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**Rx Only (U.S. Only)**

612-00061-001 Rev D

01/2013



# NESS L300<sup>®</sup>

User's Guide

**NESS**  
**L300<sup>®</sup>**



# **User's Guide**

**User's Guide Copyright**

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**Patents Pending**

Aspects of this device are covered by several patents and patent applications including US Pat 7,899,556.

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**Environmental Policy**

Service personnel are advised that when changing any part of the NESS L300, care should be taken to dispose of those parts in the correct manner; where applicable, parts should be recycled. For more detailed information regarding these recommended procedures, please contact Bioness Inc. Bioness Inc is committed to continuously seeking and implementing the best possible manufacturing procedures and servicing routines.

**Conformity Certification**

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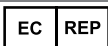







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## List of Symbols

	Caution
	Complies with United States and Canadian Product Safety Standards
	Complies with the European Union Medical Device Directive
<b>SN</b>	Serial Number
	Double Insulated (Equivalent to Class II of IEC 536)
	Type BF Applied Part(s)
	Non-Ionizing Radiation
	European Authorized Representative
	Date of Manufacture
	Manufacturer
	This Product Must not be Disposed of with Other Household Waste
	Consult Instructions for Use
	Re-Order Number
	Lot Number
	Certification of Radio Products for the Japanese Market

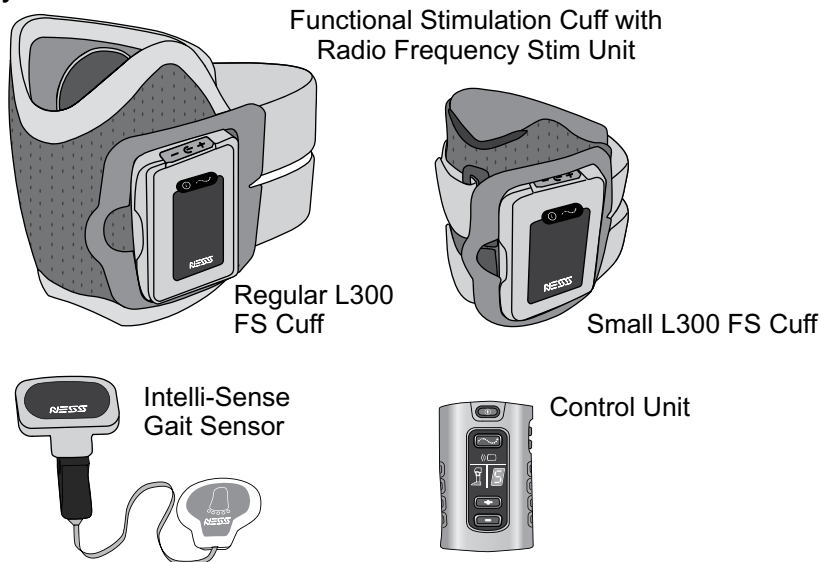




# Introduction

Central nervous system injuries often cause a gait disorder called foot drop. People who have foot drop are unable to raise their foot while walking. They often drag their foot, resulting in instability and increased effort during gait.

The NESS L300 Foot Drop System is an advanced neuroprosthesis designed to improve gait in people suffering from foot drop. The NESS L300 incorporates cutting-edge technology and sophisticated design features to improve walking and quality of life.



The NESS L300 consists of a Functional Stimulation (FS) Cuff (available in regular and small sizes) with a Radio Frequency (RF) Stim Unit, an Intelli-Sense Gait Sensor, and a Control Unit. These components communicate wirelessly to send electrical pulses to the peroneal nerve, which controls the muscles of the lower leg. When stimulated at the appropriate phase of walking, the muscles raise the foot, thereby preventing foot drop.

**System Features:**

- The FS Cuff includes a cradle for the RF Stim Unit and an advanced ergonomic locator to ensure constant, snug contact with the leg. The FS Cuff can be put on with one hand.
- The Intelli-Sense Gait Sensor can detect when the foot is in the air and on the ground and regulate stimulation appropriately.
- The wireless hand-held Control Unit monitors system status and manages system performance.

Your clinician has prescribed the NESS L300 Foot Drop System to treat your foot drop. This User's Guide describes your NESS L300 Foot Drop System and how to operate your system to achieve maximum benefits. Be sure to read this guide before using your NESS L300. If you have any questions, consult your clinician or your local distributor immediately.

# Health and Safety Information

## Indications for Use

The NESS L300 Foot Drop System is intended to provide ankle dorsiflexion in individuals (adults and pediatrics) who have foot drop following an upper motor neuron injury or disease. During the swing phase of gait, the NESS L300 electrically stimulates muscles in the affected leg to provide dorsiflexion of the foot. The NESS L300 may improve gait, facilitate muscle re-education, prevent or retard disuse atrophy, maintain or increase joint range of motion, and increase local blood flow.

## Contraindications

- Patients with a demand-type cardiac pacemaker, defibrillator, or any electrical or metallic implant should not use the NESS L300.
- The NESS L300 should not be used where a cancerous lesion is present or suspected.
- The NESS L300 should not be used on a leg where a regional disorder, such as a fracture or dislocation, could be adversely affected by motion from the stimulation.
- The NESS L300 should not be used on a leg where strength testing or strength training is planned.

## Warnings

- The long-term effects of chronic electrical stimulation are unknown.
- The FS Cuff should not be worn over swollen, infected, or inflamed areas or skin eruptions, such as phlebitis, thrombophlebitis, and varicose veins.

- Simultaneous connection of the NESS L300 to the patient and high-frequency surgical equipment may result in skin burns where the stimulator electrodes adhere and damage to the RF Stim Unit.
- Do not use the NESS L300 within three feet of short wave or microwave therapy equipment. Such equipment may produce instability in the RF Stim Unit output.
- The NESS L300 should only be configured by an authorized clinician.

## **Precautions**

- Inflammation in the region of the NESS L300 FS Cuff may be aggravated by motion, muscle activity, or pressure from the FS Cuff. Stop using the NESS L300 until the inflammation is gone.
- Use caution if you have a suspected or diagnosed heart problem.
- Use the FS Cuff with caution:
  - If you have a tendency to hemorrhage following acute trauma or fracture.
  - Following recent surgical procedures when muscle contraction may disrupt the healing process.
  - Over areas of the skin that lack normal sensation.
  - If you have suspected or diagnosed epilepsy.
- Some patients may experience a skin irritation, an allergic reaction, or hypersensitivity to the electrical stimulation or the electrical conductive medium. Irritation may be avoided by having your clinician change the stimulation parameters, type of electrodes, or electrode placement.
- Do not use the NESS L300 without electrodes.
- After removing the FS Cuff, it is normal for the areas under the electrodes to be red and indented. The redness should disappear in approximately

one hour. Persistent redness, lesions, or blisters are signs of irritation. Alert your clinician and stop using the NESS L300 until any inflammation is gone.

- Stop using the NESS L300 and consult your clinician if stimulation does not start at the correct time during gait.
- Do not wear the NESS L300 during x-ray examinations.
- Turn off the NESS L300 when at a refueling place. Do not use the NESS L300 near flammable fuel, fumes, or chemicals.
- Only your treating clinician should determine electrode placement and stimulation settings.
- Use only NESS L300 electrodes supplied by Bioness Inc.
- Obtain physician clearance prior to use if you have an alteration in normal arterial or venous flow in the region of the FS Cuff because of local insufficiency, occlusion, arteriovenous fistula for hemodialysis, or a primary disorder of the vasculature.
- Obtain physician clearance before stimulating an area with a structural deformity.
- The safe use of the NESS L300 during pregnancy has not been established.
- Skin problems where the FS Cuff is worn may be aggravated by the NESS L300.
- Turn off the NESS L300 before removing or replacing the electrodes.
- Adult supervision and assistance should be provided for anyone needing help while using the NESS L300 system.
- Protect all electronic components from contact with water, such as from sinks, bathtubs, shower stalls, rain, snow, etc.
- Do not leave the NESS L300 stored where temperatures may exceed the acceptable environmental range: -20°C to +60°C (-4°F to +140°F). Temperature extremes can damage the components.

- Do not attempt to repair your NESS L300. Contact Bioness if you experience a technical problem not covered in this guide.
- The FS Cuff is to be worn only on the leg of the patient for whom it is fitted. It should not be worn by anyone else or on any other part of the body.
- Turn off the NESS L300 before putting on the FS Cuff. Do not turn on the NESS L300 until the FS Cuff is fastened in place.
- Shut off the NESS L300 before driving, operating machinery, or performing any activity in which involuntary muscle contractions could injure you.
- Protect the NESS L300 electronic components from condensation. When moving the components between hot and cold temperatures, place them in an airtight plastic bag, and let them slowly (for at least two hours) adjust to the temperature change before use.
- Medical electrical equipment needs special precautions for electromagnetic compatibility.

## **Adverse Reactions**

In the unlikely event that any of the following occurs, stop using your NESS L300 immediately and consult your physician.

- Signs of significant irritation or pressure sores where the FS Cuff contacts the skin.
- A significant increase in muscle spasticity.
- A feeling of heart-related stress during stimulation.
- Swelling of the leg, knee, ankle, or foot.
- Any other unanticipated reaction.

Skin irritations and burns have been reported with the use of powered muscle stimulators.

## **Skin Care Guidelines**

In the absence of proper skin care, extended use of electrical stimulation may cause skin irritation or a skin reaction to the electrodes or the FS Cuff. Skin irritation tends to occur after approximately three months of use. To promote healthy skin with long-term use of the NESS L300, it is important to follow a daily skin-care routine.

- Clean the skin where the electrodes adhere with a wet washcloth. If any oils or lotions are on the skin, then clean with soap and water. Rinse well.
- Always check the skin for redness or a rash when putting on and taking off the FS Cuff.
- Replace the electrodes at least every two weeks, even if they appear to be in good condition.
- After taking off the FS Cuff, always re-cover hydrogel electrodes with the protective plastic covers, where applicable.
- Excess body hair where the electrodes adhere may reduce electrode contact with the skin. If necessary, remove excess body hair with an electric shaver or scissors. Do not use a razor. A razor can irritate the skin.
- When positioning the FS Cuff, make sure the electrodes uniformly contact the skin.
- Ventilate the skin by removing the FS Cuff for at least 15 minutes every three to four hours.

If skin irritation or a skin reaction occurs, stop using your NESS L300 immediately. Contact your clinician, dermatologist, or Bioness Clinical Specialist. Resume use only when the skin is completely healed, and then follow a skin conditioning protocol per the recommendation of your health-care specialist.



**Caution: Do not put on or operate the NESS L300 before being properly fitted and trained by a certified clinician.**



**Caution: The Intelli-Sense Gait Sensor has not been validated for use by individuals weighing more than 136 kilograms (300 pounds).**



**Caution: Do not use the Intelli-Sense Gait Sensor with a rigid insole, such as a custom rigid orthosis or an ankle foot orthosis.**



**Caution: Use only NESS L300 electrodes supplied by Bioness Inc. Do not use the NESS L300 without electrodes.**



**Caution: Change the electrodes every two weeks.**



**Caution: Changes or modifications to the NESS L300 not expressly approved by Bioness Inc could void the user's authority to operate the equipment.**



**Caution: Use only the charger included in your NESS L300 System Kit. Use of any other charger could damage the system.**



**Caution: The control unit neck strap is meant to be worn around the neck and if not used properly could cause bodily harm.**

**If you have any questions or concerns, please contact your local distributor.**



# Environmental Conditions that Affect Use

## Radio Frequency (RF) Communication

Several components of the NESS L300 communicate via radio communication and have been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 (RF Devices) of the FCC (Federal Communications Commission) Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate RF energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.

Consult the dealer or an experienced radio/TV technician for assistance.

The antenna for each transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Portable and mobile RF communications equipment can affect the NESS L300 System.

## Conformity Certification

**The NESS L300 System 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.

## Travel

The NESS L300 System charger set with interchangeable blades is compatible with both European and U.S. voltage: 110/220 V, 50/60 Hz.

Turn off your L300 system before going through airport security. Wear loose clothing so that you can easily show the security person your NESS L300. The NESS L300 will likely set off the security alarm. Either ask for a “hand scan” or be prepared to remove your NESS L300 so that security can scan it. You may want to carry a copy of your NESS L300 prescription. A prescription can be useful when passing through customs as well.

**Note:** The NESS L300 contains radio transmitters. The Federal Aviation Administration (FAA) rules require that all radio-transmitting devices be turned off during flight.

## Electromagnetic Emissions

The NESS L300 System needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this manual.

### **The NESS L300 System was tested and certified to use the following:**

- DC power supply as provided by Bioness Inc, manufactured by Friwo, Part No. FW7555M/05.
- "Y" cable (2-way splitter) as provided by Bioness Inc. Manufactured by Tamuz Electronics Ltd.

## Warnings

- The use of accessories, transducers, and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the NESS L300 System as replacement parts for internal components, may result in increased emissions or decreased immunity of the NESS L300 System.
- The NESS L300 System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.
- The use of the accessory, transducer, or cable with equipment and systems other than those specified may result in increased emissions or decreased immunity of the NESS L300 System.

- The NESS L300 System may be interfered with by other equipment, even if that other equipment complies with CISPR (International Special Committee on Radio Interference, International Electrotechnical Commission (IEC)) emission requirements.

