

WalkAide® System

User Manual



**Independence.
One step at a time.**



INNOVATIVE
NEUROTRONICS

© 2010 Innovative Neurotronics. All rights reserved. All trademarks and registered trademarks are the property of their respective holders.

LM01 R8

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



INNOVATIVE
NEUROTRONICS



Medical Device & QA Services
76, Stockport Road
Timperley, Cheshire
WA15 7SN
United Kingdom
Tel: 0161 980 4310
e-mail: info@mdqa.co.uk

Table of Contents

1.0	The WalkAide Stimulator System	2
	Indications of Use	3
	Contraindications	3
	Warnings About FES	4
	WalkAide Specific Warnings	5
	Precautions	6
	Adverse Reactions	7
	Cautions	8
2.0	Symbols and Definitions	9
3.0	WalkAide Controls and Indicators	10
4.0	General Operating Instructions	11
	4.1 Applying the WalkAide	12
	4.2 Removing the WalkAide	14
	4.3 Skin Care	14
	4.4 Instructions for Exercise Mode	15
	4.5 Changing the Battery	16
	4.6 Changing the Electrodes	17
5.0	Maintenance and Cleaning of the WalkAide and Accessories	18
6.0	Troubleshooting—Frequently Asked Questions	19
7.0	Wearing Schedule	21
8.0	WalkAide User Statement of Understanding	22
9.0	Medical ID Card	23
10.0	Technical Information—Specifications	25

1.0 The WalkAide Stimulator 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 appropriate time during the walking cycle. A foot drop occurs when a person is unable to actively lift the foot, resulting 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 consists of a WalkAide Control Unit, a WalkAide cuff, four electrodes, and an electrode lead cable. A foot sensor is an optional item.

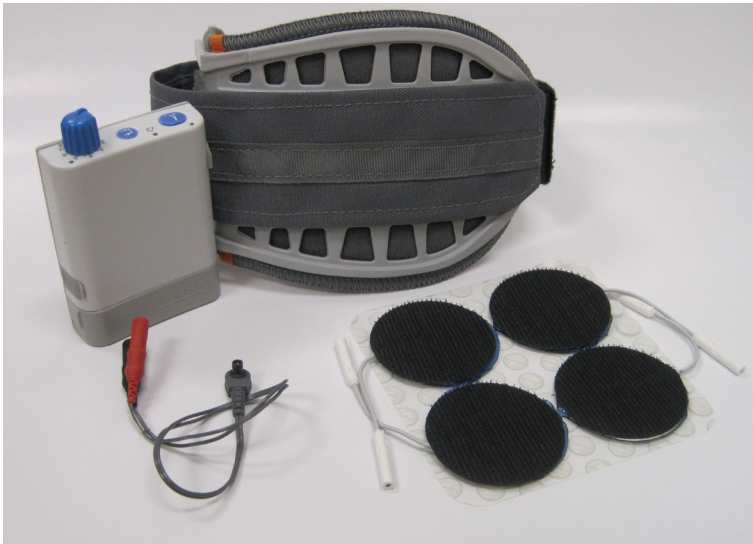


Figure 1: WalkAide System

Indications of Use

The Innovative Neurotronics WalkAide System is a surface functional neuromuscular stimulator system that is intended to address foot drop in patients who have sustained damage to upper motor neurons or pathways in the brain or spinal cord. During the swing phase of walking, the WalkAide electrically stimulates the appropriate nerve that signals the ankle to dorsiflex and may thus improve the patient's walking ability. Medical benefits of Functional Electrical Stimulation (FES) may include prevention of muscle disuse or weakness, increased local blood flow, muscle strengthening, 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.

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, 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 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 unknown in this particular application.

WalkAide Specific Warnings

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

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

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

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

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

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

Precautions

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

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

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

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

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

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

Proper Use—The safety and efficacy of FES depends on the proper use and handling of the FES system. Improper use of the device or electrodes can result in injury to the 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 your clinician 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 surface functional electrical stimulation devices. 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.

Cautions

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.
10. **TURN OFF** the unit if sitting for an extended period of time.

2.0 Symbols and Definitions

Meaning of Symbols



Attention, consult accompanying documents



Type BF Equipment



Indicates Error Signal



Indicates battery location and positioning



Indicates impulse, STIM button



Indicates connector location for optional Patient Foot Sensor



Indicates input/output connector location for WalkLink



Indicates exercise button

3.0 WalkAide Controls and Indicators

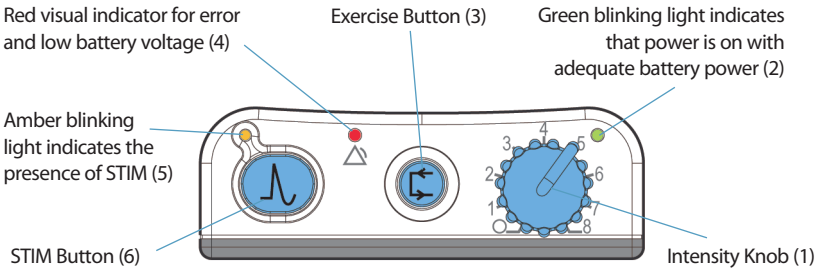


Figure 2: Top view of WalkAide unit

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.

