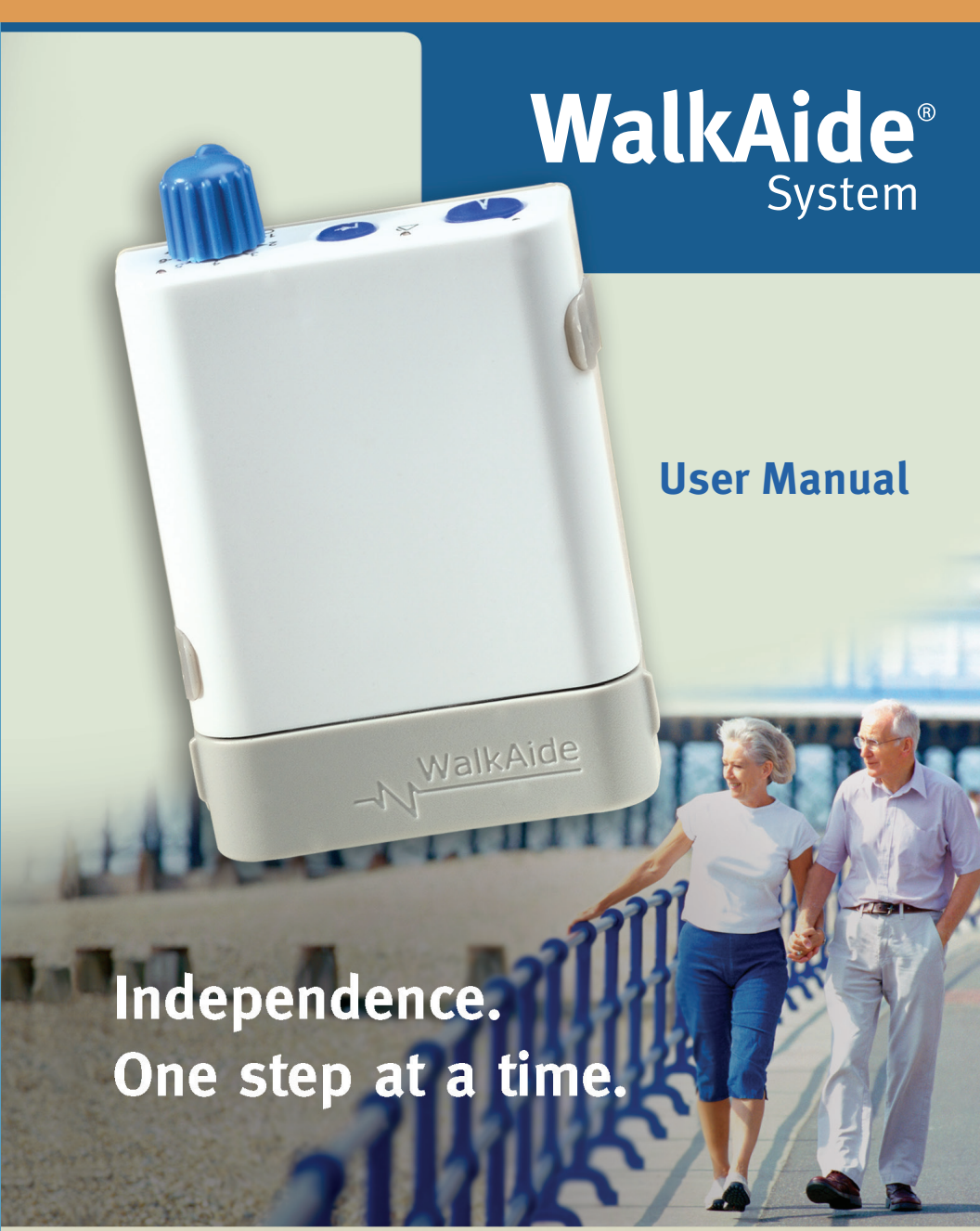
INNOVATIVE
NEUROTRONICS

290201000 Rev. 1

WalkAide® System

User Manual



Independence.
One step at a time.