## **NESS L300 System Kit**

**Your Small NESS L300 System Kit includes the following:**

- Small L300 FS Cuff, Right or Left, with (XS) Strap
- L300 RF Stim Unit
- Intelli-Sense Gait Sensor
- Control Unit
- System Charger Set
- Small L300 FS Cuff Strap (XXS)
- Gait Sensor Pads
- Shoe Spacers
- Gait Sensor Replacement Battery
- Small Electrode Bases
- Cloth Electrode Mesh Bag
- Control Unit Neck Strap
- Control Unit Wrist Strap
- Control Unit Belt Pouch
- Phillips Screwdriver
- User's Guide
- User's Reference Card

**Your Regular NESS L300 System Kit includes the following:**

- Regular L300 FS Cuff, Right or Left, with (M) Strap
- L300 RF Stim Unit
- Intelli-Sense Gait Sensor
- Control Unit
- System Charger Set
- Regular L300 FS Cuff Strap (S)
- Regular L300 FS Cuff Strap (L)
- Gait Sensor Pads
- Shoe Spacers
- Gait Sensor Replacement Battery
- Cloth Electrode Mesh Bag
- Control Unit Neck Strap
- Control Unit Wrist Strap
- Control Unit Belt Pouch
- Phillips Screwdriver
- User's Guide
- User's Reference Card



Regular L300 FS Cuff  
and RF Stim Unit



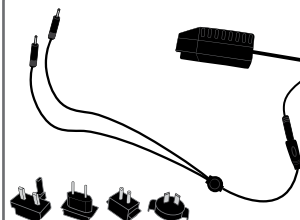
Small L300 FS Cuff  
and RF Stim Unit



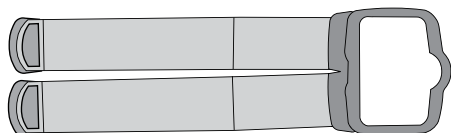
Intelli-Sense Gait Sensor



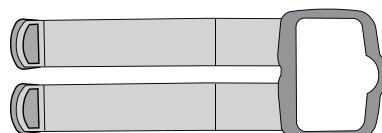
Control Unit



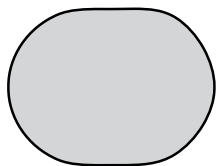
System Charger Set



Regular FS Cuff Strap  
(S, M, L)



Small FS Cuff Strap  
(XXS, XS)



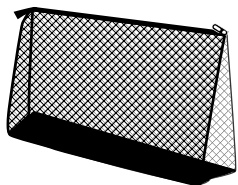
Gait Sensor Pads



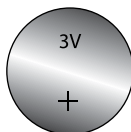
Shoe Spacers



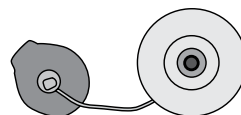
Phillips Screwdriver



Cloth Electrode Mesh Bag



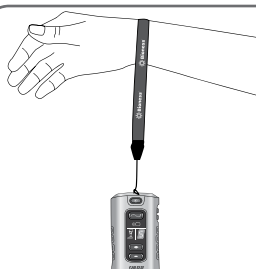
Gait Sensor  
Replacement Battery



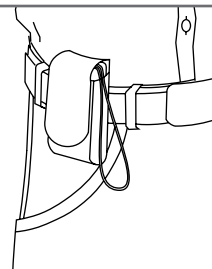
Small Electrode Bases  
(only in the Small NESS  
L300 System Kit)



Control Unit Neck Strap



Control Unit Wrist Strap



Control Unit Belt Pouch



# NESS L300 System Components

## Functional Stimulation (FS) Cuff

Your L300 FS Cuff (see figure 5-1) is lightweight and easily fits under most clothing. It features a cradle for the RF Stim Unit and an anatomically designed locator for accurate placement on your leg. It also features a strap that can be fastened with one hand.

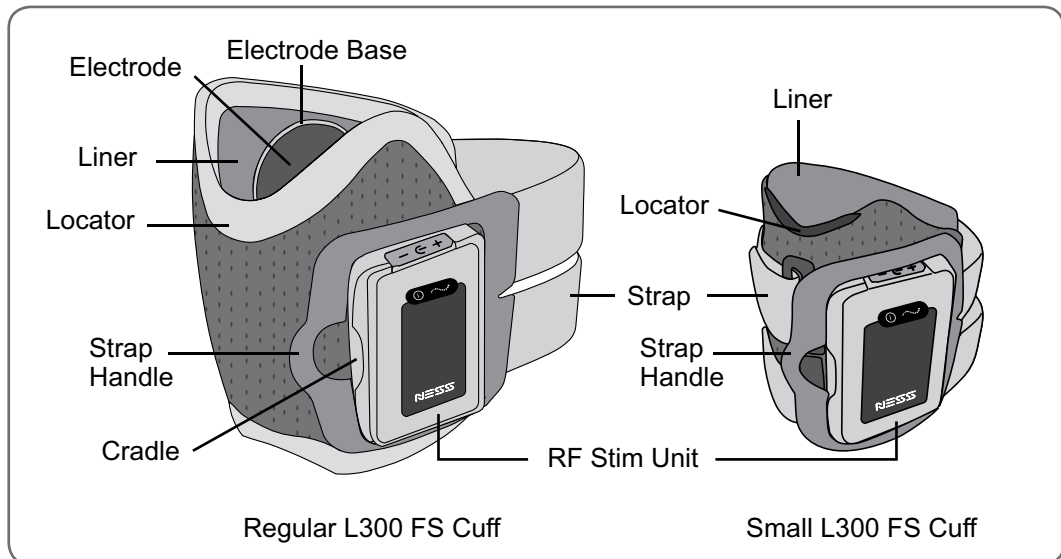


Figure 5-1: Regular L300 FS Cuff and Small L300 FS Cuff.

## Electrodes and Electrode Bases

There are three types of electrodes that can be used with the L300 FS Cuff to deliver stimulation.

With a Small NESS L300 System the following electrodes and electrode bases can be used (See Figure 5-2):

- Small L300 Quick Fit Electrode - Size A or B (as fitted by your clinician)
- Small L300 Cloth Electrodes
- Small L300 Electrode Bases (used with the Small L300 Cloth Electrodes)

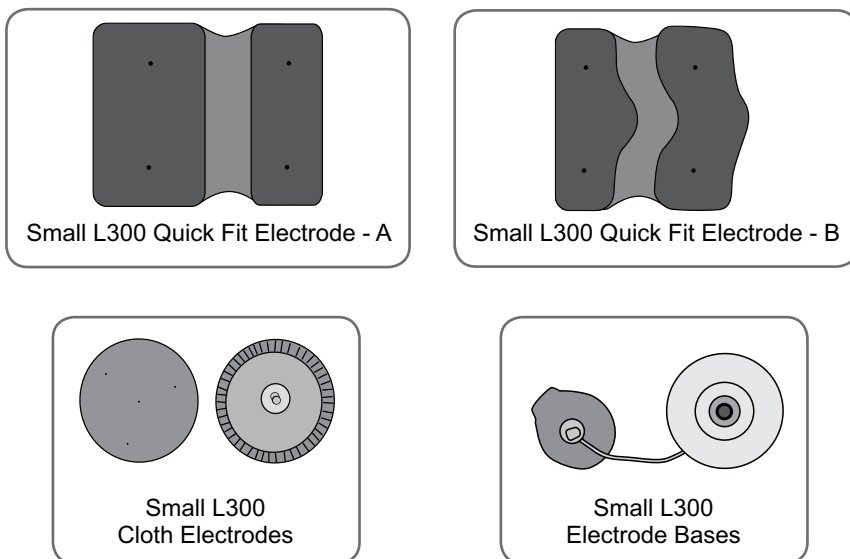


Figure 5-2: Electrodes and Bases for the Small L300 FS Cuff.

With a Regular NESS L300 System the following electrodes and electrode bases can be used (See Figure 5-3):

- Regular L300 Quick Fit Electrode, left - A or right - A
- Regular L300 Cloth Electrodes
- Regular L300 Cloth Electrode Bases
- Regular L300 Hydrogel Electrodes
- Regular L300 Hydrogel Electrode Bases

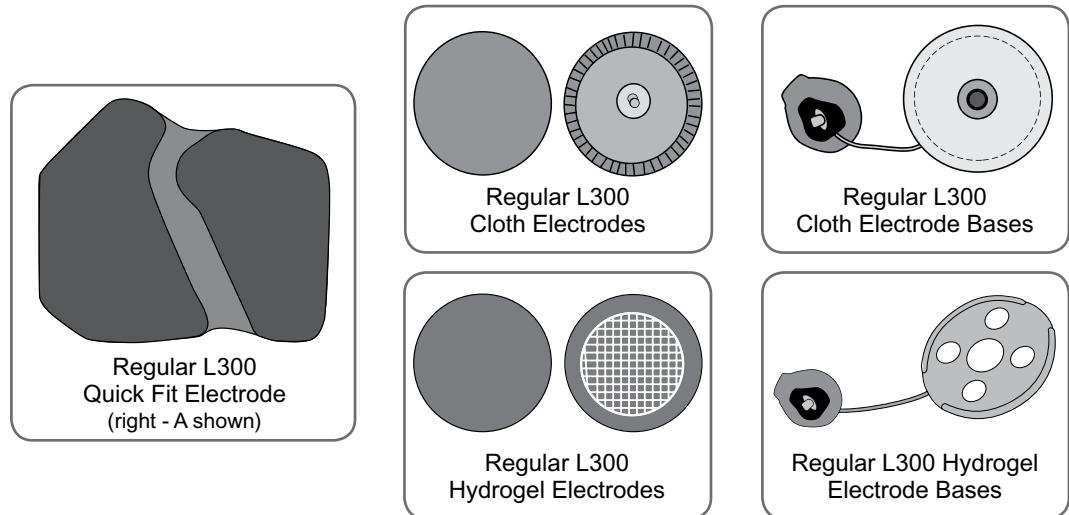


Figure 5-3: Electrodes and Bases for the Regular L300 FS Cuff.

Your clinician will fit you with the appropriate electrode option and attach them to your L300 FS Cuff. Afterward, you will need to replace the electrodes every two weeks.

## RF Stim Unit

The RF Stim Unit fits into the cradle of the L300 FS Cuff. See Figure 5-1. It responds to signals from the Control Unit and Intelli-Sense Gait Sensor to turn stimulation on/off. It has a rechargeable battery, a status light, and a stimulation light. See Table 5-1. The RF Stim Unit emits an audio alert when radio communication fails or the component malfunctions. Remove the RF Stim Unit when cleaning the FS Cuff and for maintenance.



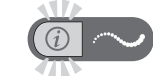




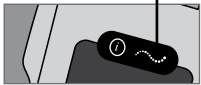


RF Stim Unit	Display	Description	Definition
<b>Status Light</b> 		Flashes GREEN	System is On
		Flashes YELLOW	Low Battery
		Alternately Flashes YELLOW and GREEN	Battery Charging
		Solid GREEN	Battery Fully Charged
		Flashes RED	Radio Communication Failure
		Solid RED	RF Stim Unit Malfunction
<b>Stimulation Light</b> 		Flashes YELLOW SLOWLY	Stimulation is Off
		Flashes YELLOW RAPIDLY	Stimulation is On

Table 5-1: RF Stim Unit displays and definitions.

## Intelli-Sense Gait Sensor

The Intelli-Sense Gait Sensor detects when your foot is in the air and on the ground, and wirelessly signals the other NESS L300 components to move your foot accordingly. The Intelli-Sense Gait Sensor features a pressure sensor and a transmitter. The pressure sensor fits under the insole of the shoe of your weak foot, attached to a Gait Sensor pad. See Figure 5-4. The transmitter is worn clamped to the inner rim of your shoe. (Shoe spacers are provided to protect the shoe from damage from the clamp.) The Intelli-Sense Gait Sensor can be transferred to a different shoe, or additional sensors can be purchased for different shoes. You do not need to detach the Intelli-Sense Gait Sensor between uses.

The Intelli-Sense Gait Sensor is powered by a small non-rechargeable battery. The battery will need to be replaced after approximately six months of use. A Phillips screwdriver is provided for changing the battery.



**Caution: The Gait Sensor has not been validated for use by individuals weighing more than 136 kilograms (300 pounds).**

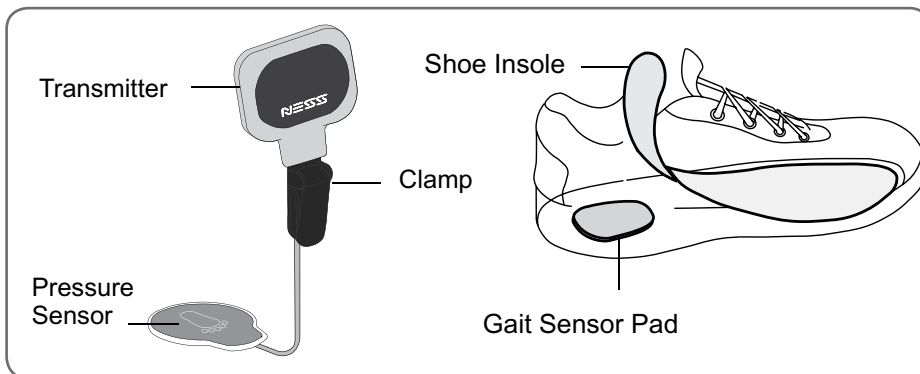


Figure 5-4: Intelli-Sense Gait Sensor.

## Control Unit

The Control Unit is used to turn on/off the system, select an operating mode (gait, training, standby, or clinician), fine-tune stimulation intensity, adjust audio alert volume, and monitor system performance. See Figure 5-5. The Control Unit communicates wirelessly with the RF Stim Unit and Intelli-Sense Gait Sensor. It is powered by a single rechargeable AAA battery.

Your NESS L300 System Kit includes a system charger set for charging the Control Unit and RF Stim Unit. It also includes a belt pouch, wrist strap, and neck strap for carrying the Control Unit. A Phillips screwdriver is provided for changing the Control Unit battery.

