Manufactured by Bioness Neuromodulation Ltd.
A Bioness Inc Company
19 Ha'Haroshet Street
PO Box 2500
Industrial Zone
Ra'Anana 43654, Israel

Worldwide Corporate Office
Bioness Inc
25103 Rye Canyon Loop
Valencia, CA 91355 USA
Telephone: 800-211-9136
Email: info@bioness.com
Website: www.bioness.com

EC REP

European Authorized Representative
NESS Europe B.V.
Stationsweg 41
3331 LR Zwijndrecht, The Netherlands
Telephone: +31.78.625.6088
Email: international@nl.bioness.com
Website: www.bioness.com/Landing.php?reset

Rx Only (US Only)

612-00314-001 Rev. A

Bioness®
LiveOn®

NESS L300®Plus

Clinician's Guide

NESS
L300® Plus
Clinician's Guide

Bioness®

Rx Only (US Only)

Environmental Policy

Service personnel are advised that when changing any part of the NESS L300 Plus System, care should be taken to dispose of those parts in the correct manner; where applicable, parts should be recycled. When the life cycle of the NESS L300 Plus System has been completed, the product should be discarded according to the laws and regulations of the local authority. 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.

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Conformity Certification

CE 0473

C ETL US LISTED Intertek 3106069

Table of Contents

List of Symbols

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

Introduction

Central nervous system (CNS) injuries and/or diseases 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. Many people with CNS injuries/diseases also suffer from thigh muscle weakness. Weak thigh muscles can cause considerable difficulties with flexing or extending the knee during ambulation.

The NESS L300 Plus System is intended to provide ankle dorsiflexion and knee flexion or extension in individuals with foot drop and thigh muscle weakness following an upper motor neuron injury or disease.

This NESS L300 Plus *Clinician's Guide* describes:

- The NESS L300 Plus System.
- The NESS L300 Plus Intelli-Gait Software.
- How to fit the NESS L300 Plus System.
- How to program the NESS L300 Plus System.

This guide also includes important safety instructions. Be sure to review the safety instructions with patients before they use the NESS L300 Plus System.

If you have any questions, please call your local distributor, or visit the Bioness website: www.bioness.com /Landing.php?reset.

Device Description and Safety Information

Device Description

The NESS L300 Plus System consists of four main components:

- **L300 Functional Stimulation (FS) Cuff with L300 Radio Frequency (RF) Stim Unit**—delivers electrical pulses over the common peroneal nerve and to the motor point of the tibialis anterior muscle. The L300 FS Cuff produces ankle dorsiflexion in the swing phase of gait, to prevent foot drop.
- **Thigh FS Cuff with Thigh RF Stim Unit**—delivers electrical pulses:
  - Over the tibial and common fibular (peroneal) portions of the sciatic nerve to stimulate the hamstrings, to flex the knee.
  - Over the femoral nerve to stimulate the quadriceps, to extend the knee.
- **Intelli-Sense Gait Sensor**—used to sense and wirelessly transmit heel events in the affected leg.
- **L300 Plus Control Unit**—used to wirelessly control and monitor the NESS L300 Plus System.

These components communicate wirelessly to provide synchronized ankle dorsiflexion and knee flexion or extension in functional and therapeutic modes.

Indications for Use

The NESS L300 Plus System is intended to provide ankle dorsiflexion and knee flexion or extension in individuals with foot drop and thigh muscle weakness following an upper motor neuron injury or disease.

During gait, the NESS L300 Plus System electrically stimulates muscles in the affected leg to provide dorsiflexion of the foot and knee flexion or extension; thus, it may improve the individual's gait.

The NESS L300 Plus System may also:

- Facilitate muscle re-education.
- Prevent or retard disuse atrophy.
- Maintain or increase joint range of motion.
- 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 Plus System.
- The NESS L300 Plus System should not be used on a leg where a cancerous lesion is present or suspected.
- The NESS L300 Plus System should not be used on a leg with a regional disorder, such as a fracture or dislocation, which could be adversely affected by motion from the stimulation.

Warnings

- The long-term effects of chronic electrical stimulation are unknown.
- The L300 and Thigh FS Cuffs 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 Plus System to the patient and high-frequency surgical equipment may result in skin burns where the stimulator electrodes touch and damage to the L300 and Thigh RF Stim Units.
- The NESS L300 Plus System should only be configured by an authorized clinician.
- The Clinician's Programmer should only contain the Windows Mobile for Pocket PC operating system and Bioness Inc proprietary software. Third-party software packages are not supported and may interfere with proper operation of the NESS L300 Plus System, and void the warranty.

Precautions

- Inflammation in the region of the L300 and Thigh FS Cuffs may be aggravated by motion, muscle activity, or pressure from the FS Cuffs. Advise patients to stop using the NESS L300 Plus System until any inflammation is gone.
- Use caution when treating patients with suspected or diagnosed heart problems.
- Use caution with patients who have suspected or diagnosed epilepsy.
- Advise patients to use the L300 and Thigh FS Cuffs with caution:
  - If the patient has 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.