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

INNOVATIVE NEUROTRONICS

CE 2797

EC REP

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Table of Contents

1.0 The WalkAide System

The WalkAide is a battery-operated, single channel electrical stimulator that is used to improve walking ability. It stimulates a foot lift at the correct time during walking. A foot drop occurs when a person cannot lift the foot on their own. This results in the foot slapping on the floor or the toes dragging during walking. The WalkAide stimulates a nerve as it passes below the knee and activates the muscles that raise the foot. The WalkAide Patient Kit includes a WalkAide Control Unit, a WalkAide cuff, and an electrode lead cable. A foot sensor is an optional item.

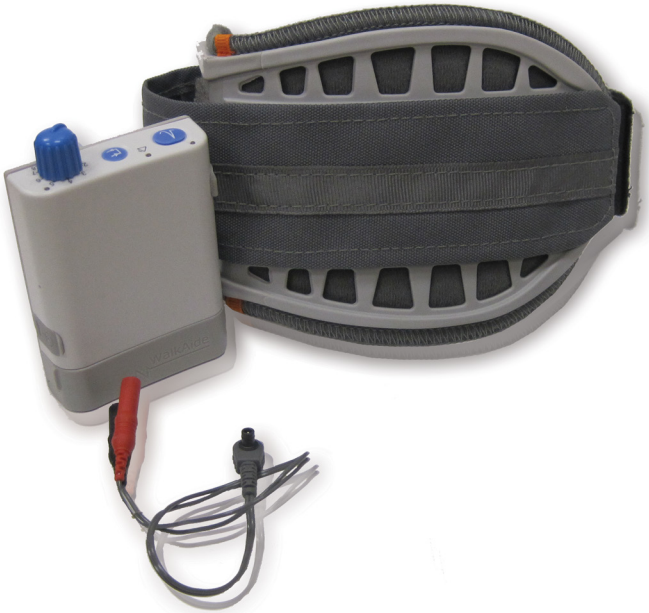


Figure 1: WalkAide System

Indications of Use

The WalkAide System is intended to address Footdrop in certain patients. These patients have damage to the spinal cord or brain. When it is time to take a step during walking, the WalkAide System electrically stimulates the nerve that activates the muscles that lifts the foot at the ankle.
This makes it possible to take a step and not drag the foot.
Medical benefits of Functional Electrical Stimulation (FES) may prevent or delay-muscle wasting that might come with disuse. FES may also increase local blood flow, muscle re-education, and improve joint range of motion.

Contraindications

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

- Stimulation should not be applied over the neck or mouth. Severe spasm of the neck muscles may occur. The resulting contractions may be strong enough to close the airway or make it hard to breathe.

- Stimulation should not be applied over, or in proximity to, cancerous lesions.

- Stimulation should not be applied over swollen, infected or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.

- Do not use if person has a history of seizure disorder.

Warnings About FES

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

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

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

Pregnancy—The safety of FES for use during pregnancy or over the menstruating uterus has not been established.

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

Skin Irritation—Improper or prolonged use of electrodes may result in increased risk of skin irritation or burns and poor results. Infrequently, there is an allergic response to the electrode adhesive or gel. Do not place electrodes on skin which is already irritated. This will increase the risk of discomfort or skin irritation.

Medical Supervision—Only a physician can determine that the use of a WalkAide is appropriate for the patient. Only a WalkAide trained clinician is qualified to fit and program the WalkAide for the patient's specific requirements. After fitting and programming the WalkAide is intended for patient use at home and in the community. Trained clinician or physician should be contacted in cases described further in this User Manual.

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. These devices include; cellular phones and two-way radios. These transmitters may cause undesirable stimulation to the user.

Defibrillator—External defibrillation of a person wearing a FES device can damage the device or injure the 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 not known.

WalkAide Specific Warnings

Walking—Care should be taken when using the WalkAide for people who experience dizziness or have difficulty with balance. The WalkAide is not designed to prevent falling.