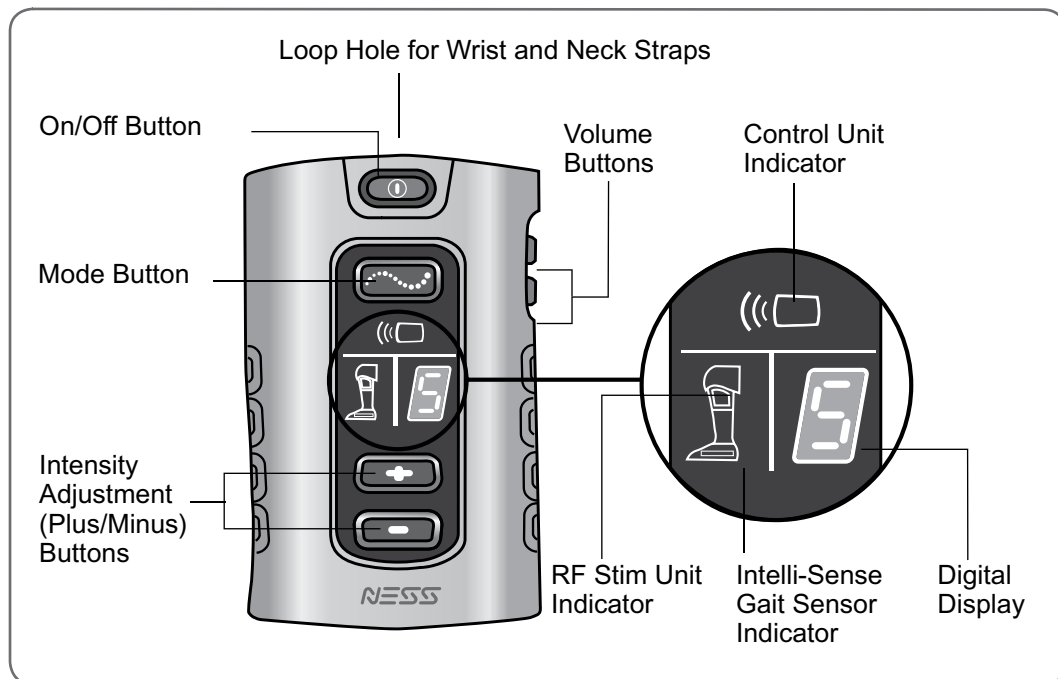


Figure 5-5: Control Unit operating buttons, indicators, and digital display.

## Control Unit Operating Buttons

The Control Unit operating buttons and their functions are described in Table 5-2.






Control Unit	Operating Button	Description	Function
		On/Off	Turns On/Off the Control Unit
		Mode	Selects Standby, Gait, Training, or Clinician Mode
		Volume	Adjusts Volume of Audio Alerts and Turns On/Off Audio Feedback for Stimulation
		Intensity Adjustment (Plus/Minus)	Adjusts Stimulation Intensity Level

Table 5-2: Control Unit operating buttons and functions.

## ***Control Unit Operating Modes***

The Control Unit has four operating modes: standby, gait, training, and clinician. Only clinicians use clinician mode.

### **Standby Mode**

In standby mode, the NESS L300 System is on and waiting for commands. Stimulation is off.

### **Gait Mode**

Gait mode is used when walking. In gait mode, the Gait Sensor signals the RF Stim Unit when your heel or forefoot leaves the ground, turning stimulation on. It also signals when your heel or forefoot contacts the ground, turning stimulation off.

### **Training Mode**

Training mode is used to train muscles when you are not walking (for example, sitting or lying down). Training mode should not be used when walking. Training mode works independently of the Intelli-Sense Gait Sensor. Stimulation is delivered in cycles pre-set by your clinician. Training mode is designed to facilitate muscle re-education, prevent or retard disuse atrophy of the lower leg muscles, maintain or improve range of motion of the ankle joint, and improve local blood circulation. Training mode also can be used to check if the FS Cuff is positioned properly. If your foot does not respond to the stimulation as it should, reposition the FS Cuff.

## ***Control Unit Digital Display and Indicator Lights***

The Control Unit digital display and indicator lights indicate stimulation intensity level, operating mode, battery charge status, electronic registration status, and error messages. See tables 5-3 and 5-4.












Control Unit	Display	Description	Definition
		On/Off Button Flashes GREEN	System is On
		Mode Button Flashes YELLOW SLOWLY	System is in Gait/ Training/Clinician Mode, Stimulation is Off
		Mode Button Flashes YELLOW RAPIDLY	System is in Gait/ Training/Clinician Mode, Stimulation is On
		Displays 0–9	Intensity Level
		Intensity Level and “t” Alternate in the Digital Display	Training Mode
		A Component Indicator Flashes YELLOW	Component Low Battery
		Rotating GREEN Circle	Control Unit Charging
		Horizontal GREEN Line	Control Unit Fully Charged

Table 5-3: Control Unit visual displays and definitions.






Control Unit	Display	Description	Definition
		RF Stim Unit Indicator Flashes RED and Intensity Level Flashes	Faulty Electrode Contact
		Control Unit and RF Stim Unit Indicators Alternately Flash RED and “E” Flashes	Radio Communication Failure Between the Control Unit and RF Stim Unit
		Gait Sensor and RF Stim Unit Indicators Alternately Flash RED and “E” Flashes	Gait Sensor Hibernation or Radio Communication Failure between the Gait Sensor and RF Stim Unit
		A Component Indicator is Solid RED and “E” Appears	Component Malfunction

Table 5-4: Control Unit error displays and definitions.

## ***Control Unit Audio Indicators***

**The Control Unit beeps to indicate:**

- The system is on.
- A button was pressed.
- Low battery.
- An error (usually accompanied by a visual indicator).

# Setting Up the NESS L300 System

## Positioning the L300 FS Cuff

**To position the L300 FS Cuff:**

1. Clean the skin where the electrodes will touch with a wet washcloth. If any oils or lotions are on the skin, clean the skin with soap and water. Rinse well.
2. If necessary, trim excess body hair from the area using scissors. Do not use a razor. A razor can irritate the skin.
3. While seated, slightly straighten your leg as shown in Figure 6-1. The outline of your kneecap should be clearly defined. (Place your foot on a footrest, if necessary.)

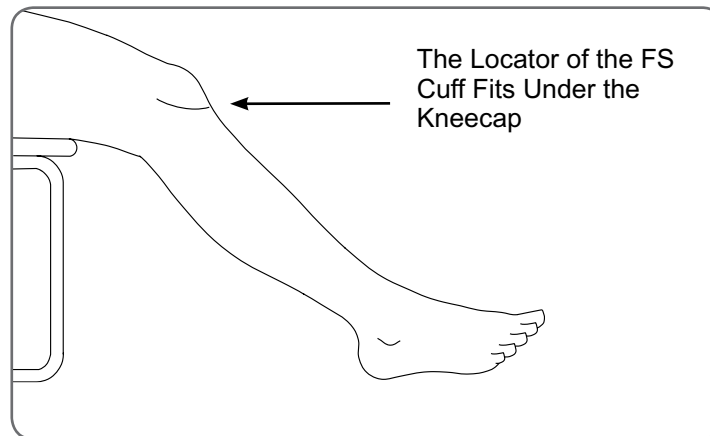


Figure 6-1: Recommended knee angle for positioning the L300 FS Cuff.

4. Make sure the electrodes are securely attached. Then, grasp the front of the L300 FS Cuff by the cradle and tilt the bottom of the FS Cuff up. Slide the locator up your leg until it rests snugly and comfortably below your kneecap. See Figure 6-2.

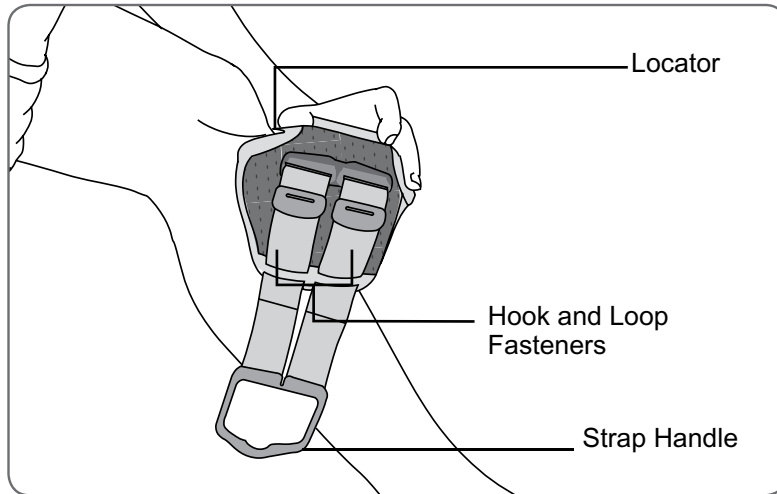


Figure 6-2: Tilting the L300 FS Cuff for placement on your leg.

5. Hold the locator in place and lower the L300 FS Cuff until it rests flush against your leg.
6. Grasp the handle of the L300 FS Cuff strap. See Figure 6-3. With your thumb on the FS Cuff cradle, fasten the strap handle around the cradle. With the Small L300 FS Cuff you may need to use your other hand to stabilize the cuff on the leg.
7. Make sure the L300 FS Cuff is correctly positioned. See Figure 6-4. If it is not, take off the FS Cuff and reposition it. Adjust the hook and loop fasteners (see Figure 6-2) to ensure a snug fit.

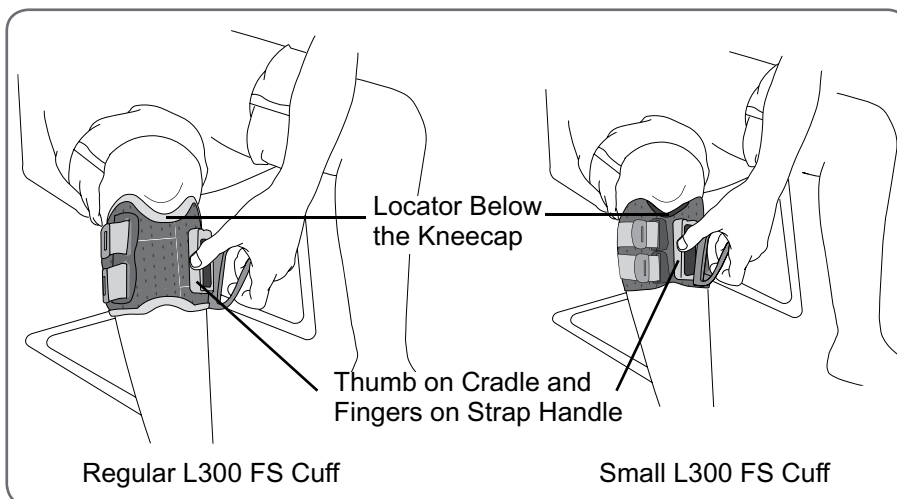


Figure 6-3: Fastening the L300 FS Cuff strap.

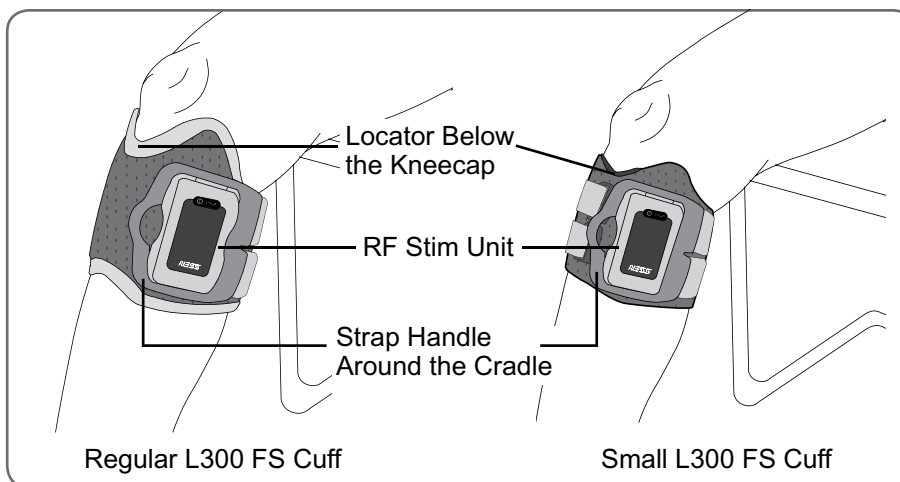


Figure 6-4: L300 FS Cuff fastened on the right leg.

## Removing the L300 FS Cuff

**To remove the L300 FS Cuff:**

1. Turn off the Control Unit.
2. Unhook the L300 FS Cuff strap handle from the cradle.
3. Slowly lift the L300 FS Cuff away from your skin.
4. If using hydrogel electrodes (Regular L300 FS Cuff users only) gently peel the electrodes from your skin, and reapply the electrode covers to the electrodes.
5. Fully charge the Control Unit and RF Stim Unit batteries.

**Note:** Remove the L300 FS Cuff several times daily, to allow the skin below the FS Cuff to breathe.



**Caution: Change the electrodes every two weeks.**

## Positioning the Intelli-Sense Gait Sensor

The Intelli-Sense Gait Sensor pressure sensor is placed under the insole of your shoe. If your shoe does not have a detachable insole, place the sensor on top of the insole. Then, place a generic soft, thin (one layer versus two) insole over it. Generic insoles can be purchased from drugstores, shoe stores, or Bioness.



**Caution: Do not use the Gait Sensor with a rigid insole, such as a custom rigid orthosis or an ankle foot orthosis.**

### To position the Intelli-Sense Gait Sensor:

1. Lift the shoe insole.
2. Attach a Gait Sensor pad under the insole, in the position that was defined by your clinician. See Figure 6-5.

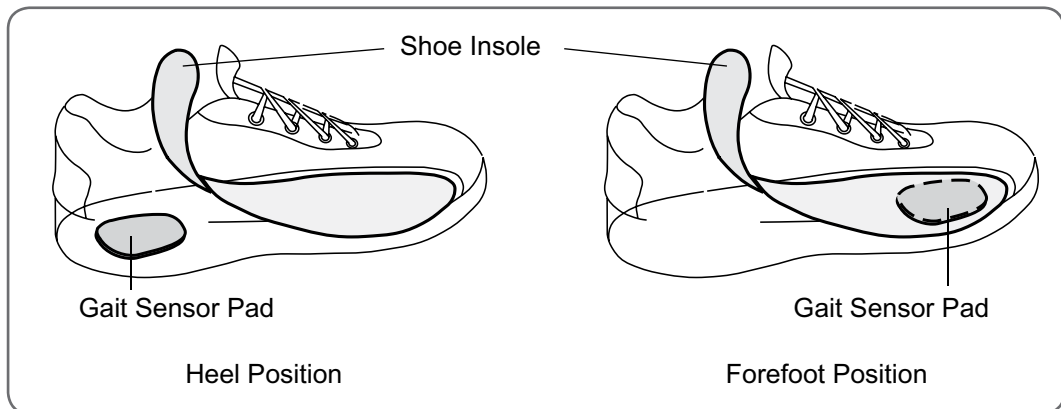


Figure 6-5: Placement of the Gait Sensor pad.