- Specific physician clearance should be obtained before using the NESS L300 Plus System on patients who have an alteration of normal arterial or venous flow in the region of the L300 and/or Thigh FS Cuffs because of local insufficiency, occlusion, arteriovenous fistula for the purpose of hemodialysis, or a primary disorder of the vasculature.
- Specific physician clearance should be obtained before using the NESS L300 Plus System on patients who have a structural deformity in the area to be stimulated.
- The safe use of the NESS L300 Plus System during pregnancy has not been established.
- Keep the NESS L300 Plus System out of the reach of children.
- The L300 and Thigh FS Cuffs are to be worn only on the leg of the patient for whom they are fitted. They should not be worn by anyone else or on any other part of the body.
- Skin problems where the L300 and Thigh FS Cuffs are worn may be aggravated by the NESS L300 Plus System.
- Some patients may experience a skin irritation, an allergic reaction, or hypersensitivity to the electrical stimulation or the electrical conductive medium. In some cases, irritation may be avoided by changing the stimulation parameters, type of electrodes used, or electrode placement.
- After removing the L300 and Thigh FS Cuffs, 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. Use of the NESS L300 Plus System should be temporarily halted until any irritation is resolved completely.
- Do not use the NESS L300 Plus System without electrodes.
- Use only electrodes supplied by Bioness Inc.
- Change the electrodes at least every two weeks.
- Only the treating clinician should determine electrode placement and stimulation settings.
- Turn off the NESS L300 Plus System before removing, replacing, and wetting the electrodes.
- Turn off the NESS L300 Plus System before putting on the L300 and Thigh FS Cuffs. Do not turn on the NESS L300 Plus System until the L300 and Thigh FS Cuffs are fastened in place.
- Advise patients to turn off the NESS L300 Plus System before driving, operating machinery, or performing any activity in which involuntary muscle contractions may put the patient at undue risk of injury.
- Advise patients to turn off the NESS L300 Plus System when at a refueling place. They should not use the NESS L300 Plus System near flammable fuel, fumes, or chemicals.
- Advise patients to stop using the NESS L300 Plus System and consult their clinician if stimulation does not start at the correct time during gait.

- Protect all electronic components from contact with water, such as from sinks, bathtubs, shower stalls, rain, snow, etc.
- Do not leave the NESS L300 Plus System stored where temperatures may exceed the acceptable environmental range: -25°C to +55°C (-13°F to +131°F). Temperature extremes can damage the components.
- The NESS L300 Plus 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. See Chapter 3 and the Appendix.
- Do not attempt to repair the NESS L300 Plus System. Changes or modifications to the NESS L300 Plus System components not expressly approved by Bioness Inc could void the user's authority to operate the equipment.

Please call your local distributor, or visit the Bioness website: www.bioness.com/Landing.php?reset, if you experience a clinical or technical problem not covered in this guide.

Adverse Reactions

In the unlikely event that any of the following occurs, advise patients to stop using the NESS L300 Plus System immediately and to consult their physician:

- Signs of significant irritation or pressure sores where the L300 and/or Thigh FS Cuffs contact 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 NESS L300 Plus System electrodes or the L300 and/or Thigh FS Cuffs.

To promote healthy skin with long-term use of the NESS L300 Plus System, it is important that patients follow a daily skin-care routine:

- Clean the skin where the electrodes touch 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 L300 and Thigh FS Cuffs.
- Wet the cloth electrodes before use and after every three to four hours of use.
- Replace the electrodes at least every two weeks, even if they appear to be in good condition.
- Store the L300 hydrogel electrodes with the protective plastic covers attached. Do not allow the hydrogel electrodes to dry.
- Store the cloth electrodes where they can air dry.
- Excess body hair where the L300 hydrogel 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 L300 and Thigh FS Cuffs, make sure the electrodes uniformly contact the skin.
- Ventilate the skin by removing the L300 and Thigh FS Cuffs for at least 15 minutes every 3 to 4 hours.

If skin irritation or a skin reaction occurs, advise patients to stop using the NESS L300 Plus System immediately. They should contact their clinician or dermatologist, and the Bioness Clinical Relations Department, Option 3. Patients should resume use of the L300 Plus System only when the skin is completely healed, and then follow a skin-conditioning protocol per the recommendation of a health-care specialist.

If you have any questions or concerns, please call your local distributor, or visit the Bioness website: www.bioness.com /Landing.php?reset.

Environmental Conditions that Affect Use

Radio Frequency (RF) Communication Information

Several components of the NESS L300 Plus System 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 Plus System.

Conformity Certification

The NESS L300 Plus 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.
2. This device must accept any interference received, including interference that may cause undesired operation.

Travel and Airport Security

The NESS L300 Plus system charger is compatible with Australian, U.K., European Union, and U.S. voltages: 110/220 V, 50/60 Hz.

Patients should turn off the NESS L300 Plus System before going through airport security. They should wear loose clothing so that they can easily show the security person their NESS L300 Plus System. The NESS L300 Plus System will likely set off the security alarm. Patients should be prepared to remove the NESS L300 Plus System so that security can scan it, or to ask for the system to be scanned if they do not want to remove it. They may want to carry a copy of their NESS L300 Plus System prescription. A prescription can be useful when passing through customs as well.

To request a copy of their prescription, patients may call their local distributor or visit the Bioness website: www.bioness.com /Landing.php?reset. A Bioness representative can fax or mail a copy.

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

Electromagnetic Emissions

The NESS L300 Plus 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. See Appendix.

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

- DC power supply as provided by Bioness Inc, manufactured by FRIWO, Part No. FW7555M/05.
- W cable (3-way splitter) as provided by Bioness Inc, Model No. L3P-5A10. Manufactured by Tamuz Electronics Ltd.

The NESS L300 Plus System was tested and certified with the following accessories:

- Clinician's Programmer (PDA): iPAQ 21x provided by HP.
- PDA DC power supply: PSC11R provided by HP.
- Clinician's Programmer Configuration Cradle: provided by Bioness Inc.

Warnings

- Do not use the NESS L300 Plus System within three feet of shortwave or microwave therapy equipment. Such equipment may produce instability in the output of the L300 and Thigh RF Stim Units.
- Advise patients to remove the NESS L300 Plus System before undergoing any diagnostic or therapeutic medical procedure such as x-ray examination, ultrasound, Magnetic Resonance Imaging (MRI), etc.
- The NESS L300 Plus 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 accessories, transducers, and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the NESS L300 Plus System as replacement parts for internal components, may result in increased emissions or decreased immunity of the NESS L300 Plus System.
- 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 Plus System.
- The NESS L300 Plus 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.

The NESS L300 Plus System

The NESS L300 Plus System incorporates the NESS L300 Foot Drop System with a Thigh FS Cuff for stimulation of the quadriceps or hamstrings. The NESS L300 Plus System is designed for individuals with foot drop who require added knee support during gait and who would benefit from therapeutic training of the quadriceps or hamstrings to strengthen knee extension or flexion.