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

Placement—Use the WalkAide on the leg only. Stimulation should not be applied transcerebrally. Stimulation should not be applied to the chest, neck or head. To apply electrical current into the heart may cause cardiac arrhythmias.

Stimulation—Stop using the WalkAide if stimulation does not come on at the correct time when walking. Also stop using the WalkAide if there is a change in the sensation perceived while the stimulation is on.

Environment—WalkAide is not intended for use in flammable environments such as oxygen and anesthetics.

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

Precautions

Heart Disease—Use caution in applying FES to persons who might have heart disease. More clinical data is needed to show that such persons will not experience adverse results.

Sensory Loss—Use caution when placing electrodes on areas of the skin with reduced response to normal sensory stimuli. This may increase the risk of skin burns.

Hazardous—FES devices should be kept out of the reach of children, pets, or pests.

Epilepsy—Use caution in applying electrical stimulation to persons who might have 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 where the electrodes make contact with the skin. Do not expose the electrodes to lint or dust. Stimulation may not be effective.

Proper Use—The function of FES depends on the proper use of the FES system. Improper use of the system can result in injury to the patient. Regularly check parts for wear and replace as needed. Electrodes should be firmly secured to the skin. Never use the WalkAide if it appears to be faulty. If there is a change in the way the WalkAide usually works do not use the WalkAide and contact your clinician immediately.

Operating Equipment—The WalkAide should not be used while operating potentially dangerous equipment. This includes automobiles, power lawn mowers and 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. This may increase the risk of injury. A medical doctor and clinician should be consulted before using with FES.

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

Caution—Do not unplug foot sensor from WalkAide while sensor is in the shoe

Caution—The use of accessories other that the ones supplied by Innovative Neurotronics with the equipment, or recommended for use by Innovative Neurotronics, may result in increased emissions or decreased immunity of the WalkAide device.

Adverse Reactions

Skin irritation and burns beneath the electrodes have occurred with the use of FES devices. Do not leave the electrodes in place for long periods of time without checking or cleaning the skin underneath. It is normal to see somewhat reddened areas under the electrodes. However, the redness should disappear within an hour. Signs of irritation are sustained redness, small pimple-like lesions or blisters. DO NOT continue stimulation over irritated skin.

Notify the medical doctor if these conditions persist and do not use the WalkAide until the problem is resolved.

Cautions

Functional electrical stimulation (FES) uses electrical stimulation to activate muscles. Basic rules of FES use include:

1. **ALWAYS** use the WalkAide under the specific instruction of a trained WalkAide clinician and follow all instructions when using the WalkAide independently at home or in the community.
2. **NEVER** use the WalkAide while bathing, driving or operating motorized equipment.
3. **DO NOT** use the WalkAide if it is not working 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 on any body part other than on one leg below the knee.
7. **AVOID** dropping the WalkAide unit. 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 is not serviceable by your clinician.
10. **TURN OFF** the unit if sitting for a long period of time.
11. **KEEP** Foot Sensor Cord and Electrode Leads away from babies and small children to avoid strangulation, swallowing, and inhalation.
12. **DO NOT** modify the equipment in any way. This may interfere with the safe operation and intended function.

2.0 Symbols and Definitions


Type BF Equipment


Indicates Error Signal


Indicates battery location and positioning


Indicates impulse, STIM button


Indicates connector location for optional Patient Foot Sensor


Indicates input/output connector location for WalkLink


Indicates exercise button


Important safety instructions

3.0 WalkAide Controls and Indicators

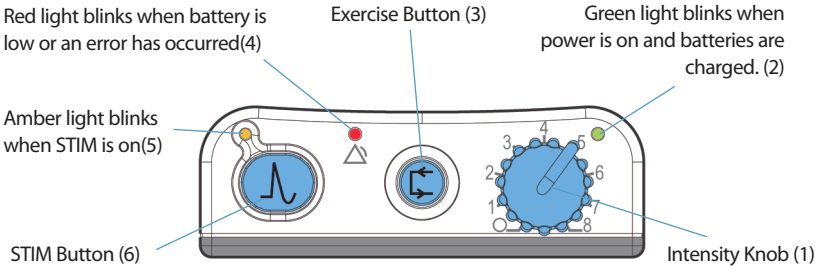


Figure 2: Top view of WalkAide unit

Audible Alarms:

1. Low Battery:	An audible alarm every minute with red and green blinking lights.
2. Depleted Battery:	An audible alarm every 1-2 seconds with red and green blinking lights
3. 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.
4. Device Error:	An audible alarm of 4 beeps every 2 seconds.

