bluetooth) is working correctly.
- Check to ensure that there is a working battery in the WalkAide.

1. Have the client sit in a chair with the legs extended, resting affected leg on a low stool.

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

3. Use the peripheral nerve stimulator to find the appropriate stimulation site of the common peroneal nerve (Figures 9 and 10). If the client is apprehensive about stimulation or there is some concern if the nerve is functional or hypersensitive on the affected side, stimulation may be applied on the unaffected side first.



Figures 9 and 10 – The peripheral nerve stimulator and the WalkAide stimulate the muscles that raise the foot.

4. **Make sure the WalkAide is turned 'OFF'** and attach it to the cuff on the medial flattened area. Position the cuff around the mid-calf region and tighten the Velcro strap to hold it in place below the potential electrode sites. This places the cuff in a convenient location to hook up the electrodes.

5. Put a small amount of water on the electrodes and/or client's skin specifically in the area of electrode placement. Place the back electrode slightly posterior and distal to the head of the fibula and the front electrode on the upper 1/3 of the tibialis anterior muscle over its muscle belly (Figure 9).

6. Connect the electrodes to the WalkAide Electrode Lead Cable on the WalkAide. Make sure the **BLACK** lead (negative) is connected to the **BACK** electrode and the **RED** lead (positive) is connected to the **FRONT** electrode (Figure 11).

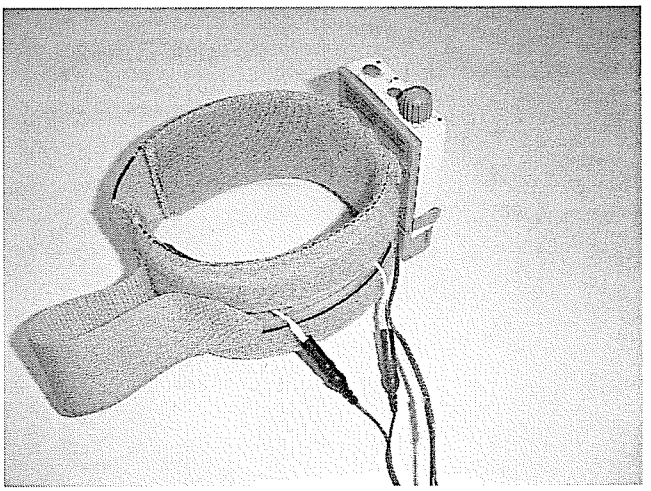


Figure 11 – Connecting the electrodes.

7. **Turn the WalkAide 'ON'** by turning the light blue Intensity Knob in a clockwise direction to the "1" (on) position. A green light will flash intermittently to indicate that the unit is on. ALWAYS start at a low level of intensity and gradually increase.

8. Press down on the large black '**Stim**' button labeled '⌐∧¬' for 1-2 seconds. An amber light next to the '**Stim**' button will appear to indicate that the unit is stimulating. Watch the ankle for dorsiflexion. Turn up the intensity if the movement produced is too small or move the **back** electrode slightly to the rear and try again. Even a small shift of the electrode may change the amplitude or direction of the foot movement (for example, from dorsiflexion to eversion by shifting the electrode anteriorly with more recruitment of the peroneals). **The goal is to produce a relatively pure dorsiflexion with as low stimulus intensity as possible.** Note the numerical value of the intensity level used to produce an effective dorsiflexion movement.

9. Once the optimal electrode positions have been found, **turn 'OFF' the WalkAide** and disconnect the Electrode Lead Cable from the electrodes.

10. Release the Velcro strap and properly align the cuff over and around the pretibial region (i.e., line the center of the cuff with the anterior crest of the tibia and note the number of finger widths from the top of the cuff to the base of the patella). Press over the electrodes to ensure that the Velcro backing adheres to the inside of the cuff.

11. Carefully remove the cuff with the electrodes that are now connected by Velcro to the inside of the cuff. Thread the leads from the electrodes through the holes on the cuff. Connect the **black** lead (negative) to the **back** electrode and the **red** lead (positive) to the more **anterior** electrode.