Components of the NESS L300 Plus System are shown in Figure 4-1. The system includes an L300 FS Cuff with RF Stim Unit, a Thigh FS Cuff with RF Stim Unit, an Intelli-Sense Gait Sensor, and an L300 Plus Control Unit. These components communicate wirelessly to provide synchronized ankle dorsiflexion and knee flexion or extension.

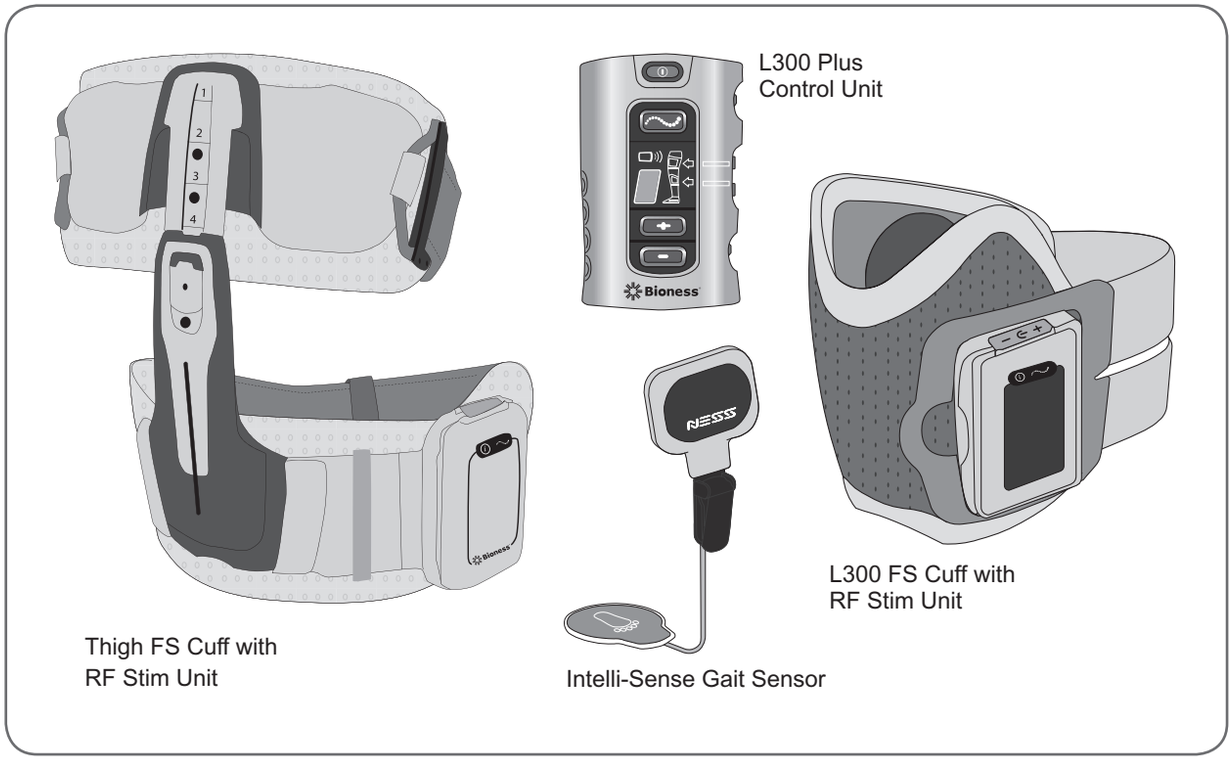


Figure 4-1: The NESS L300 Plus System.

L300 FS Cuff

The L300 FS Cuff is a lightweight, low-profile neuroprosthesis that straps onto the leg directly under the patella. See Figure 4-2. The L300 FS Cuff can easily be worn under clothing and is available in right and left configurations for lower leg circumferences ranging from 29 cm to 51 cm.

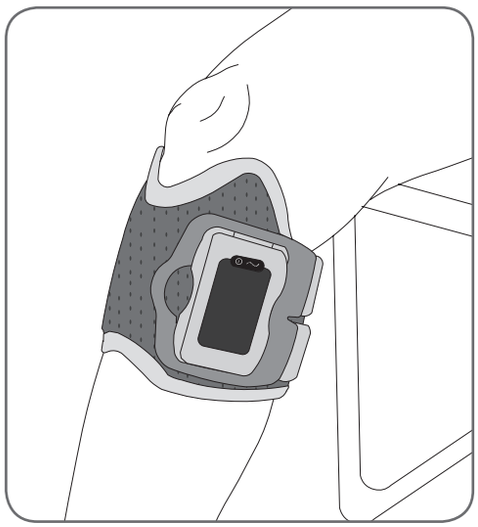


Figure 4-2: L300 FS Cuff, right configuration.

The L300 FS Cuff is used to stimulate the common peroneal nerve (normally found posterior and slightly distal to the head of the fibula) and the motor point of the tibialis anterior muscle. Stimulation produces contraction of the tibialis anterior and peroneal muscles, thus causing balanced dorsiflexion (without excessive inversion or eversion).

Stimulation in the L300 FS Cuff is generated by the attached L300 RF Stim Unit and controlled by the L300 Plus Control Unit and the Intelli-Sense Gait Sensor. Stimulation is delivered by one large electrode or two smaller electrodes positioned on the inside liner of the FS Cuff.

The effectiveness of producing muscle contraction force in the L300 FS Cuff depends on amplitude, duration, frequency, and waveform of the electrical stimulation signal. The clinician can impact the force, efficiency, and timing of the muscle contraction by adjusting stimulation parameters (for example, amplitude) to provide sufficient foot clearance during walking.

The L300 FS Cuff features:

- An L300 RF Stim Unit. See Figure 4-3.
- A cradle for the L300 RF Stim Unit.
- A locator.
- An adjustable strap.
- A liner.
- Three electrode options:
  - Large Cloth Electrode, L300 Systems.
  - L300 Hydrogel Electrodes and Hydrogel Electrode Bases.
  - L300 Cloth Electrodes and Cloth Electrode Bases.