3. For heel position placement point the wire of the Intelli-Sense Gait Sensor toward the toe of the shoe. For forefoot position placement point the wire of the Intelli-Sense Gait Sensor toward the heel of the shoe. Then, attach the pressure sensor to the Gait Sensor pad. See Figure 6-6. Refer to the foot image on the pressure sensor for positioning.

**Note:** The image of the foot on the gait sensor pad will be reverse when in the forefoot position.

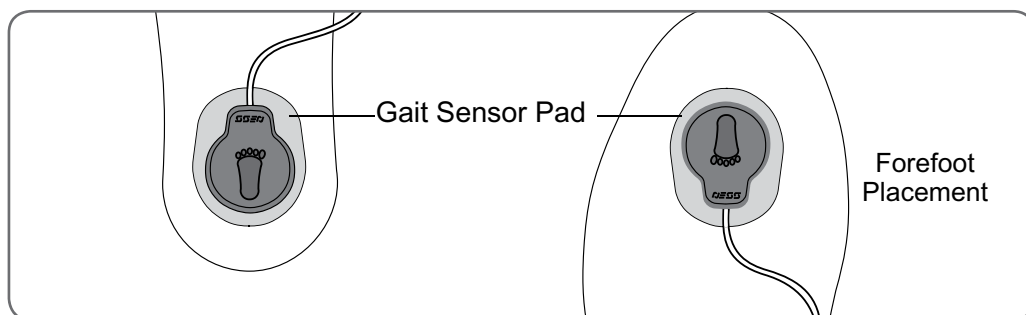


Figure 6-6: Positioning the Gait Sensor in the shoe.

4. Cover the clamp on the transmitter with the shoe spacer, if desired. See Figure 6-7. The teeth of the clamp may scuff the shoe, if not covered.

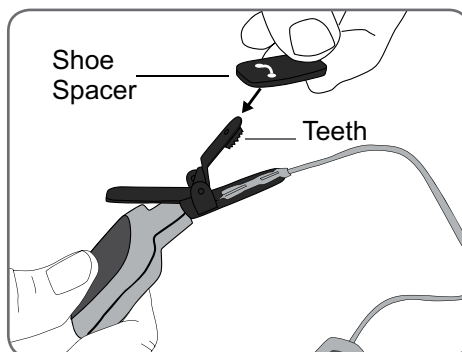


Figure 6-7: Covering the clamp with the shoe spacer.



5. Clamp the Gait Sensor transmitter on to the inner rim of the shoe. Face the NESS logo on the transmitter away from the ankle. See Figure 6-8.

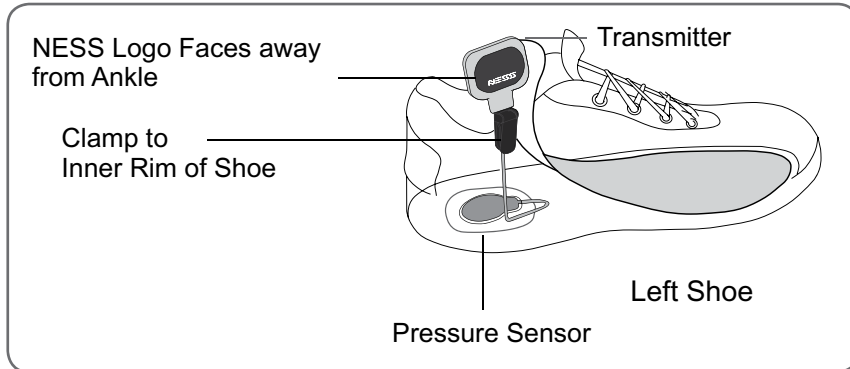


Figure 6-8: Clamping the transmitter to the inner rim of the shoe. (Gait sensor in the heel position in a left shoe shown.)

6. Cover the pressure sensor with the insole. Tuck any excess wire under the insole. See Figure 6-9.

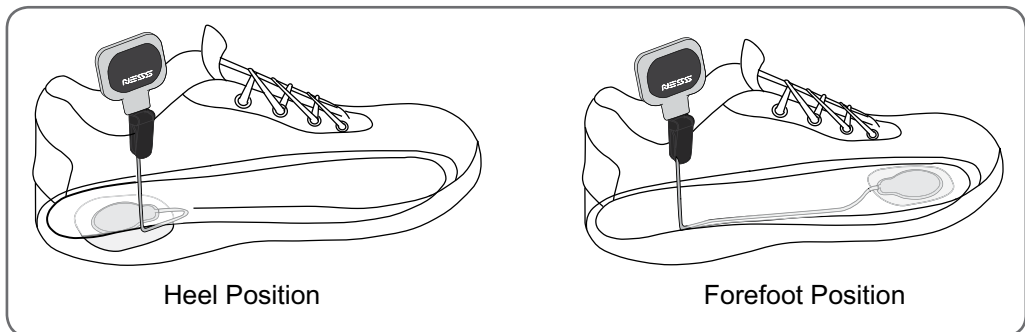


Figure 6-9: Insole covering the pressure sensor and wire. (Left shoe shown.)

## ***Switching Shoes/Gait Sensors***

When switching the Intelli-Sense Gait Sensor to a different shoe, make sure to place a Gait Sensor pad in the other shoe first.

**If multiple Gait Sensors are placed in multiple shoes and you want to switch shoes:**

1. Turn off the system.
2. Switch shoes.
3. Turn the system back on.

# Operating the NESS L300 System

## RF Communication Safety Features



The Control Unit, RF Stim Unit, and Intelli-Sense Gait Sensor must be within RF communication range of each other and their batteries charged for the NESS L300 System to operate. If the components become separated, or if a battery is discharged, RF communication will be lost and the system will stop working until RF communication is restored.

### If RF communication fails:

- The Control Unit and RF Stim Unit indicators will flash RED and “E” will flash in the digital display.
- The Control Unit will emit an audio alert.
- The NESS L300 will deliver a warning **default stimulation** to lift the foot for six seconds before shutting down.




## Operating the Control Unit





### *Turning On/Off the Control Unit*



To turn on the Control Unit, press the  on/off button once. The system will start in standby mode. All display indicators will light up for a few seconds while the system performs a self-test. The  on/off button will flash GREEN to indicate the system is on.

To turn off the Control Unit, press the  on/off button once.

## Selecting an Operating Mode



**Gait Mode.** To select gait mode, turn on the Control Unit, and press the  mode button *briefly*. The Control Unit will beep and the  mode button will start flashing YELLOW SLOWLY (indicating that stimulation is off). When stimulation is on, the  mode button will flash YELLOW RAPIDLY.

**Training Mode.** To select training mode, turn on the Control Unit. Press and *hold* the  mode button until the Control Unit beeps, the  mode button starts flashing YELLOW SLOWLY (indicating that stimulation is off), and  ("t" for training) alternates with the intensity level in the digital display. When stimulation is on, the  mode button will flash YELLOW RAPIDLY.

**Standby Mode.** To return to standby mode from gait or training mode, press the  flashing mode button briefly. The Control Unit will beep, and the  mode button will stop flashing.

## ***Adjusting Stimulation Intensity***

When the Control Unit is first turned on, the stimulation intensity level will be “5”. This level is set by your clinician. Normally, you will not need to adjust stimulation intensity other than when walking on different surfaces or in different shoes.


To adjust stimulation intensity, press the  plus or  minus intensity adjustment button on the Control Unit. The Control Unit will beep with each change in level. The new level will show in the digital display.

**Note:** An intensity level of “0” equals no stimulation.

If your foot slightly drags or catches on the floor while walking, increase stimulation intensity to lift the foot higher.

If your foot rises too high while walking or if stimulation is unpleasant, decrease stimulation intensity. Be sure your foot does not drag or catch on the floor after decreasing the intensity level.

## ***Adjusting the Volume of Audio Alerts***


Use the  volume buttons to adjust the volume of the audio alerts.

Each time one of the buttons is pressed, the volume level will change. The Control Unit will beep to demonstrate the new volume.

To mute the audio alerts, lower the volume to the lowest setting.

When the system is turned off, the active volume level is saved. If the active volume level is “mute”, the default volume level is automatically restored.

## ***Turning On Audio Feedback During Stimulation***

You can choose to receive an audio alert when stimulation turns on. To turn on Audio Feedback, turn on the Control Unit and press and hold the  up volume button for three seconds.

To turn off Audio Feedback, press the  down volume adjust button or turn off the Control Unit.

# Maintenance and Cleaning

## Charging the Batteries

When a system component has a low battery, the Control Unit will beep and the component indicator light will flash YELLOW. See Table 8-1.

When the RF Stim Unit battery is low, the RF Stim Unit status light will also flash YELLOW.

When the Intelli-Sense Gait Sensor battery is low, the Control Unit low-battery audio alert will become more persistent as the battery weakens.




Display	Definition
 Flashing YELLOW	Low Battery: Control Unit
 Flashing YELLOW	Low Battery: RF Stim Unit
 Flashing YELLOW	Low Battery: Intelli-Sense Gait Sensor

Table 8-1: Low battery displays and definitions.

## To charge the batteries in the Control Unit and RF Stim Unit:

1. Open and assemble the System Charger Set. The System Charger set comes with four interchangeable blades for U.S. and international outlets. Select the appropriate blade that fits the chosen power outlet and slide the blade onto the end of the charger. Then connect the "Y" cable to the charger cable.
2. Open the cover of the charging ports (found at the bottom of the Control Unit and at the top of the RF Stim Unit). See Figure 8-1.

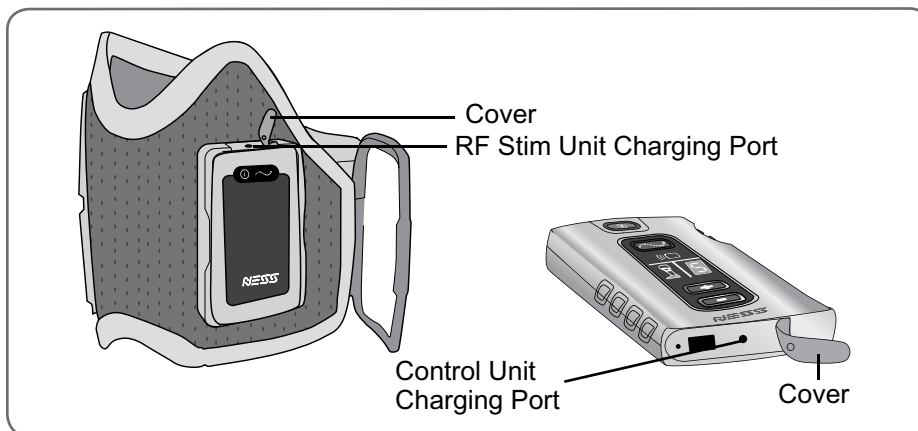


Figure 8-1: RF Stim Unit and Control Unit charging ports (L300 Regular FS Cuff shown).



**Caution: The batteries must be charged before first use, daily, and after extended storage.**

**Caution: Only the Control Unit and RF Stim Unit batteries are rechargeable.**

**Caution: Remove the FS Cuff before charging the batteries.**





**Caution: Do not use the RF Stim Unit or Control Unit while charging.**

**Caution: Use only the charger included in your NESS L300 System Kit. Use of any other charger could damage the system.**

3. Connect the system charger set to the Control Unit and RF Stim Unit. See Figure 8-2.

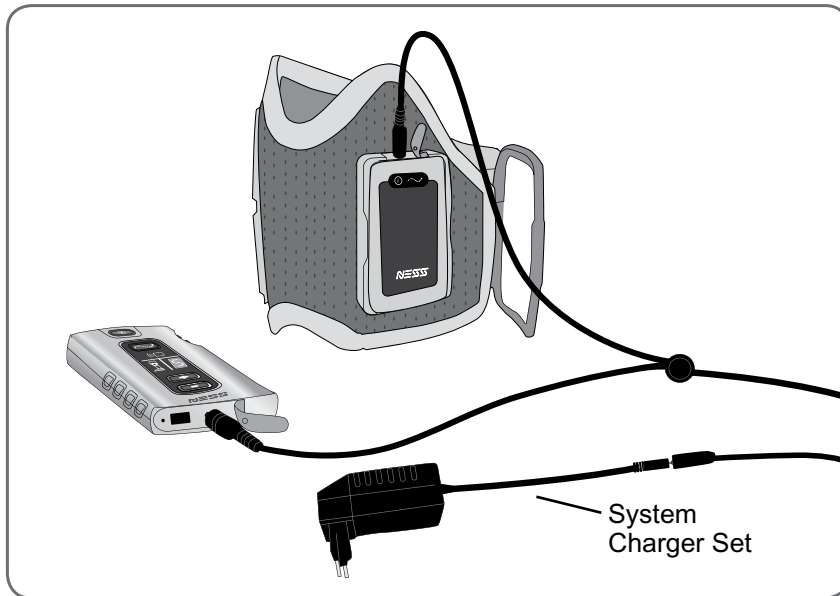






Figure 8-2: Charging set-up. (L300 Regular FS Cuff shown).

4. Plug the system charger set into a wall socket.
5. Verify that the  rotating GREEN circle appears in the Control Unit digital display, and the  status light on the RF Stim Unit is alternately flashing YELLOW and GREEN. See figures 8-3 and 8-4.

**Note:** It is possible to charge the Control Unit and RF Stim Unit separately, but Bioness recommends that the Control Unit and RF Stim Unit be charged at the same time.