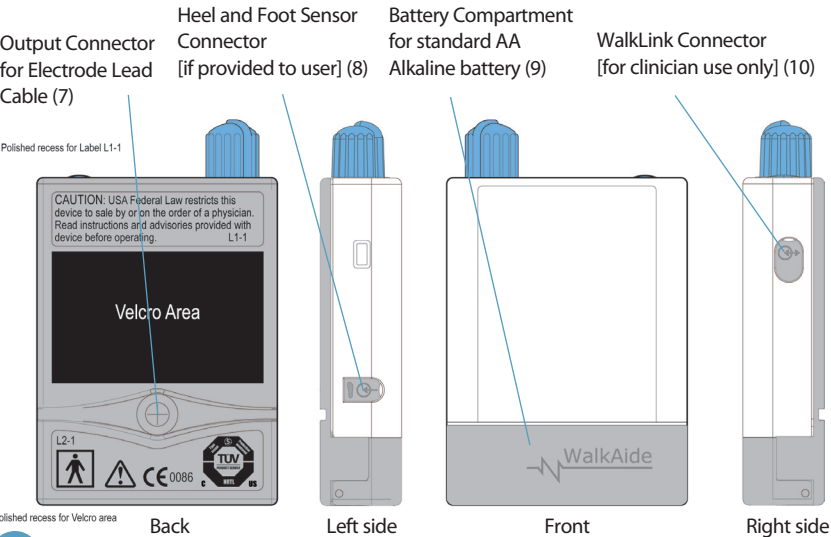


Figure 3: Back, side(s) and front views of WalkAide unit

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.

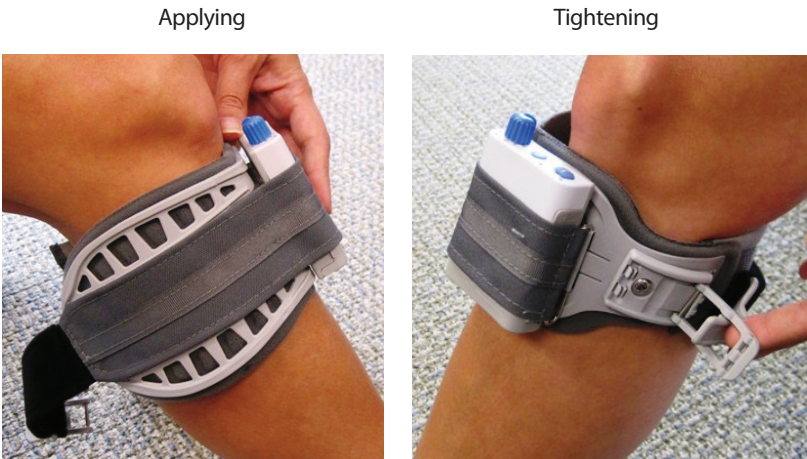


Figure 4: One-handed application

The clinician will find the optimal stimulation areas and set up the placements of the electrodes on the initial visit. The electrode red and black 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 positioned on the leg correctly to achieve effective and efficient stimulation.


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 adequately prepare the skin may cause improper contact and provide less than ideal stimulation.
2. **Always** make sure the WalkAide unit is turned OFF prior to handling. The Intensity Knob (1) should be positioned at 0.
3. Sit in a chair with the leg slightly extended.
4. a) Add a small amount of water to area where electrodes go to improve stimulation.
4. b) 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 and 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 and plug the connector into the side of the WalkAide unit marked .
7. Turn the WalkAide unit ON by rotating the light blue Intensity Knob (1) in a clockwise direction. A green light (2) will flash intermittently.
8. Adjust the intensity to the level determined by the clinician.
9. Check the intensity of the stimulation and quality of the foot movement by pushing and holding the large STIM button (6) for 1 to 2 seconds (Figure 6).



Figures 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 to attain optimal foot movement. Always adjust the intensity level to the level determined by the clinician. Higher 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 Intensity Knob (1) in a counter-clockwise position until it clicks at 0.
2. Release the Velcro strap at the back of the leg.
3. Slowly peel the cuff away from the leg taking extra care with the removal of the electrodes from the skin.
4. Place the plastic backings onto the electrodes.
5. Check the skin for signs of irritation.
6. For storage, place plastic backings on electrodes and then place the cuff containing the electrodes and WalkAide unit in a resealable plastic bag so that the electrodes do not dry out. Keep the resealable plastic bag and unit 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 unintentional stimulation during handling and to conserve battery power when it is not being worn.

4.3 Skin Care

Always check the skin prior to and after using the WalkAide. It is normal to have somewhat reddened areas under the electrode placements as this indicates increased blood flow in these areas. 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.

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 while at rest for a period of time determined by the 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 intermittent stimulation.