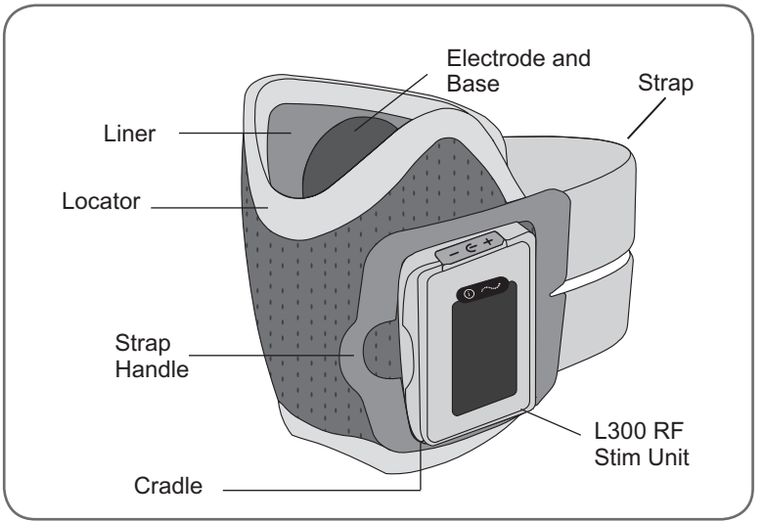


Figure 4-3: L300 FS Cuff.

L300 RF Stim Unit

The L300 RF Stim Unit generates the electrical stimulation used to dorsiflex the foot. It snaps into the cradle of the L300 FS Cuff and responds to wireless signals from the L300 Plus Control Unit and the Intelli-Sense Gait Sensor to turn stimulation on/off.

The L300 RF Stim Unit includes:

- A status light.
- A stimulation light.
- A rechargeable battery.

The battery charging port is located at the top of the L300 RF Stim Unit, under the flexible cover. See Figure 4-4. The NESS L300 Plus System Kit includes a system charger set for charging the L300 RF Stim Unit. Remove the L300 FS Cuff from the leg before charging the L300 RF Stim Unit.

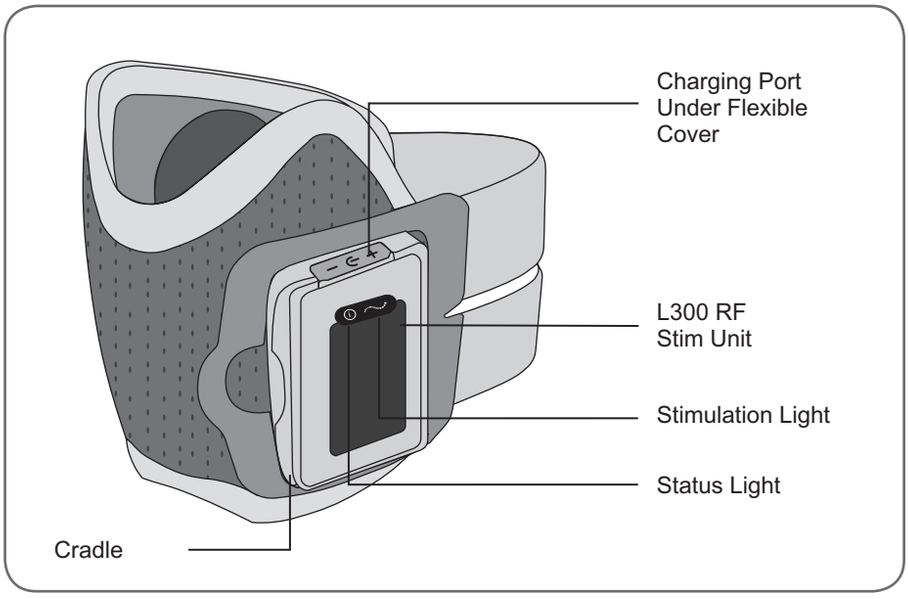


Figure 4-4: L300 RF Stim Unit.

Note: The L300 RF Stim Unit should only be removed from the cradle for maintenance and when cleaning the L300 FS Cuff.

The L300 RF Stim Unit emits visual and audio alerts when:

- Stimulation is on.
- RF communication fails.
- The battery charge level is low.
- The battery is charging.
- The L300 RF Stim Unit malfunctions. See Table 4-1.

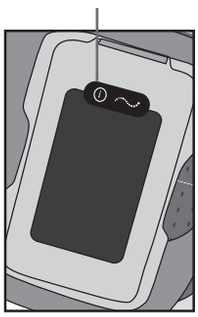
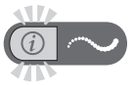
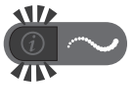
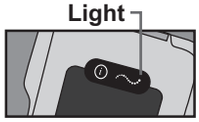
L300 RF Stim Unit	Display	Description	Definition
Status Light 		FLASHES GREEN	System is On
		FLASHES YELLOW	Low Battery
		ALTERNATELY FLASHES YELLOW and GREEN	Battery Charging
		SOLID GREEN	Battery Fully Charged
		FLASHES RED	Radio Communication Failure
		SOLID RED	Malfunction
Stimulation Light 		FLASHES YELLOW SLOWLY	Stimulation is Off
		FLASHES YELLOW RAPIDLY	Stimulation is On

Table 4-1: L300 RF Stim Unit displays.

Cradle

The cradle for the L300 RF Stim Unit is located on the medial side of the L300 FS Cuff. The L300 RF Stim Unit easily snaps in and out of the cradle. See Figure 4-5.

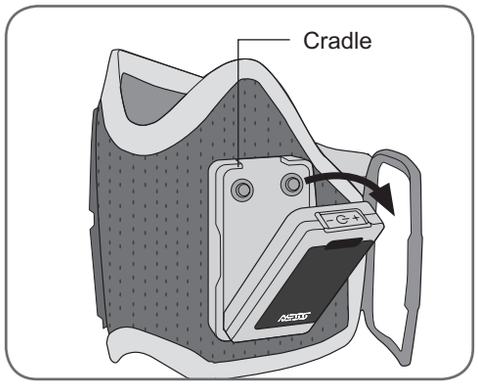


Figure 4-5: RF Stim Unit cradle.