6. The charging process will continue until a  horizontal GREEN line appears in the Control Unit digital display and the RF Stim Unit  status light is solid GREEN. See figures 8-3 and 8-4. The charging process should last approximately three hours. The Control Unit and RF Stim Unit can remain connected to the charger after charging is complete.

**Note:** If the Control Unit battery is completely discharged, a “b” (for boot) will flash for a few seconds in the Control Unit digital display when charging is started.

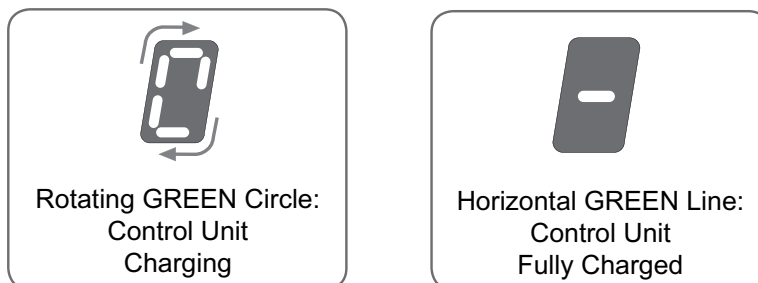


Figure 8-3: Control Unit charging displays.



Figure 8-4: RF Stim Unit charging displays.

## Replacing the Batteries

### ***RF Stim Unit Battery***

The RF Stim Unit rechargeable battery should be replaced approximately every two years by a Bioness certified technician.

### ***Intelli-Sense Gait Sensor Battery***

The battery in the Intelli-Sense Gait Sensor is not rechargeable. It should be replaced approximately every six months. The Gait Sensor indicator on the Control Unit will begin to flash YELLOW approximately two weeks before the Gait Sensor completely loses its charge. The Control Unit will also emit an alarm.

**To install a new Gait Sensor battery (Lithium coin cell, CR2430):**

1. Use the Phillips screwdriver supplied in the system kit to unscrew the two screws from the battery cover. See Figure 8-5.

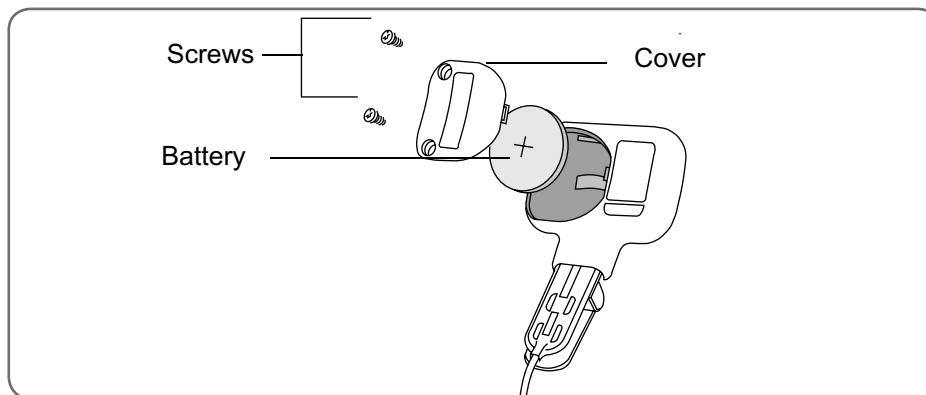


Figure 8-5: Replacing the Gait Sensor battery.

2. Slide the cover out.
3. Note the “+” orientation of the old battery.
4. Remove the old battery and properly dispose of it according to your local environmental regulations.
5. Insert the new battery. The “+” should face outward.
6. Slide the cover back into place, and tighten the screws.
7. Press the Gait Sensor pressure sensor to activate the sensor.



Remove the old battery, and properly dispose of it according to your local environmental regulations.

## ***Control Unit Battery***

The battery in the Control Unit is a rechargeable AAA battery. It should be replaced approximately every two years.

### **To install a new Control Unit battery (AAA NiMH 1.2 V):**

1. Remove the screw from the battery cover on the back of the Control Unit. See Figure 8-6. (The screw may be under a small label. If so, gently peel off one end of the label. Reapply the label after the battery is replaced.)
2. Remove the battery cover.
3. Note the "+/-" orientation of the old battery.

4. Insert the new rechargeable battery in the proper "+/-" orientation.
5. Slide the cover into place, and tighten the screw.
6. Fully charge the new battery before first use.



**Caution: Use of a non-rechargeable AAA battery can damage the Control Unit.**

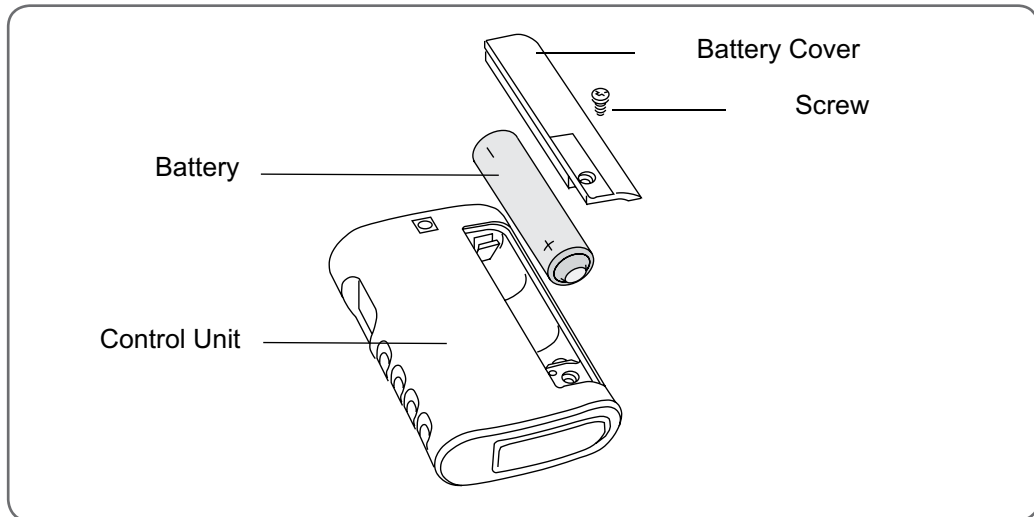


Figure 8-6: Replacing the Control Unit battery.



Remove the old battery, and properly dispose of it according to your local environmental regulations.

## Replacing the L300 Quick Fit Electrodes

You will need to replace the L300 Quick Fit Electrodes at least every two weeks.



**Caution: Use only L300 electrodes supplied by Bioness.**

**Caution: Do not use your NESS L300 system without electrodes.**

**Caution: Do not fold or twist the L300 Quick Fit Electrode.**

### To replace the L300 Quick Fit Electrodes: (See Figure 8-7)

1. Turn off the Control Unit and remove the L300 FS Cuff.
2. Gently remove the used L300 Quick Fit Electrode from the L300 FS Cuff.
3. Wet the entire new L300 Quick Fit Electrode with water.
4. Remove excess water from the L300 Quick Fit Electrode with a cloth.
5. Align the orange and blue snaps on the L300 Quick Fit Electrode with the orange and blue plug holes on the L300 FS Cuff.
6. Press firmly to snap the L300 Quick Fit Electrode into the L300 FS Cuff.

**Note:** Remove and re-wet the entire L300 Quick Fit Electrode every time you remove the L300 FS Cuff from your leg for more than one hour, and after every three to four hours of use. When wetting the L300 Quick Fit Electrode, always remove it from the L300 FS Cuff.

**Note:** Store the L300 Quick Fit Electrode where it can air dry, when not in use.

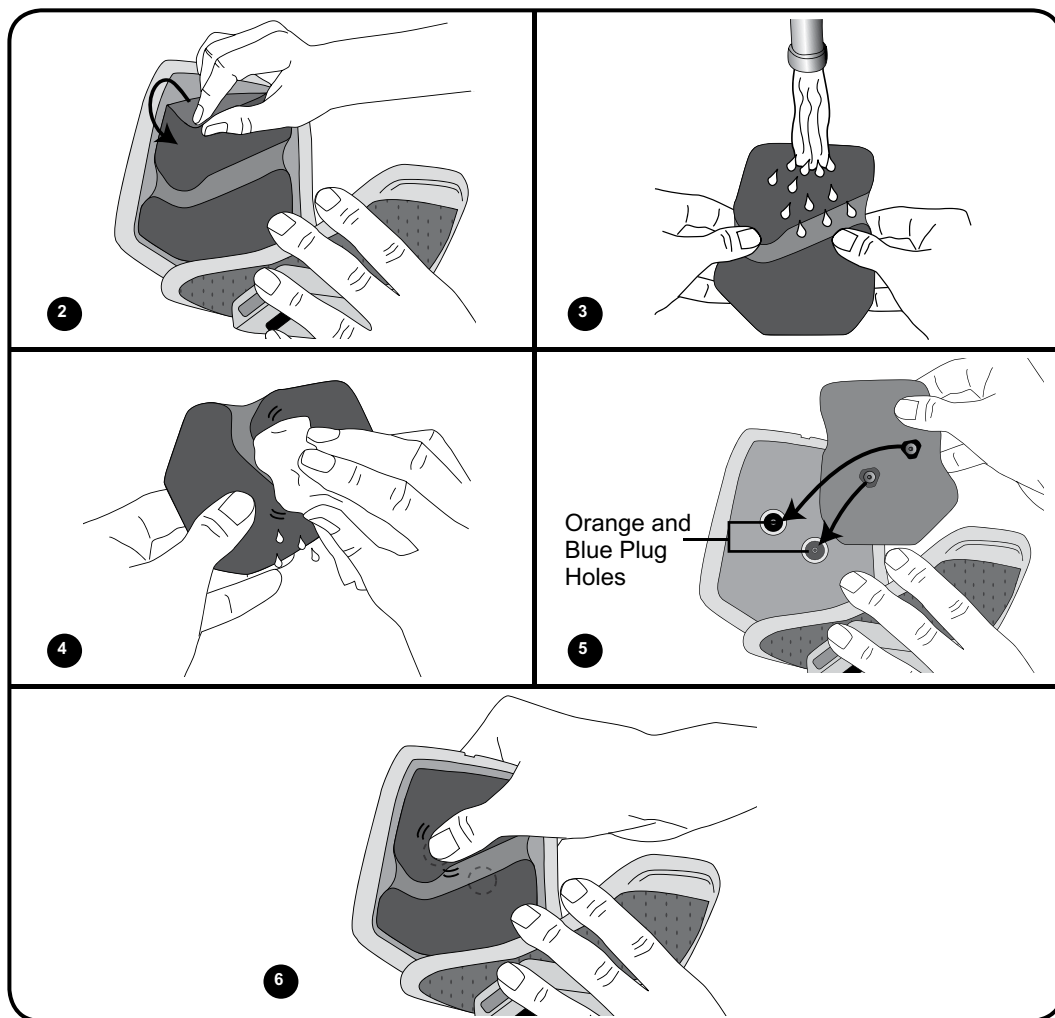


Figure 8-7: Replacing the L300 Quick Fit Electrode. (Regular L300 Quick Fit Electrode and Regular L300 FS Cuff shown.)

## Replacing the Cloth Electrodes

First fittings will be done by your clinician. Afterward, you will need to change the cloth electrodes at least every two weeks and the cloth electrode bases every year.



**Caution: Use only L300 cloth electrodes supplied by Bioness.**

**Caution: Do not use your NESS L300 system without electrodes.**

### To replace the L300 Cloth Electrodes: (See Figure 8-8)

1. Turn off the Control Unit and remove the L300 FS Cuff..
2. Gently pull the used cloth electrodes from the cloth electrode bases. Be careful not to detach the electrode bases from the L300 FS Cuff.
3. If necessary, clean the electrode bases with a damp cloth. Do not use a chemical-based cleaning substance.
4. Wet the new cloth electrodes with water until they are saturated.
5. With a soft cloth, gently wipe or blot excess water off the back (side with the snap) of the cloth electrodes.
6. Attach the cloth electrodes to the electrode bases.

**Note:** Remove and re-wet the cloth electrodes every time you remove the L300 FS Cuff from your leg for more than one hour, and after every four hours of use. When wetting the cloth electrodes, always remove them from the FS Cuff. If the cloth electrodes dry out, your response to the stimulation may change. If you need to adjust stimulation intensity more often than usual, try re-wetting the cloth electrodes following the steps listed above.



Note: Store the L300 Cloth Electrodes, when not in use in the Cloth Electrode Mesh Bag or in a location where they can air dry.

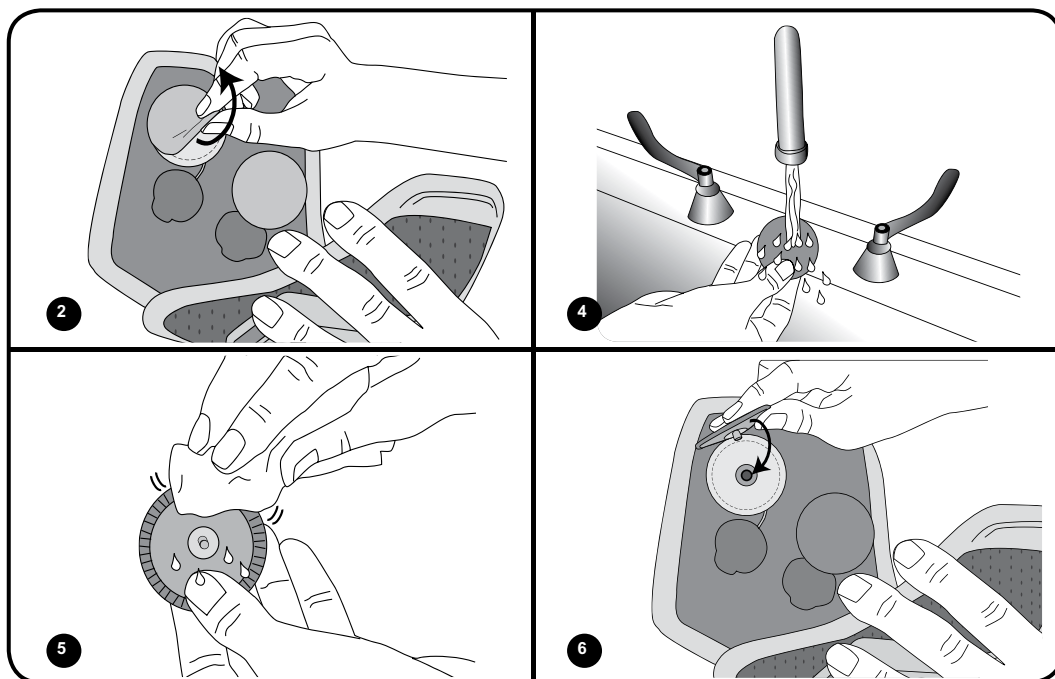


Figure 8-8: Replacing the L300 Cloth Electrodes. (Regular L300 Cloth Electrodes and Regular L300 FS Cuff shown.)