Figure 7: Using the Exercise Mode

3. The clinician has already programmed the duration of this exercise session and will provide instructions on the appropriate level of stimulation intensity, which may or may not be the same as the intensity used for walking.
4. The WalkAide unit will stop stimulating when the programmed exercise session is finished.
5. Turn the unit OFF.
6. After 1–2 seconds, the WalkAide can be turned on again (automatically returning to walking mode) and the stimulation intensity can be adjusted to the desired level for walking.

4.5 Changing the Battery

The expected 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 visual indicator lights will flash and an audible alarm will sound 2 long beeps each minute indicating that the **battery should be replaced immediately**.

To replace the battery, grip the sides of the gray cover to the battery compartment and pull open (Figure 8). The WalkAide requires **a single alkaline AA battery to operate**. **DO NOT** use rechargeable or other types of batteries.

When the alkaline battery becomes depleted, please dispose of the battery properly in accordance with all local and national regulations.

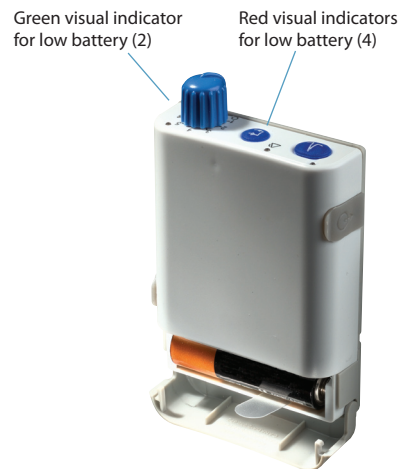
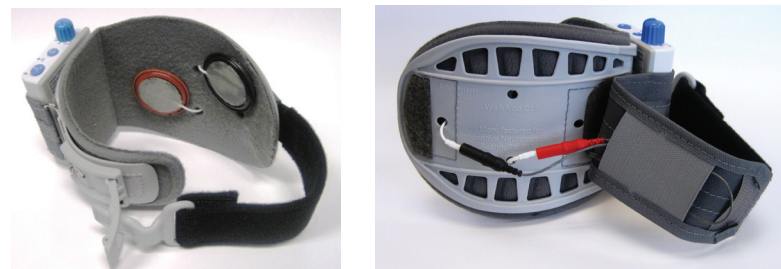


Figure 8:
Changing the battery

4.6 Changing the Electrodes

For proper skincare and maximum 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 and feed the leads through the holes toward the outside of the cuff. The BLACK lead is connected to the Electrode Locators. The RED lead is connected to the electrode on the Red Electrode Locator. Feed the excess wires in the strap pouch as indicated in the image below.



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

Connect the leads from the electrodes to the WalkAide Electrode Lead Cable (Figure 10).

- 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 periodically, this unit 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 detergent or may be used to wipe the outside of the WalkAide unit. DO NOT use a strong cleaning solution that contains bleach or immerse the WalkAide unit in water.

● Storing the WalkAide

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

● Washing the WalkAide Cuff

Remove the electrodes and the WalkAide unit 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 properly, in accordance with all local and national regulations.

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. If the green light is still not blinking, discontinue use of the WalkAide and contact the clinician.

2. Why is the green light blinking while the red light is on?

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, discontinue use of the WalkAide and contact the clinician.

3. What if the foot does not lift as far as it should?

The amber light should be blinking during stimulation to indicate that a stimulus is being delivered through the electrodes. Adjust the intensity level or replace or re-wet the electrodes. If the foot lift is still insufficient then discontinue use and schedule an appointment with the clinician.

4. Why doesn't the stimulation come on at the appropriate time?

This generally indicates the cuff may have shifted or a change in the walking pattern. Discontinue use and schedule an appointment with the clinician so that appropriate adjustments can be made to the WalkAide.

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 backings after removing the WalkAide and before placing in the resealable plastic bag.

9. What indicates that the WalkAide is on?

A green blinking light positioned near the Intensity Knob indicates that the power is on with adequate battery power.

10. Under what circumstances 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 to Enhance the Break-In Period

- Remove the WalkAide system every 2 hours to check skin integrity.
- Slowly work into full-time wearing of the WalkAide system.
- Remove the cuff at regular intervals and inspect the skin under the electrodes. These areas will be pink due to increased blood flow under the electrodes.
- **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.
 - If soreness or irritation occurs in the area under the electrodes, reduce the wearing time and contact your WalkAide clinician.
- Wet the electrodes with plenty of 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 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, Inc. • Austin, TX • 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—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	<ul style="list-style-type: none">ON/OFF/Intensity; Stimulation, ExerciseError
Shipping and Storage Conditions:	<div>Device (Long Term) Temperature: -4° – 140°F (-20° – +60° C) Relative Humidity: 95% max., non-condensing</div> <div>Electrodes (Long Term) Temperature: 41° – 80.6°F (5° – 27° C) Humidity: 35 – 50%</div> <div>Electrodes (Short Term - less than 1 month) Temperature: 32° – 104° F (0° – 40° C) Humidity: 35 – 50%</div>

Do not hesitate to contact your clinician should you have any questions regarding this device and its safe operation and use.

If further assistance is required, please contact:
Innovative Neurotronics, Inc.
Austin, TX
888-884-6462 • www.walkaide.com