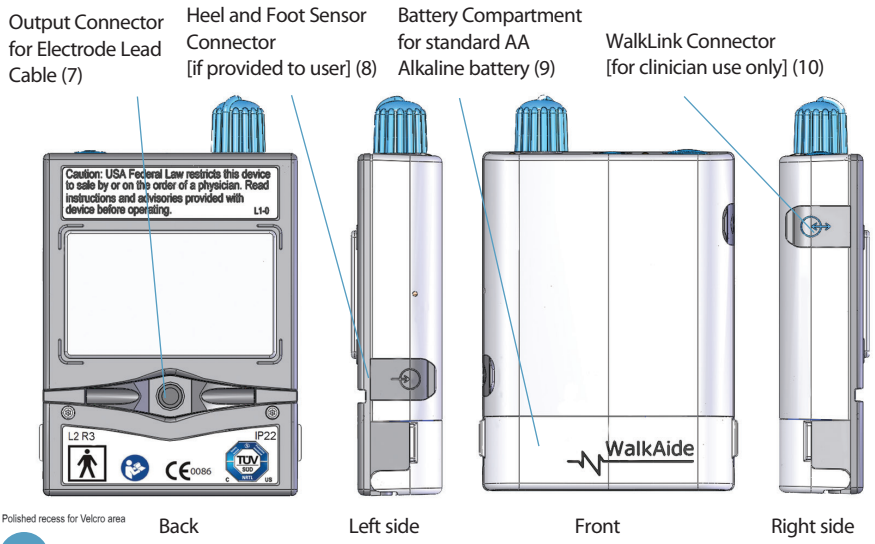


Figure 3: Back, side(s) and front views of WalkAide unit

4.0 General Operating Instructions

The WalkAide is designed for single-handed application and removal (Figure 4). It may take a bit of practice to develop a routine that works best for each person. The WalkAide is applied directly to the leg and can be easily worn under most clothing.

Applying **Tightening**

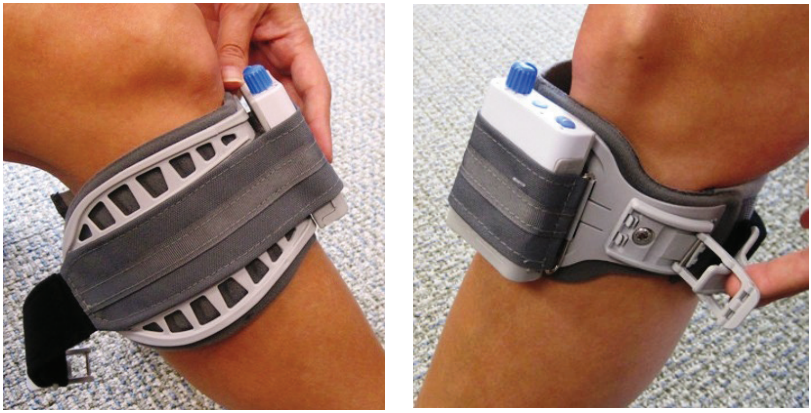


Figure 4: One-handed application

At the initial visit, the clinician will determine the best fit location for the cuff and electrodes. The red and black electrode locators will be placed on the inside of the cuff and will not need to be adjusted within the cuff afterwards. The cuff must be worn on the leg correctly for the WalkAide to work properly.