## Replacing the Hydrogel Electrodes

For Regular L300 FS Cuff users the Regular L300 Hydrogel Electrodes are one of the electrode options for home use. You will need to replace the hydrogel electrodes at least every two weeks.



**Caution: Use only L300 hydrogel electrodes supplied by Bioness.**

**Caution: Do not use your NESS L300 System without electrodes.**

### **To replace the L300 Hydrogel Electrodes: (See Figure 8-9)**

1. Turn off the Control Unit and remove the L300 FS Cuff..
2. Gently pull the used electrodes from the electrode bases. Be careful not to detach the electrode bases from the L300 FS Cuff.
3. If necessary, clean the electrode bases with a damp cloth. Do not use a chemical-based cleaning substance.
4. Separate the two new electrodes along the perforation.
5. Split the two-piece covers on each new electrode and discard them.
6. Attach the grid side of the electrodes to the electrode bases, and then press firmly.
7. Remove the covers from the electrodes.

**Note:** Save the covers. Always reapply the covers between uses. When reapplying the covers, make sure the Bioness logo faces up.

**Note:** If the electrode gel becomes dry, rehydrate it with one to two drops of water.

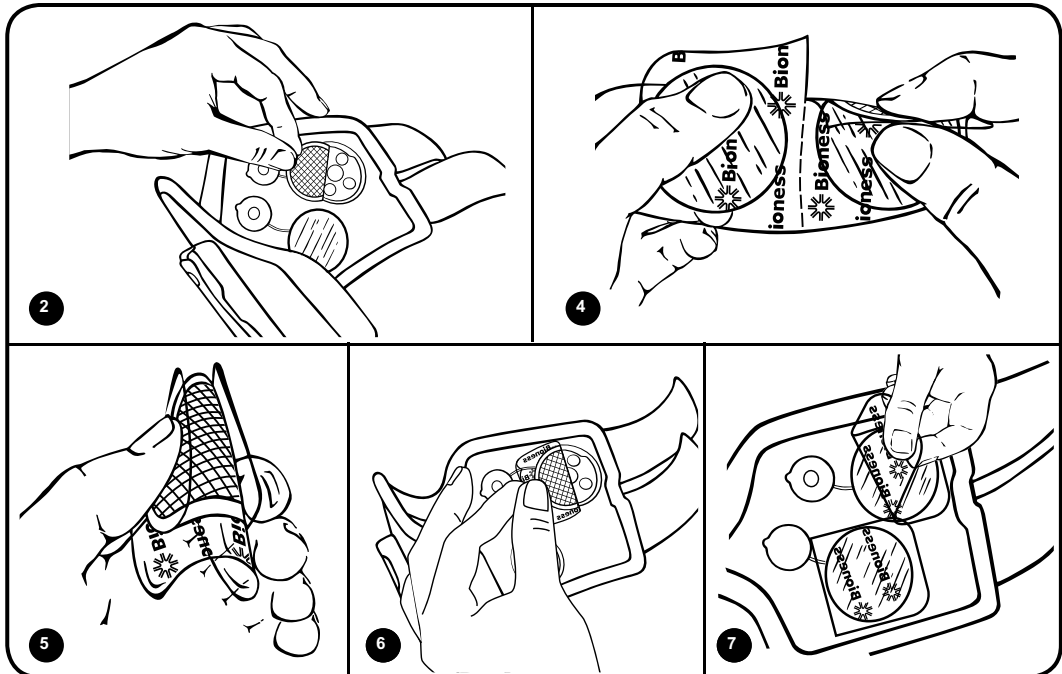


Figure 8-9: Replacing the L300 Hydrogel Electrodes. (Regular L300 Hydrogel Electrodes and Regular L300 FS Cuff shown.)

## Replacing the Electrode Bases

You will need to replace the electrode bases after one year of use. Contact Bioness to purchase replacement electrode bases.

For Regular L300 FS Cuff users, if you are switching from hydrogel to cloth electrodes, or from cloth electrodes to hydrogel electrodes, you will need to be seen by a qualified clinician for a first fitting. Your clinician will need to fit the electrode bases and adjust your stimulation settings.

### **To replace the electrode bases: (See Figure 8-10)**

1. If your clinician installed wire concealers over the electrode base wires, remove the wire concealers.
2. Mark the position of the used electrode bases on the FS Cuff liner with a permanent marker.
3. Disconnect the electrode base snaps from the plug holes.
4. Remove the used electrode bases from the L300 FS Cuff.
5. Attach the new electrode bases where the previous bases were attached.
6. Connect the electrode base snaps to the plug holes.
7. Recover the wires and snaps with the wire concealers, if desired.

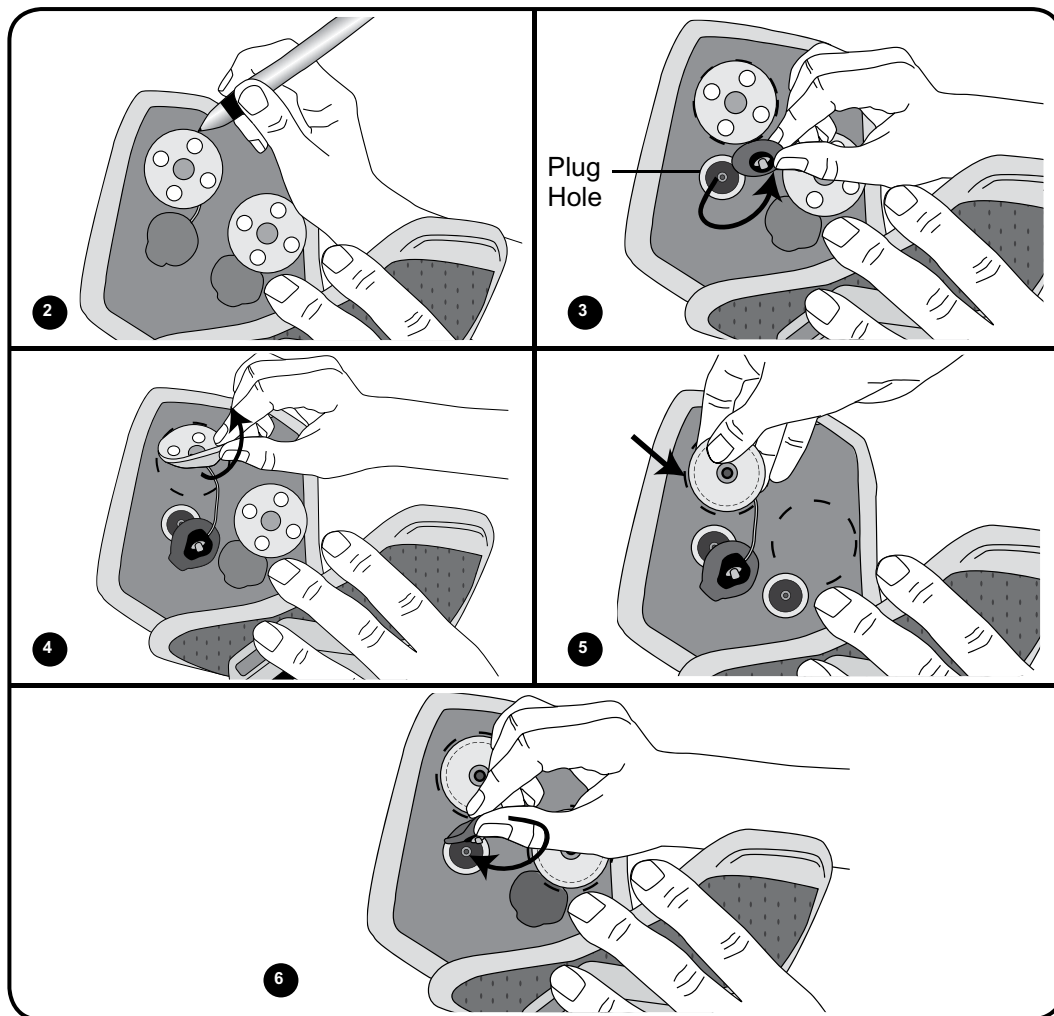


Figure 8-10: Replacing the L300 Electrode Bases.  
(Regular L300 FS Cuff shown.)

## Removing the RF Stim Unit

The only time you should remove the RF Stim Unit is to clean the FS Cuff or replace the RF Stim Unit.

### To remove the RF Stim Unit:

1. Turn off the Control Unit.
2. Pull the top of the RF Stim Unit away from the cradle. See Figure 8-11. If the fit is too tight, open the flexible cover over the charging port for a better grasp.
3. Remove the bottom of the RF Stim Unit from the cradle.

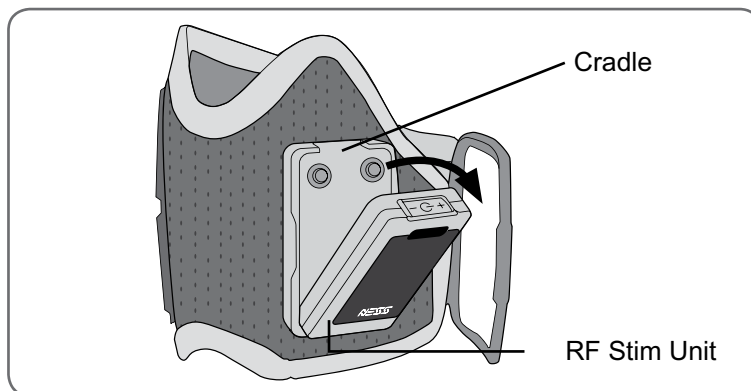


Figure 8-11: Removing the RF Stim Unit.

## Inserting the RF Stim Unit

### To insert the RF Stim Unit:

1. Insert the bottom of the RF Stim Unit into the cradle. Then, gently push the top of the RF Stim Unit into the cradle until it snaps in.

## Cleaning Your NESS L300 Components

All NESS L300 components may be cleaned by carefully wiping them with a damp cloth. The electrical components are not waterproof. **Do not immerse them in water.** The L300 FS Cuff is the only component that can be immersed in water to clean. Bioness recommends cleaning the L300 FS Cuff when replacing the electrodes.

### To clean the L300 FS Cuff:

1. Remove the RF Stim Unit.
2. Gently remove the electrodes from the electrode bases. For hydrogel electrodes, re-apply the electrode covers. *Do not remove the electrode bases.*
3. Immerse the L300 FS Cuff for 30 minutes in lukewarm water and mild detergent. *Do not use a washing machine.*
4. Rinse the L300 FS Cuff thoroughly under running water.
5. Immerse the L300 FS Cuff for an additional 15 minutes in clean, lukewarm water.
6. Rinse the L300 FS Cuff again under running water.
7. Gently blot excess moisture from the L300 FS Cuff with a towel. Do not wring the FS Cuff. Lay the FS Cuff flat in the shade to dry. *(Do not hang dry.)* Drying time will vary from 4 to 12 hours depending on climate and humidity. For faster drying, place the FS Cuff in front of a circulating *cold-air* fan. *Do not use a hot-air dryer or other heat source to dry.*
8. When the L300 FS Cuff is completely dry, insert the RF Stim Unit and attach the electrodes.





# Electronically Registering New Components

When a NESS L300 Control Unit, RF Stim Unit, or Intelli-Sense Gait Sensor is replaced, the new component must be electronically registered to the other NESS L300 components for the system to communicate wirelessly.

**NOTE:** Components can only be *successfully* registered once. Additional attempts will elicit an error indication.

## Registering a New Control Unit

### ***Set-Up***

1. Connect the new Control Unit and RF Stim Unit to the system charger set during registration.
2. Place the L300 FS Cuff with RF Stim Unit attached, the Intelli-Sense Gait Sensor, and the new Control Unit close together on a table but not touching. See Figure 9-1.
3. Turn off the old Control Unit and put it in an envelope for shipping to Bioness. Then, place it at least 30 feet from the NESS L300 components you are registering.
4. Make sure all other NESS L300 components are at least 9.14 meters (30 feet) from the NESS L300 components you are registering.

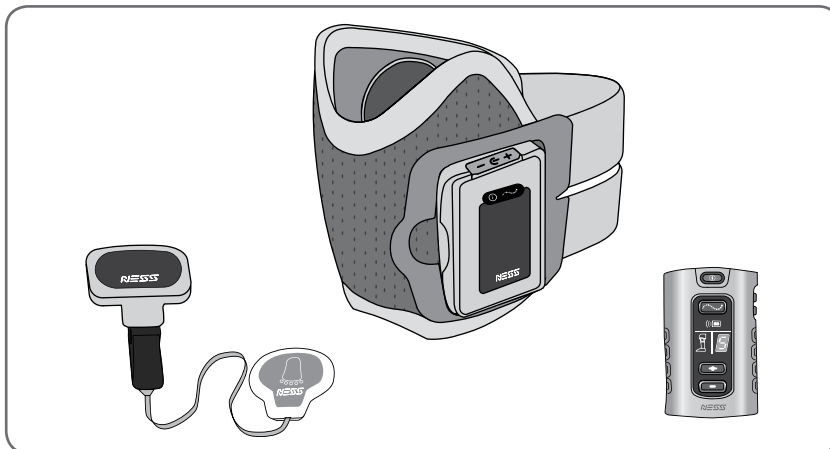


Figure 9-1: Registration setup.