Locator

The L300 FS Cuff locator is used to accurately place the L300 FS Cuff on the leg, thus ensuring accurate placement of the L300 electrode(s). Using one hand, patients can easily slide the locator up the leg, fitting it snugly under the patella. See Figure 4-6.

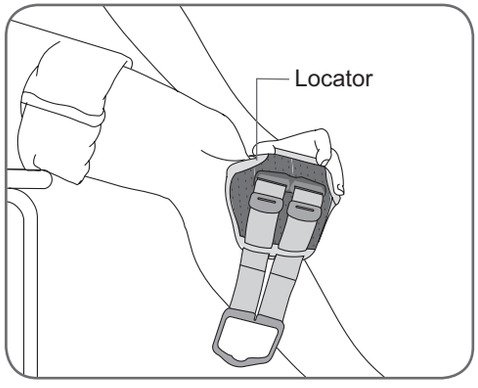


Figure 4-6: Positioning the L300 FS Cuff locator.

Strap

The L300 FS Cuff strap holds the L300 FS Cuff on the lower leg. The strap wraps around the leg and fastens around the L300 RF Stim Unit cradle The L300 FS Cuff strap is available in three sizes: small, medium, and large. The strap is removable, replaceable, and washable. See Figure 4-7.

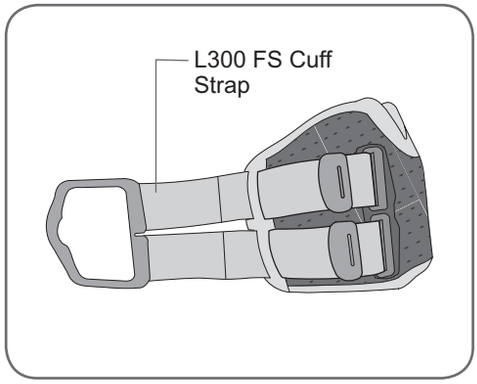


Figure 4-7: L300 FS Cuff strap.

Liner

The liner is for attaching the L300 electrode(s) and wire concealers to the L300 FS Cuff. See Figure 4-8.

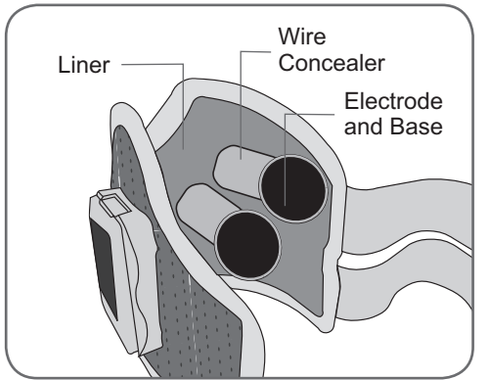


Figure 4-8: L300 FS Cuff liner.

Electrode Options

The L300 electrodes deliver the stimulation generated by the L300 RF Stim Unit to dorsiflex the foot.

The following electrodes may be used with the L300 FS Cuff:

- Large Cloth Electrode, L300 Systems. See Figure 4-9.
- L300 Hydrogel Electrodes and Hydrogel Electrode Bases.
- L300 Cloth Electrodes and Cloth Electrode Bases.

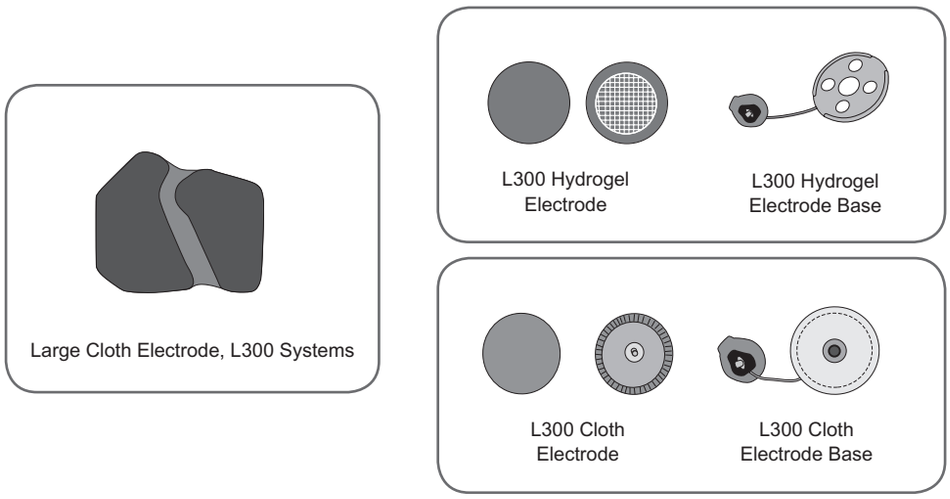


Figure 4-9: L300 electrodes and bases.

Large Cloth Electrode, L300 Systems

The large cloth electrode, L300 systems, snaps to the plug holes of the L300 FS Cuff. See Figure 4-10. One large cloth electrode is used. No base is required.

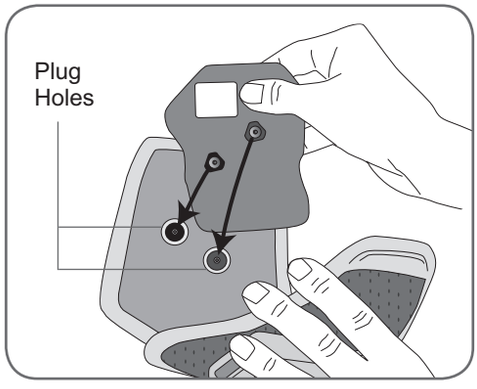


Figure 4-10: Snapping the large cloth electrode to the L300 FS Cuff plug holes.

L300 Hydrogel Electrodes and Bases

The L300 FS Cuff uses two hydrogel electrodes and two hydrogel electrode bases. The L300 hydrogel electrode bases snap to the plug holes of the L300 FS Cuff. See Figure 4-11.