4.1 Applying the WalkAide

1. The skin in the area around the head of the fibula should be clean and free of lotions. Failure to prepare the skin may cause less than ideal stimulation.
2. **Always** make sure the WalkAide unit is turned OFF prior to handling. The blue Intensity Knob (Figure 2) should be positioned at O.
3. Sit in a chair with the leg slightly extended.
4. Moisten the electrodes with water and place the cuff in the correct position below the knee. The electrodes will be on the outside of the leg. The WalkAide unit will be on the inside of the leg just below the knee.
5. The cuff must be positioned on the leg correctly to achieve effective and efficient stimulation. Use the orange visual indicator as a reference for accurate placement of the cuff. (Figure 5).

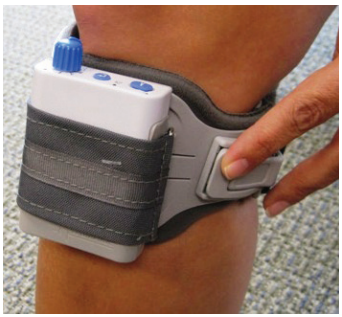


Figure 5: WalkAide and cuff

4.1 Applying the WalkAide (cont'd)

6. If a Foot Sensor was provided, place the Foot Sensor into the shoe. Plug it into the side of the WalkAide unit marked →.

7. Turn the WalkAide unit ON by turning the blue Intensity Knob (Figure 2, 1) in a clockwise direction. A green light (2) will flash. You should also hear a beep.

8. Set the intensity to the level determined by the clinician.

9. Check the intensity level and quality of the foot movement by pushing and holding the large STIM button for 1 to 2 seconds (Figure 6).

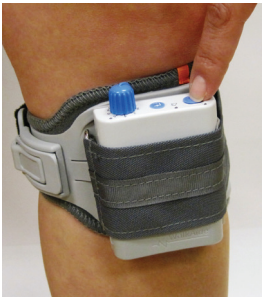


Figure 6: Testing the stimulation and proper placement of the WalkAide

This button is labeled ⎍. The intensity level of the stimulation or the placement of the cuff may need to be adjusted for optimal foot movement. Always set the intensity level as instructed by the clinician. High levels of stimulation may result in discomfort or skin irritation.

10. Stand up and walk as usual. The WalkAide can be used with or without shoes, although proper footwear is recommended.

4.2 Removing the WalkAide

1. Turn the WalkAide unit OFF by rotating the blue Intensity Knob (Figure 2, 1) in a counter-clockwise direction until it clicks at O.
2. Release the strap buckle at the back of the leg.
3. Slowly peel the cuff down and away from the leg. Take extra care with the removal of the electrodes from the skin.
4. Place the plastic backing onto the electrodes.
5. Check the skin for signs of irritation.
6. For storage, place plastic backing on electrodes. Then place the cuff, with the electrodes, and WalkAide unit in a resealable plastic bag. This preserves electrode life. Store the WalkAide and electrodes out of direct sunlight.

The WalkAide may be worn all day but must be removed at night before going to bed. Be sure to turn the WalkAide unit OFF to prevent unwanted stimulation during handling. This will also conserve battery power when it is not being worn.

Figures 6A: Storing the WalkAide in the WalkAide carrying case

4.3 Skin Care

Always check for skin irritation before and after using the WalkAide; including redness lasting more than one hour. Suggestions to prevent skin irritation.

- Remove electrodes **GENTLY** down and away from the body. Use a drop of water to separate the electrode from the skin.
- **DO NOT** place electrodes over irritated areas. The clinician may be able to suggest alternative sites.
- **DO NOT** place electrodes over skin coated with lotions or oils.
- **DO NOT** place the electrodes over sores, open wounds, rashes or freshly shaved leg. Shave at night, before donning the WalkAide the next morning.

4.4 Instructions for Exercise Mode

The Exercise Mode is **NOT** to be used while walking. It is designed to apply repeated stimulation to the leg during a seated activity determined by a clinician.

1. Assume a comfortable sitting position and apply the WalkAide unit.
2. Adjust the Intensity Knob (1) and then press the Exercise Button (3) for more than 3 seconds (Figure 7). An amber light (5) will flash on the top of the WalkAide unit and will beep. This will start the exercise stimulation.