NOTE: The plastic insert inside the cuff can be custom fitted to each individual. The length of the insert may need to be trimmed if the client complains of pinching at the back of the knee when sitting. The insert can also be heat molded to accommodate individual anatomical variations.

12. Place the electrode leads and connectors in the groove of the cuff and cover with the Velcro strap (Figure 12).

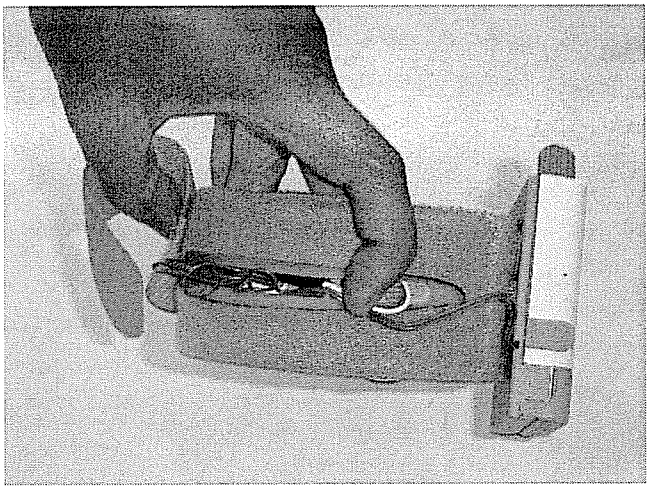
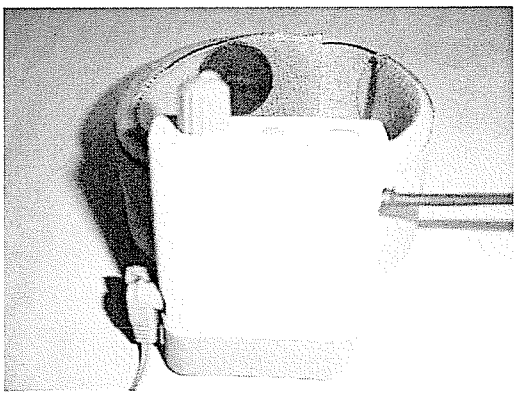


Figure 12 – Electrodes in channel.

13. Replace the WalkAide unit and cuff in the correct position on the client's leg.

14. Place a **Heel Sensor** (if desired) in the client's shoe on the affected side and connect its cable to the WalkAide unit.

15. Connect the WalkLink Cable to the WalkLink unit and then to the WalkAide for the initial walking trial. The WalkLink allows the clinician to provide appropriate stimulation to the foot from toe-off to initial contact (Figures 13 and 14). *(A lanyard is provided to allow the patient to 'wear' the WalkLink during later walking trials when the hand stimulation function is not needed by the clinician.)*



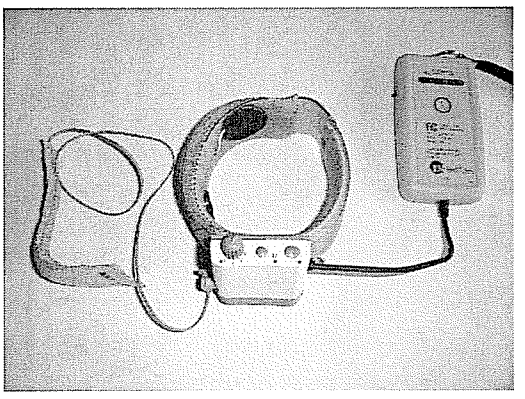


Figure 13 and 14 – WalkAide on with WalkLink and Heel Sensor connected.

16. **Turn the WalkAide 'ON'** and adjust the intensity to the same level determined during initial fitting. Test the stimulation by holding the blue '**STIM**' button for 1-2 seconds to ensure appropriate placement of the electrodes and cuff prior to walking.