## **Registration**







1. Turn off the new Control Unit.
2. Simultaneously press and hold for three seconds the  mode and  minus buttons. The Control Unit will beep when registration begins.
3. The Control Unit digital display will show  two alternating GREEN arches while registration is in process. See Figure 9-2. Registration of a new Control Unit may take up to four minutes.
4. When registration is complete,  ("C" for complete) will appear in the digital display and the Control Unit indicator will turn GREEN for a few seconds. See Figure 9-2. The Control Unit will beep.
5. If  ("E" for error) appears in the digital display, an error has occurred. Repeat the procedure. ( "E" may also indicate that the registration procedure was successful on a prior attempt and not noticed.)



Figure 9-2: Registration digital displays.

6. After registration is complete, turn on your NESS L300 System. If the new Control Unit is registered, the RF Stim Unit will turn on. If you see an RF failure indication between the Control Unit and RF Stim Unit, wait 20 minutes for the RF Stim Unit to enter energy-saving mode, and then repeat the registration procedure.
7. Once the Control Unit is registered, locate the System ID Number on the NESS L300 carrying case (for example, A334). Write the number on the blank label on the back of the Control Unit. See Figure 9-3. This ID number identifies which NESS L300 system the new Control Unit is registered to.

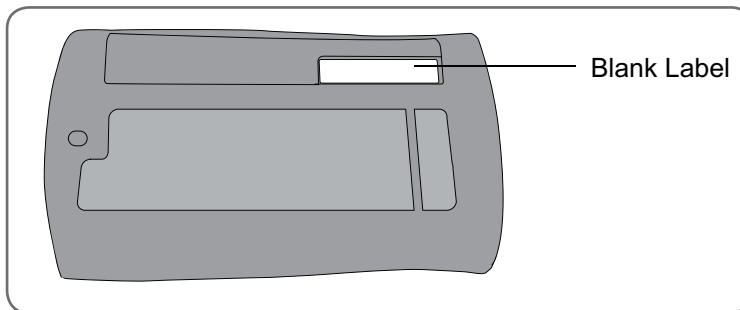


Figure 9-3: Label on the Control Unit for the System ID Number.

## Registering a New RF Stim Unit

### *Set-Up*

1. Turn off the Control Unit.
2. Remove the old RF Stim Unit from the cradle of the L300 FS Cuff.



**Caution: Do not turn on the Control Unit, if the RF Stim Unit is not in the cradle.**

3. Put the old RF Stim Unit in an envelope for shipment to Bioness. Place it at least 30 feet from the components you are registering.
4. Locate the System ID Number on the NESS L300 carrying case (for example, A334). Write the number on the blank label on the back of the new RF Stim Unit. See Figure 9-4. This number identifies which NESS L300 system the new RF Stim Unit will register to.
5. Attach the new RF Stim Unit to the L300 FS Cuff.
6. Connect the Control Unit and the new RF Stim Unit to the system charger set during registration.

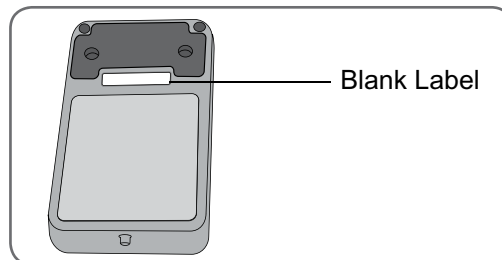




Figure 9-4: Label on the RF Stim Unit for the System ID Number.

7. Place the L300 FS Cuff with the attached new RF Stim Unit, the Control Unit, and the Intelli-Sense Gait Sensor close to each other on a table but not touching.
8. Make sure all other NESS L300 components are at least 9.14 meters (30 feet) from the NESS L300 components you are registering.

## ***Registration***

1. Make sure the Control Unit has been off for 20 minutes, and that the RF Stim Unit is in energy-saving mode.
2. Simultaneously press and hold for three seconds the  mode and  minus buttons on the Control Unit. The Control Unit will beep when registration begins. See Figure 9-5.

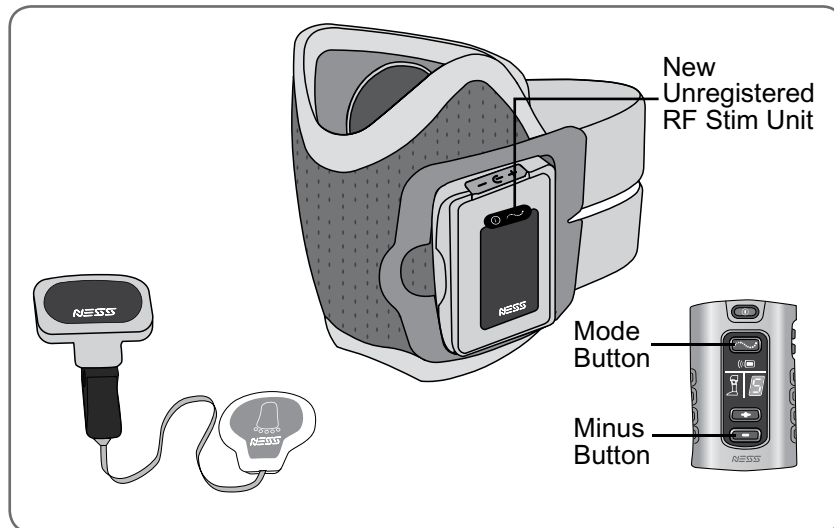






Figure 9-5: Registering a new RF Stim Unit.

3. The Control Unit digital display will show  two alternating GREEN arches while registration is in process. Registration should take several seconds to complete.
4. When registration is complete,  ("C" for complete) will appear in the digital display and the RF Stim Unit indicator will turn GREEN for a few seconds. The Control Unit will beep.
5. If  ("E" for error) appears in the digital display, an error has occurred. Repeat the procedure. ( "E" also can mean that the registration procedure was successful on a prior attempt and not noticed.)






After registration is complete, turn on the Control Unit. If the new RF Stim Unit is registered, the RF Stim Unit will turn on. If you see an RF failure indication, wait 20 minutes for the RF Stim Unit to enter energy-saving mode, and then repeat the procedure.

## Registering a New Intelli-Sense Gait Sensor

### ***Set-Up***

1. Connect the Control Unit and RF Stim Unit to the system charger set during registration.
2. Place the new Intelli-Sense Gait Sensor, L300 FS Cuff with RF Stim Unit, and Control Unit close together on a table but not touching.
3. Make sure all other NESS L300 components (including the used Intelli-Sense Gait Sensor in your shoe) are at least 9.14 meters (30 feet) from the components you are registering.

## ***Registration (Important: Read Steps 1–4 Before Starting)***

1. Turn off the Control Unit.
2. Simultaneously press and hold for three seconds the  mode and  minus buttons on the Control Unit. The Control Unit will beep when registration begins.
3. The Control Unit digital display will show  two alternating GREEN arches while registration is in process.
4. **Within 15 seconds of initiating the registration procedure**, repeatedly press and release the pressure sensor.
5. When registration is complete,  (“C” for complete) will appear in the digital display, the Gait Sensor indicator will turn GREEN for a few seconds, and the Control Unit will beep. If registration fails, wait 20 minutes for the RF Stim Unit to enter energy-saving mode, and then repeat the procedure.
6. After registration is complete, turn on the system and select gait mode. Press and release the pressure sensor. If the new Intelli-Sense Gait Sensor is registered, the  mode button will flash YELLOW rapidly for four seconds.
7. Locate the System ID Number on the NESS L300 carrying case (for example, A334). Write the number on the small label on the back of the new Intelli-Sense Gait Sensor. See Figure 9-6. This number identifies which system the sensor is registered to.

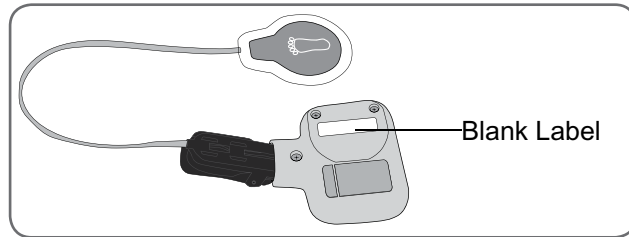




Figure 9-6: Label on the Intelli-Sense Gait Sensor for the System ID Number.



# Troubleshooting

If you have any questions or concerns, please contact your local distributor.

## ***When charging the L300, how will I know when the batteries are fully charged?***

- When the Control Unit is fully charged, a  GREEN horizontal line will appear in the Control Unit digital display.
- When the RF Stim Unit is fully charged, the  status light on the RF Stim Unit will be solid GREEN.
- Charging takes approximately three hours. Once the components are fully charged, you may keep the components connected to the system charger set.

## ***If I charge the L300 every day, will I harm the batteries?***

- No. Daily charging will not affect the lifespan or functionality of the batteries. Daily charging is recommended.

## ***While charging, "E" appears in the digital display.***

- An error occurred while charging. Reconnect the system charger set. If the problem persists, contact Bioness.





***Stimulation works in training mode but not in gait mode. When I turn on gait mode I hear a beep, the RF Stim Unit and Gait Sensor indicators on the Control Unit alternately flash RED, and “E” flashes in the digital display.***

- The Intelli-Sense Gait Sensor and RF Stim Unit are not communicating. The Gait Sensor is probably asleep. Apply pressure to the Gait Sensor pressure sensor. If this does not resolve the problem, the battery may be depleted or the Gait Sensor may be faulty. If no wire issues are apparent, replace the Gait Sensor battery and try again.



***When I turn on the Control Unit, it beeps, the Control Unit and RF Stim Unit indicators alternately flash RED, and “E” flashes in the digital display. The RF Stim Unit indicators are not lit.***

- The RF Stim Unit battery is likely discharged, preventing the Control Unit and RF Stim Unit from communicating. Turn off the Control Unit, and charge the Control Unit and RF Stim Unit fully. Then, disconnect the charger and turn on the Control Unit. The Control Unit  On/Off button and the  status light on the RF Stim Unit should flash GREEN. Communication should be restored.



***I hear a beep, the RF Stim Unit indicator on the Control Unit flashes RED, and the stimulation intensity level flashes in the Control Unit digital display.***

*If you feel stimulation but the intensity level seems weaker than usual and ankle movement is unsatisfactory, electrode contact may be compromised.*

- Turn off the Control Unit and remove the L300 FS Cuff.
- Thoroughly cleanse the skin, removing dead cells and oils.
- If you are using hydrogel electrodes, remove and replace the worn electrodes. Press firmly on the new electrodes until they are securely attached to the bases. Then, remove the covers.
- If you have cloth electrodes, remove the cloth electrodes and wet them with water until saturated. Blot the snap side of the electrodes before re-adhering them to the electrode bases.
- Replace hydrogel and cloth electrodes every two weeks.

*If you do not feel stimulation:*

- Turn off the Control Unit and remove the L300 FS Cuff.
- For hydrogel electrodes, confirm that the covers have been removed.
- For cloth electrodes, remove and wet the cloth electrodes, if they are dry.
- Make sure the RF Stim Unit is properly snapped into the cradle on the L300 FS Cuff. Press firmly near the upper edges of the RF Stim Unit until it is flush with the cradle.
- Make sure the electrode bases are snapped into the plug holes of the L300 FS Cuff.

***The electrodes or electrode bases are frayed, peeling, damaged, or falling off the L300 FS Cuff.***

- Replace any worn or damaged electrodes or electrode bases.

***How will I know when the Intelli-Sense Gait Sensor battery charge level is low?***

- A Gait Sensor battery will last for approximately six months, and then it will need to be replaced. When the Gait Sensor battery charge level is low, the Gait Sensor indicator on the Control Unit will flash YELLOW and the Control Unit will emit an audio alert. The audio alert will become more persistent as the battery weakens.



***One of the component indicators is solid RED, an "E" appears in the digital display, and the Control Unit beeps.***

- The respective component is malfunctioning. Turn off the Control Unit and turn it back on. If the problem persists, then stop using the NESS L300 system and contact Bioness.



***One of the component indicators is flashing YELLOW.***

- The respective component battery charge level is low. Charge or replace the battery.

***My ankle is not moving (or my foot does not lift satisfactorily), and the system is not indicating any errors.***

- Turn off the Control Unit and reposition the L300 FS Cuff. Make sure the strap is snug and the L300 FS Cuff is secure.

***Stimulation is inconsistent when I am walking, but the system is not indicating any errors.***


- Stop walking and shift your weight from side to side. If the problem persists, check for proper placement of the pressure sensor, reposition the pressure sensor slightly forward in your shoe, or loosen your shoelace if it is tight. Also, check the Intelli-Sense Gait Sensor wires for wear or fraying, and check the transmitter and pressure sensor for damage.







***My skin is irritated or has a skin reaction where the electrodes or L300 FS Cuff adheres.***

- Stop using the NESS L300 system immediately and contact your clinician, dermatologist, or local distributor. Resume use only when the skin is completely healed. Ask your clinician or dermatologist for a skin conditioning protocol.

***I received a replacement component and was told I need to “register” it. Why is registration important and how do I register a component?***

- A replacement Control Unit, RF Stim Unit, or Intelli-Sense Gait Sensor needs to be electronically registered to the other components in the system to communicate wirelessly. To register a component, see Chapter 9.

***I tried the registration procedure and saw a  “C” immediately, but I never saw the alternating arches in the digital display. The replacement component is not working.***

- Clinician mode (for use by clinicians only) may have been started instead of the registration process. Clinician mode is started by pressing the minus  and  on/off buttons on the Control Unit. Registration is started with the Control Unit off, and then by pressing the minus  and mode  buttons on the Control Unit. Turn off the Control Unit, and press the  minus and  mode buttons to restart the registration process.

***The Control Unit (or RF Stim Unit) does not light up when turned on.***

- The battery needs to be charged. Charge the battery. If the problem persists, contact your local distributor.