Figure 7: Using the Exercise Mode

3. The clinician has programmed the length of this exercise session. They will also provide instructions on the appropriate intensity setting. This may or may not be the same as the intensity used for walking.

4. The WalkAide unit will stop stimulating when the programmed session is finished.

5. Turn the unit OFF.

6. After 1–2 seconds, the WalkAide can be turned on again and will return to walking mode. The stimulation intensity can then be adjusted to the desired level for walking.

4.5 Changing the Battery

The normal battery life is about 42 hours of continuous use. Dependent upon the use, the batteries could last from 1 to 3 weeks. When the battery is low, the red and green indicator lights will flash. An audible alarm will sound 2 long beeps each minute indicating that the **battery should be replaced as soon as possible.** If the unit beeps continuously, battery is fully depleted.

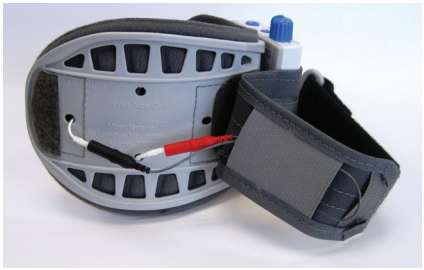
Figure 8: Changing the battery

To replace the battery; first turn the unit off. Next, grip the sides of the gray battery cover, pinch and pull open (Figure 8). The WalkAide requires **one alkaline AA battery to operate. DO NOT** use rechargeable or other types of batteries.

Please dispose of the battery in accordance with all local and national laws.

4.6 Changing the Electrodes

For proper skin care, comfort and effectiveness, the electrodes should be replaced every 1 to 2 weeks. Pull back the WalkAide attachment strap to uncover the electrode lead cables. Disconnect the black and red leads between the WalkAide and the electrodes. Remove the electrodes from the electrode locators. Place the new electrodes on the electrode locators. Feed the leads through the holes toward the outside of the cuff. Connect the **BLACK** lead to the electrode on the black electrode locator. Connect the **RED** lead to the electrode on the red electrode locator. Feed the excess wires in the strap pouch as indicated in the image below.



Figures 9 and 10: Changing the electrodes (inside and outside views)

- The **BLACK** lead is connected to the **BACK** electrode.
- The **RED** lead is connected to the **FRONT** electrode.

5.0 Maintenance and Cleaning of the WalkAide and Accessories

- **WalkAide Maintenance**
  Other than replacing the battery as needed, the WalkAide does not require any user maintenance. All other servicing needs should be referred to the clinician and manufacturer.

- **Cleaning the WalkAide**
  Rubbing alcohol or a damp cloth with MILD soap may be used to wipe the outside of the WalkAide. DO NOT use a strong cleaning solution that contains bleach or put the WalkAide in water.

- **Storing the WalkAide**
  If the WalkAide is to be stored for a long period of time and not used, remove the battery.

- **Washing the WalkAide Cuff**
  Remove the electrodes and the WalkAide prior to washing. Remove the liner from the cuff. DO NOT remove the black and red locators. Hand wash, do not use bleach and line dry only.

- **Disposal of the Device**
  When the device has reached the end of its useful life, please dispose of in accordance with all local and national laws.

- **Protection of the Device**
  We recommend using the WalkAide silicone cover accessory to better protect the WalkAide from impact, dirt and water. This does not make the WalkAide water proof. Always keep the WalkAide dry and away from the risk of getting wet.

Figure 11: WalkAide Silicone Cover

6.0 Troubleshooting—Frequently Asked Questions

1. **Why don't the control and indicator lights work?**
   This is caused by low battery voltage. Insert a fresh battery, and turn the unit on. If the green light is still not blinking, stop use of the WalkAide and contact the clinician.

2. **Why is the green and red light blinking?**
   This is an error message. Turn the WalkAide off and wait 2-3 seconds. Turn the WalkAide back on and check to see that the green light is blinking and the red light is off. If not, stop use of the WalkAide and contact the clinician.