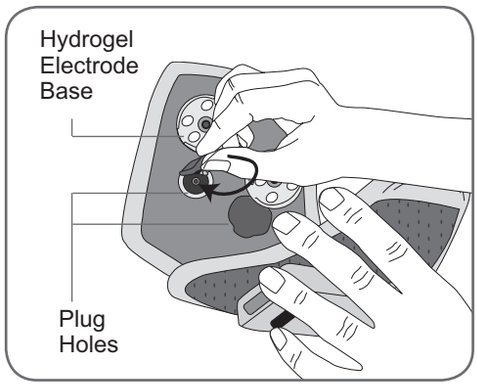


Figure 4-11: Snapping the L300 hydrogel electrode bases to the L300 FS Cuff plug holes.

The L300 hydrogel electrodes adhere to the hydrogel electrode bases. See Figure 4-12.

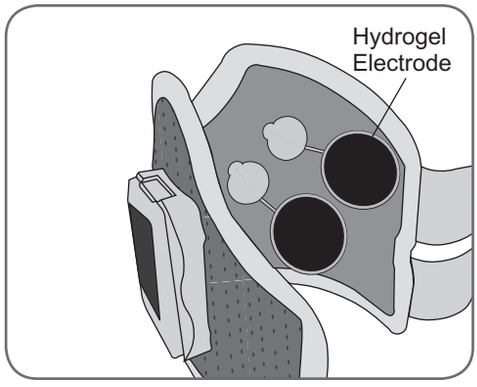


Figure 4-12: L300 hydrogel electrodes adhered to the bases.

L300 Cloth Electrodes and Bases

The L300 FS Cuff uses two cloth electrodes and two cloth electrode bases. The L300 cloth electrode bases snap to the plug holes of the L300 FS Cuff. The L300 cloth electrodes snap to the L300 cloth electrode bases. See Figure 4-13.

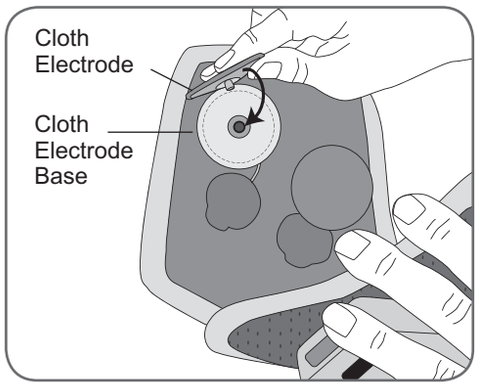


Figure 4-13: Snapping the L300 cloth electrodes to the L300 cloth electrode bases.

Thigh FS Cuff

The Thigh FS Cuff is a lightweight neuroprosthesis that straps onto the hamstrings or quadriceps to assist with knee flexion or extension. See Figures 4-14. The Thigh FS Cuff can easily be worn under a loose pant leg and is available in left and right configurations, in two sizes: regular and large.

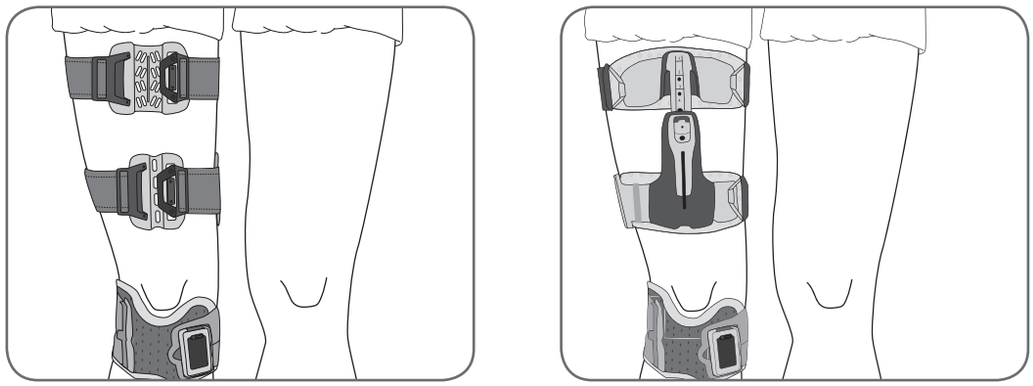


Figure 4-14: Thigh FS Cuff on the hamstrings (left) and quadriceps (right).

The Thigh FS Cuff is used to stimulate the tibial and common fibular (peroneal) portions of the sciatic nerve to contract the hamstrings or the femoral nerve to contract the quadriceps.

Stimulation in the Thigh FS Cuff is generated by the attached Thigh RF Stim Unit and controlled by wireless communication with the L300 Plus Control Unit and the Intelli-Sense Gait Sensor. Stimulation is delivered by two surface electrodes positioned on the inside of the Thigh FS Cuff.

The effectiveness of eliciting muscle contraction force in the Thigh FS Cuff depends on amplitude, duration, frequency, and waveform of the electrical stimulation signal. The clinician can impact the force, efficiency, and timing of the muscle contraction by adjusting stimulation parameters to provide sufficient knee flexion or extension during walking. The clinician may also adjust the orientation of the distal cloth electrode.

The Thigh FS Cuff features:

- A proximal and distal panel. See Figure 4-15.
- An adjustable elongation bar.
- A Thigh RF Stim Unit.
- A cradle for the Thigh RF Stim Unit.
- A locator.
- Adjustable straps.
- Two Thigh cloth electrodes.