***After I fully charged the Control Unit and RF Stim Unit, I disconnected and then immediately reconnected the system charger set. The charging icons displayed again. Are the components still fully charged or do I need to repeat the charging process?***

- If you just charged your system and the fully charged icons were displayed, your system is still fully charged. You do not have to repeat the charging process.

# Technical Specifications

<b>Control Unit Specifications</b>	
<b>Classification</b>	Internally powered, continuous operation
<b>Operation Modes</b>	Gait, Training, Clinician, and Standby
<b>Battery Type</b>	Rechargeable AAA NiMH 1.2 V, 900–1100 mAh
<b>Controls</b>	On/Off illuminated button Mode illuminated button for changing operating modes Intensity +/- buttons to fine-tune intensity level Volume buttons to adjust volume of audio alerts
<b>Indications</b>	Three status LEDs: Control Unit, RF Stim Unit, and Intelli-Sense Gait Sensor Numerical display designates relative stimulation intensity Illuminated buttons designate system operating mode “Beeps” for audio alerts
<b>Carrying Options</b>	In pocket, neck strap, wrist strap, or belt pouch
<b>Dimensions</b>	Length: 73 mm (2.9 in.) Width: 46 mm (1.8 in.) Height: 18 mm (0.7 in.)
<b>Weight</b>	45 grams (1.5 oz.)
<b>Environmental Ranges</b>	Transport and storage temperature: -20°C to +60°C (-4°F to +140°F) Operating conditions temperature: 5°C to 40°C (41°F to 104°F) Charging temperature: 5°C to 40°C (41°F to 104°F) Relative humidity: 25% to 85% Atmospheric pressure: 900 hPa to 1060 hPa

<b><i>RF Stim Unit Specifications</i></b>	
<b>Classification</b>	Internally powered, continuous operation with type BF applied parts
<b>Operating Voltage</b>	3.7 V
<b>Battery Type</b>	Proprietary rechargeable Li-Ion (Lithium Ion) 3.7 V, 700 mAh
<b>Indications</b>	Status (fault, battery, charging) and Stimulation LEDs “Beeps” for audio alerts
<b>Dimensions</b>	Length: 74 mm (2.9 in.) Width: 43 mm (1.7 in.) Height: 15 mm (0.6 in.)
<b>Weight</b>	50 grams (1.6 oz.)
<b>Environmental Ranges</b>	Transport and storage temperature: -20°C to +60°C (-4°F to +140°F) Operating conditions temperature: 5°C to 40°C (41°F to 104°F) Charging temperature: 5°C to 40°C (41°F to 104°F) Relative humidity: 25% to 85% Atmospheric pressure: 900 hPa to 1060 hPa

<b>Pulse Parameters</b>	
<b>Pulse</b>	Balanced Biphasic
<b>Waveform</b>	Symmetric or Asymmetric
<b>Intensity</b>	0–80 mA, 1-mA resolution (positive phase)
<b>Max Voltage</b>	120 V



	Symmetric			Asymmetric		
Positive Pulse Duration (μsec)	100	200	300	100	200	300
Negative Pulse Duration (μsec)	100	200	300	400	800	1200
Inter-Phase Interval (μsec)	50			0		
Total Pulse Duration (μsec)	250	450	650	500	1000	1500
Max Load	5000 ohm (Subject to max voltage limitation)					
Pulse Repetition Rate	20–45 Hz, 5-Hz resolution					
Gait Parameters						
Ramp Up	0–2 seconds, 0.1-second resolution					
Ramp Down	0–2 seconds, 0.1-second resolution					
Extend (Delay)	0–100% of stance time, 10% resolution					
Max. Duration of Stimulation	2–10 seconds, 1-second resolution					
Training Parameters						
On Time	4–20 seconds, 1-second resolution					
Off Time	4–60 seconds, 1-second resolution					
Ramp Up	0–2 seconds, 1-second resolution					
Ramp Down	0–2 seconds, 1-second resolution					
Total Time	1–60 minutes					

<b><i>FS Cuff Specifications</i></b>		
	<b>Regular L300 FS Cuff</b>	<b>Small L300 FS Cuff</b>
<b>Material</b>	Fabric-Polymer	Fabric-Polymer
<b>Fits Limb Circumference</b>	29–51 cm (11–20 in.)	22–31 cm (8-12.2 in.)
<b>Dimensions</b>	Height: 160 mm (6.3 in.) Width: 100 mm (3.9 in.) Depth: 125 mm (4.9 in.)	Height: 110.5 mm (4.5 in.) Width: 80 mm (3 in.) Depth: 100 mm (4 in.)
<b>Weight</b>	Approximately 150 grams (4.8 oz)	Approximately 104 grams (3.6 oz.)

<b><i>Intelli-Sense Gait Sensor Specifications</i></b>	
<b>Classification</b>	Internally powered, continuous operation with type BF applied part(s)
<b>Battery Type</b>	Lithium coin cell, CR2430, 280 mAh
<b>Dimensions of the Transmitter</b>	Length: 80 mm (3.2 in.) Width: 50 mm (2.0 in.) Height: 10 mm (0.4 in.)
<b>Weight</b>	35 grams (1.1 oz.)
<b>Environmental Ranges</b>	Transport and storage temperature: -20°C to +60°C (-4°F to +140°F) Operating conditions temperature: 5°C to 40°C (41°F to 104°F) Relative humidity: 25% to 85% Atmospheric pressure: 900 hPa to 1060 hPa

<b><i>Power Supply Specifications</i></b>	
<b>Use medical Class II safety approved power supply provided/approved by Bioness with the following ratings:</b>	
<b>Input</b>	
<b>Voltage</b>	100–240 V AC
<b>Current</b>	400 mA
<b>Frequency</b>	50–60 Hz
<b>Output</b>	
<b>Voltage</b>	5 V $\pm$ 5%
<b>Current</b>	2400 mA

**Note:** Do not use the Control Unit or RF Stim Unit while charging.

<b><i>Wireless Link Specifications</i></b>	
<b>Frequency Band</b>	2.4 GHz, ISM band
<b>Transmission Power</b>	Complies with FCC 15.247 (for U.S.) / ETSI EN 300-440 (for Europe) regulations

<b><i>Electrode and Electrode Base Specifications - Regular L300 System</i></b>	
<b>Regular Hydrogel Electrodes</b>	Two, 45-mm (1.77-in.) diameter, surface area 15.8 cm <sup>2</sup> hydrogel electrodes <b>Note:</b> Use only electrodes provided by Bioness Inc
<b>Regular Hydrogel Electrode Bases</b>	Two relocatable polymer electrode bases for individual fitting
<b>Regular Cloth Electrodes</b>	Two, 45-mm (1.77-in.) diameter, surface area 15.8 cm <sup>2</sup> non-woven polymer fabric (80% viscose, 20% polypropylene); conductive layer, stainless steel Male snap connector Low Density Polyethylene (LDPE) 10% + Ethylene Vinyl acetate (EVA)
<b>Regular Cloth Electrode Bases</b>	Two, 45-mm (1.77-in.) diameter, relocatable Thermoplastic elastomer (TPE) electrode bases
<b>Regular L300 Quick Fit Electrode (right - A and left - A)</b>	Non-woven polymer fabric (80% viscose, 20% polypropylene); conductive layer, stainless steel Male snap connector Low Density Polyethylene (LDPE) 10% + Ethylene Vinyl acetate (EVA) Surface area: 43.2 cm <sup>2</sup> \ 55.3 cm <sup>2</sup>

<b><i>Electrode and Electrode Base Specifications - Small L300 System</i></b>	
<b>Small Hydrogel Electrodes</b>	<p>Two, 36-mm (1.41-in.) diameter, surface area 10.1 cm<sup>2</sup> hydrogel electrodes</p> <p>Use only for fitting process</p> <p><b>Note:</b> Use only electrodes provided by Bioness Inc</p>
<b>Small Electrode Bases</b>	Two, 36-mm (1.41-in.) diameter, relocatable Thermoplastic elastomer (TPE) electrode bases
<b>Small Cloth Electrodes</b>	<p>Two, 36-mm (1.41-in.) diameter, surface area 10.1cm<sup>2</sup> non-woven polymer fabric (80% viscose, 20% polypropylene); conductive layer, stainless steel</p> <p>Male snap connector</p> <p>Low Density Polyethylene (LDPE) 10% + Ethylene Vinyl acetate (EVA)</p>
<b>Small L300 Quick Fit Electrode - A</b>	<p>Non-woven polymer fabric (80% viscose, 20% polypropylene); conductive layer, stainless steel</p> <p>Male snap connector</p> <p>Low Density Polyethylene (LDPE) 10% + Ethylene Vinyl acetate (EVA)</p> <p>Surface area: 31.1 cm<sup>2</sup> (in<sup>2</sup>) \ 20.6 cm<sup>2</sup> (in<sup>2</sup>)</p>
<b>Small L300 Quick Fit Electrode - B</b>	<p>Non-woven polymer fabric (80% viscose, 20% polypropylene); conductive layer, stainless steel</p> <p>Male snap connector</p> <p>Low Density Polyethylene (LDPE) 10% + Ethylene Vinyl acetate (EVA)</p> <p>Surface area: 19.9 cm<sup>2</sup> \ 18.2 cm<sup>2</sup></p>



## Appendix - EMI Tables

System Characteristics	
Transmitters	
Operating Frequency Band	2401–2482 MHz
Type of Modulation	FSK
Type of Modulating Signal	Binary data message
Data Rate [=Frequency of Modulating Signal]	250 Kbps
Effective Radiated Power	<10 dBm
Receivers	
Operating Frequency Band	2401–2482 MHz
Receiver Bandwidth	812 kHz around a selected frequency

<b>Guidance and Manufacturer's Declaration—Electromagnetic Emissions</b>		
The NESS L300 System is intended for use in the electromagnetic environment specified below. The customer or the user of the NESS L300 System should assure that it is used in such an environment.		
<b>Emissions Test</b>	<b>Compliance</b>	<b>Electromagnetic Environment – Guidance</b>
RF emissions CISPR 11	Group 1	The NESS L300 System 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 NESS L300 System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	



<b>Guidance and Manufacturer's Declaration – Electromagnetic Immunity for All Equipment and Systems</b>			
The NESS L300 System is intended for use in the electromagnetic environment specified below. The customer or the user of the NESS L300 System should assure that it is used in such an environment.			
<b>Immunity Test</b>	<b>IEC 60601 Test Level</b>	<b>Compliance Level</b>	<b>Electromagnetic Environment – Guidance</b>
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	2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV line to line 2 kV line to earth	1 kV line to line (Class II without any grounded interconnections)	Mains power quality should be that of a typical commercial or hospital environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<p>&lt;5% <math>U_T</math> (&gt;95% dip in <math>U_T</math>) for 0.5 cycle</p> <p>40% <math>U_T</math> (60% dip in <math>U_T</math>) for 5 cycles</p> <p>70% <math>U_T</math> (30% dip in <math>U_T</math>) for 25 cycles</p> <p>&lt;5% <math>U_T</math> (&gt;95% dip in <math>U_T</math>) for 5 sec</p>	<p>&lt;5% <math>U_T</math> (&gt;95% dip in <math>U_T</math>) for 0.5 cycle</p> <p>40% <math>U_T</math> (60% dip in <math>U_T</math>) for 5 cycles</p> <p>70% <math>U_T</math> (30% dip in <math>U_T</math>) for 25 cycles</p> <p>&lt;5% <math>U_T</math> (&gt;95% dip in <math>U_T</math>) for 5 sec</p>	Mains power quality should be that of a typical commercial or hospital environment. If the user of the NESS L300 System requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	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.			

<b>Guidance and Manufacturer's Declaration—Electromagnetic Immunity</b>			
The NESS L300 System is intended for use in the electromagnetic environment specified below. The customer or the user of the NESS L300 System should assure that it is used in such an environment.			
<b>Immunity Test</b>	<b>IEC 60601 Test Level</b>	<b>Compliance Level</b>	<b>Electromagnetic Environment—Guidance</b>
			Portable and mobile RF communications equipment should be used no closer to any part of the NESS L300 System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	<b>Recommended separation distance:</b> $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	$[E_1] = 10 \text{ V/m}$ in 26 MHz to 1 GHz $[E_1] = 3 \text{ V/m}$ in 1 GHz to 2.5 GHz	<b>Recommended separation distance:</b> $d = 0.4\sqrt{P}$ , 80–800 MHz range $d = 0.7\sqrt{P}$ , 800–1000 MHz range $d = 2.3\sqrt{P}$ , 1000–2500 MHz range

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.

NOTE 3:  $P$  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).

NOTE 4: Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup>

NOTE 5: Interference may occur in the vicinity of equipment marked with the following symbol:



<sup>a</sup> 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 NESS L300 System is used exceeds the applicable RF compliance level above, the NESS L300 System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the NESS L300 System.

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

## Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the NESS L300 System

The NESS L300 System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NESS L300 System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NESS L300 System 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			
	150 kHz to 80 MHz Outside ISM Bands $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 0.4\sqrt{P}$	800 MHz to 1000 MHz $d = 0.7\sqrt{P}$	1000 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	4.7 in. (0.12 m)	1.6 in. (0.04 m)	2.8 in. (0.07 m)	9.1 in. (0.23 m)
0.1	15 in. (0.38 m)	5.2 in. (0.13 m)	8.7 in. (0.22 m)	2 ft 5 in. (0.73 m)
1	3 ft 11 in. (1.2 m)	15 ft 7 in. (0.4 m)	2 ft 4 in. (0.7 m)	7 ft 7 in. (2.3 m)
10	12 ft 6 in. (3.8 m)	4 ft 2 in. (1.3 m)	7 ft 3 in. (2.2 m)	24 ft 11 in. (7.3 m)
100	39 ft 4 in. (12 m)	13 ft 1 in. (4 m)	23 ft (7 m)	75 ft 6 in. (23 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.

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in meters (m) can be determined 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:** All calculations were made according to tables 204 and 206 of IEC 60601-1-2 for not life-supporting equipment using factors of 3.5 in 0.15–800 MHz and 7 in 800–2500 MHz. There are no requirements for ISM bands in these tables.