3. **What if the foot does not lift as far as it should?**
   It may be necessary to adjust the intensity level, or replace or re-wet the electrodes. Verify that the amber light is blinking, the electrodes are making contact with the skind and are in the correct location. If the foot lift is still insufficient, discontinue use and contact your clinician.

4. **Why doesn't the stimulation come on at the appropriate time?** This may be due to a change in your walking pattern. Make sure the cuff is in the correct position. This does not correct the issue, stop use and schedule an appointment with your clinician.

5. **Is it okay to use lotion or oils on the leg?**
   No — do not apply lotions or oils to the leg in the area of the electrodes. Clean the area under the electrodes each day with a mild soap and water. Make sure the leg is clean and moist at the electrode site before applying the WalkAide.

6.0 Troubleshooting—Frequently Asked Questions (cont'd)

6. How long do the electrodes last?

The electrodes should be changed approximately every 1-2 weeks, or immediately upon excessive wear.

7. How long does the battery last?

Each AA battery will last between 1 and 3 weeks depending upon individual usage of the WalkAide. A low battery is indicated by red and green flashing lights and a beep once per minute.

8. Why are the WalkAide and accessories stored in a resealable plastic bag?

This helps to keep the electrodes from drying out while not in use. Be sure to cover the electrodes with the plastic backing after removing the WalkAide and before placing in the resealable plastic bag.

9. What indicates that the WalkAide is on?

A green blinking light near the blue Intensity Knob indicates that the power is on and batteries are good.

10. When should the clinician be contacted?

Contact the clinician any time there is/are: additional questions or concerns about the WalkAide and its proper use; a change in the medical condition or walking pattern; any WalkAide accessory shows excessive wear and tear; the WalkAide does not function properly; an error message light is seen; sustained skin irritation; and/or a request by the medical doctor.

7.0 Wearing Schedule

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

Helpful Hints For the Break-In Period

- For the first week, remove the WalkAide system every 2 hours to check skin for irritation.
- Slowly work into full-time wearing of the WalkAide system.
- Remove the cuff often and inspect the skin under the electrodes for discoloration, soreness or irritation. These areas will be red due to increased blood flow under the electrodes. Do not wear WalkAide again until redness is gone and consult your clinician.
- **DO NOT** use lotions or oils to soften the skin. Make sure the skin is clean and dry prior to applying the cuff.
- If desired, shaving the leg should be done in the evening to prevent potential irritation during daily wear.
- Wet the electrodes with water before applying the cuff. Make sure you change the electrodes approximately every 1-2 weeks, and cover them each night with the plastic backing tabs.

8.0 WalkAide User Statement of Understanding

I,_____, have reviewed the contents of the *WalkAide System User Manual* with my practitioner. I understand the general operating instructions and general maintenance of the WalkAide System. I have been advised to follow the wearing schedule and have been advised to contact my practitioner immediately with any questions I may have with the WalkAide System.

Print Patient Name: Date:

Patient Signature: Date:

Practitioner Signature: Date:

9.0 Medical Device ID Card

Medical Device ID

INNOVATIVE NEUROTRONICS

Patient Name:

Practitioner:

Phone :

Device: **WalkAide System**

Innovative Neurotronics • Reno, NV 89502 • 1-888-884-6462

This card may be cut out and placed in your wallet for medical device identification purposes.

9.0 Medical Device ID Card (cont.)

Innovative Neurotronics, Inc.
1.888.884.6462 www.ininc.us

The Innovative Neurotronics WalkAide System is an external functional neuromuscular stimulator system. This FDA cleared medical device is battery operated and is worn below the knee. It is worn to assist patients diagnosed with foot drop in their walking ability.