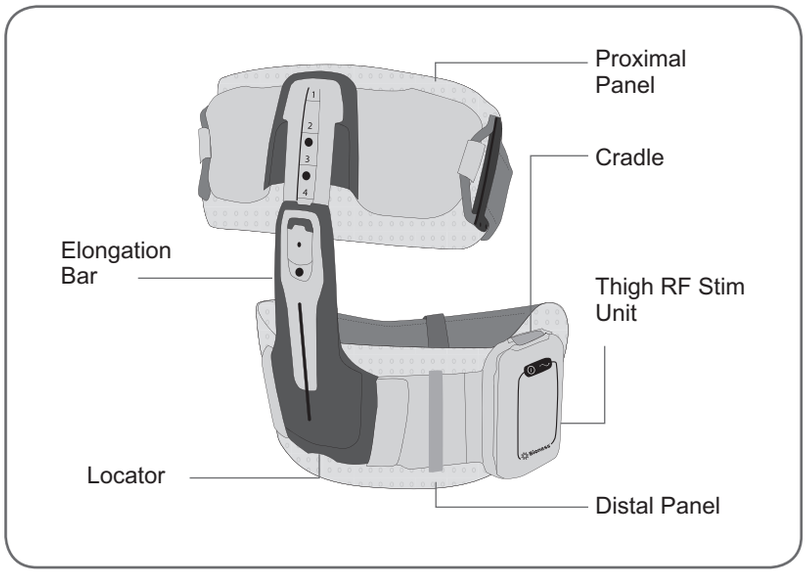


Figure 4-15: Thigh FS Cuff.

Proximal and Distal Panels

The Thigh FS Cuff proximal and distal panels have a removable silicone panel and two snaps for attaching the Thigh cloth electrodes. See Figure 4-16.

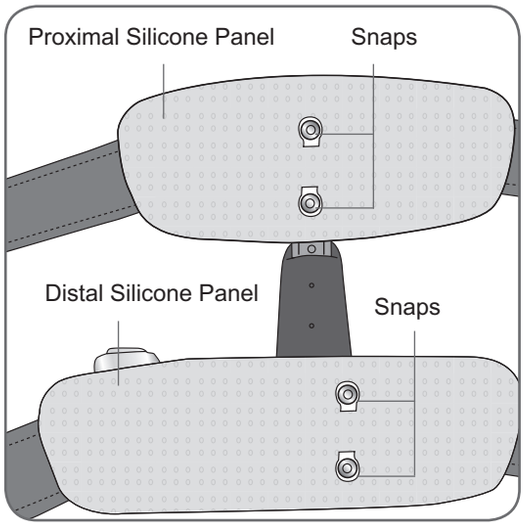


Figure 4-16: Thigh FS Cuff proximal and distal panels.

Elongation Bar

The Thigh elongation bar is used to adjust the distance between the Thigh FS Cuff proximal and distal panels. The elongation bar slides together or apart and has six adjustment holes. See Figure 4-17.

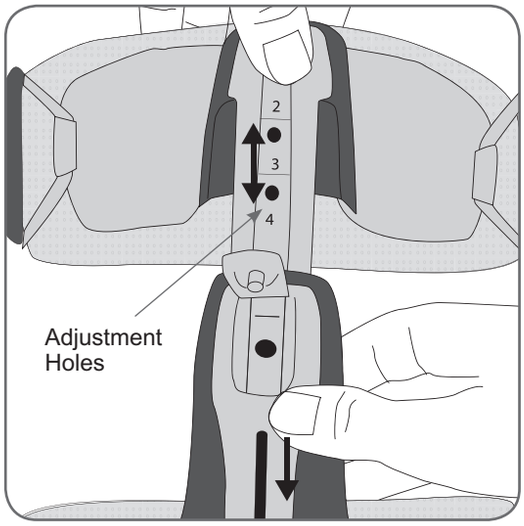


Figure 4-17: Thigh elongation bar.

Thigh RF Stim Unit

The Thigh RF Stim Unit generates the electrical stimulation used to flex or extend the knee. It snaps into the cradle of the Thigh FS Cuff, and responds to wireless signals from the L300 Plus Control Unit and Intelli-Sense Gait Sensor to turn stimulation on and off.

The Thigh RF Stim Unit includes:

- A status light.
- A stimulation light.
- A rechargeable battery.

The battery charging port is located at the top of the Thigh RF Stim Unit, under the flexible cover. See Figure 4-18. The NESS L300 Plus System Kit includes a system charger set for charging the Thigh RF Stim Unit. Remove the Thigh FS Cuff from the leg before charging the Thigh RF Stim Unit.

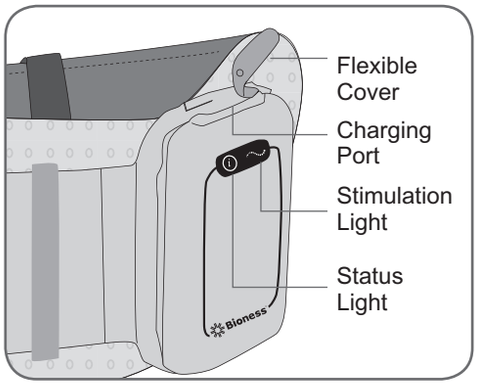


Figure 4-18: Thigh RF Stim Unit.

Note: The Thigh RF Stim Unit should only be removed from the cradle for maintenance and when cleaning the Thigh FS Cuff.

The Thigh RF Stim Unit emits visual and/or audio alerts when:

- Stimulation is on.
- RF communication fails.
- The battery charge level is low.
- The battery is charging
- The Thigh RF Stim Unit malfunctions. See Table 4-2.

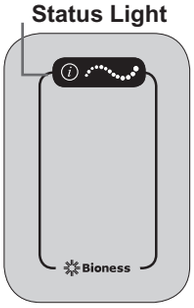
Thigh RF Stim Unit	Display	Description	Definition
Status Light 		FLASHES GREEN	System is On
		FLASHES YELLOW	Low Battery
		ALTERNATELY FLASHES YELLOW and GREEN	Battery Charging
		SOLID GREEN	Battery Fully Charged
		FLASHES RED	Radio Communication Failure
		SOLID RED	Malfunction
Stimulation Light 		FLASHES YELLOW SLOWLY	Stimulation is Off
		FLASHES YELLOW RAPIDLY	Stimulation is On

Table 4-2: Thigh RF Stim Unit displays.

Cradle

The cradle for the Thigh RF Stim Unit is located on the Thigh FS Cuff distal panel. The Thigh RF Stim Unit easily snaps in and out of the cradle. See Figure 4-19.