FDA Clearance K052329 • ISO 13485:2003 CE certified

10.0 Technical Information—Reference Part Numbers

20-1000 WalkAide Patient Kit
21-1000 WalkAide Patient Kit, Japan
20-1000R WalkAide Patient Kit, Reprocessed
20-0100 WalkAide
21-0100 WalkAide, Japan
20-0100R WalkAide, Reprocessed
20-0300 WalkAide Clinician Kit
20-0310 WalkLink Assembly

10.0 Technical Information—Specifications

Size	8.2cm(H) x 6.1cm(W) x 2.1cm(T)	
Weight	87.9 g	
Power Source	One 1.5 V Alkaline AA battery	
Maximum Current	200 mA at 500 ohm; 121 mA at 1 K ohm	
Maximum Voltage	121 V at 1 K ohm; <150 V at 1 M ohm	
Number of Operation Modes	2 - Exercise, Walking	
Number of Channels	1	
Pulse Type	Asymmetrical Biphasic	
Pulse Width	25-300 microseconds (Adjustable)	
Maximum Stimulation Period	3 seconds	
Stimulation Trigger Source	Tilt or Heel Sensor	
Controls and Indicators	ON/OFF/Intensity; Stimulation, Exercise Error	
Shipping and Storage Conditions:	Device (Long or Short Term, In or Out of Packaging) Temperature: Humidity:	 -4° to +140°F (-20° to +60° C) 0-95%, non-condensing
Operating Conditions:	Temperature: Humidity: Altitude	32° to +104° F (0° to +40° C) 0-95%, non-condensing -1300 to 8000 ft (-400 to 2400m)
IEC 60529 Rating:	IP22 Protected against finger insertion. Protected against water spray up to 15° from vertical.	
Expected Service Life:	5 years	

10.0 Technical Information—EMI Tables

Guidance and Manufacturer's Declaration Electromagnetic Emissions		
The WalkAide device is intended for use in the electromagnetic environment specified below. The customer or the user of the WalkAide should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The WalkAide device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The WalkAide device is battery powered and is suitable for use in all establishments, including domestic establishments.
Harmonic emissions IEC 61000-3-2	Not applicable (battery powered)	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable (battery powered)	

Guidance and Manufacturer's Declaration Electromagnetic Immunity			
The WalkAide device is intended for use in the electromagnetic environment specified below. The customer or the user of the WalkAide device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment –**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	Not Applicable (battery powered)	
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common	Not Applicable (battery powered)	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Not Applicable (battery powered)	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the AC mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration Electromagnetic Immunity

The WalkAide device is intended for use in the electromagnetic environment specified below. The customer or the user of the WalkAide device should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment –
			Portable and mobile RF communications equipment should be used no closer to any part of the WalkAide, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ V1 = 3 VRMS $d = 0.35 \sqrt{P}$ 80 MHz to 800 MHz, E1 = 10 V/m $d = 0.7 \sqrt{P}$ 800 MHz to 2,5 GHz, E1 = 10 V/m - where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a. should be less than the compliance level in each frequency range. b. Interference may occur in the vicinity of equipment marked with the following symbol:
Conducted RF IEC 61000-4-6	3 VRMS 150 kHz to 80 MHz	3 VRMS	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	10 V/m	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the WalkAide is used exceeds the applicable RF compliance level above, the WalkAide should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the WalkAide.

b.. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Appendix 1- EMI Tables

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the WalkAide Device

The WalkAide device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the WalkAide can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the WalkAide device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter (Meters)		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 0.35 \sqrt{P}$	800 MHz to 2,5 GHz $d = 0.7 \sqrt{P}$
0,01	0.12	0.035	0.07
0,1	0.38	0.11	0.22
1	1.2	0.35	0.70
10	3.8	1.11	2.2
100	12.0	3.5	7.0

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

NOTE 3 All calculations were made according to tables 204 and 206 of IEC 60601-1-2:2001 (tables 4 and 6 of IEC 60601-1-2:2007) for not life-supporting equipment using factors of 3.5 in 0.15-800 MHz and 7 in 800-2500MHz. There are no requirements for ISM bands in these tables.

Contact your clinician with questions regarding safe operation and use of this device.

If further assistance is required, please contact:

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