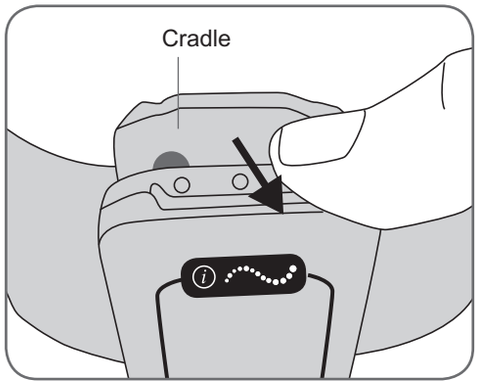


Figure 4-19: RF Stim Unit cradle.

Thigh Clinic Straps

The Thigh clinic straps are removable, replaceable, and adjustable. See Figure 4-20. The smooth side of the strap faces the patient's skin.

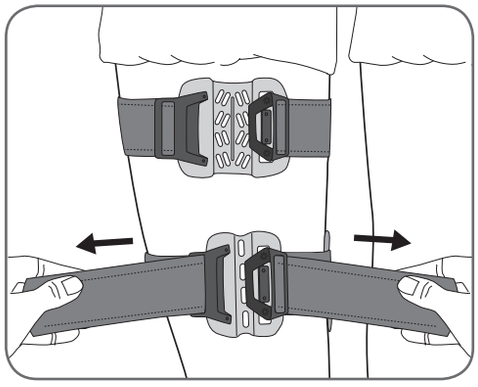


Figure 4-20: Thigh clinic straps.

Locator

The Thigh FS Cuff locator is used to accurately position the Thigh FS Cuff on the leg, to ensure repeatable electrode positioning. When the Thigh FS Cuff is correctly positioned, the locator is in line with the center of the patella (quadriceps) or the popliteal fossa (hamstrings), three finger widths proximal from the knee. See Figure 4-21.

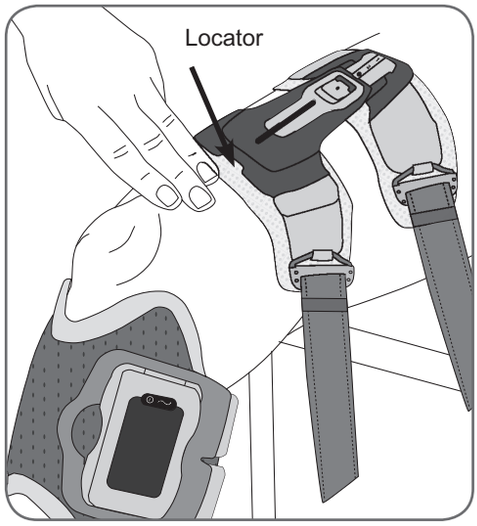


Figure 4-21: Thigh FS Cuff locator correctly positioned on the quadriceps.

Thigh Cloth Electrodes

The Thigh FS Cuff uses two cloth electrodes. The electrodes snap to the Thigh proximal and distal panels. See Figure 4-22.

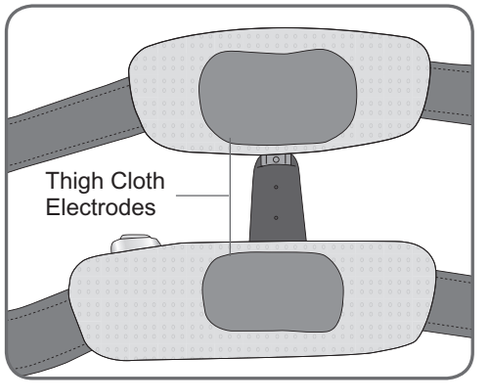


Figure 4-22: Thigh cloth electrodes attached to the Thigh FS Cuff.

Intelli-Sense Gait Sensor

The Intelli-Sense Gait Sensor detects heel events when the L300 Plus System is used for walking. The Intelli-Sense Gait Sensor wirelessly signals the L300 RF Stim Unit and the Thigh RF Stim Unit to synchronize movement of the foot and knee according to the gait cycle. See Figure 4-23.

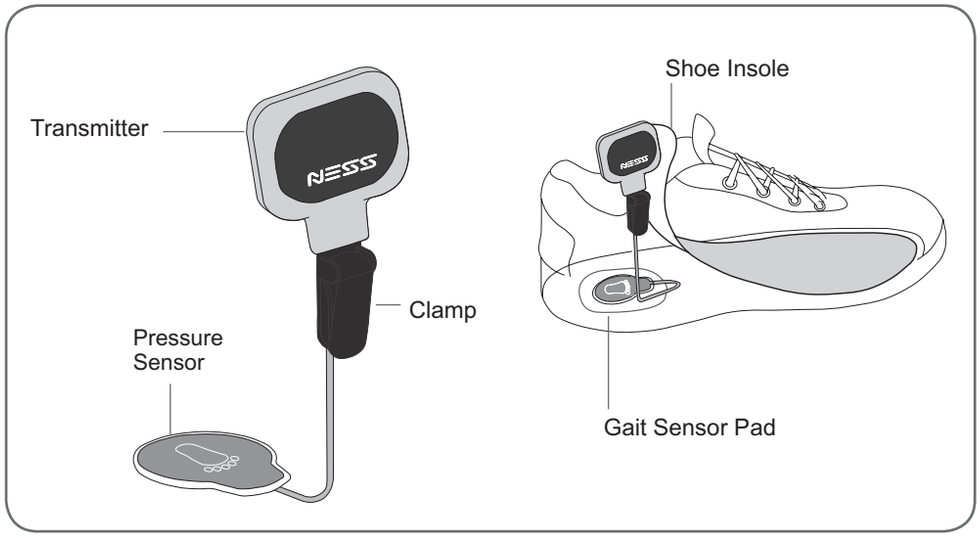


Figure 4-23: The Intelli-Sense Gait Sensor in a left shoe.

The Intelli-Sense Gait Sensor features a pressure sensor and a transmitter. The pressure sensor is worn under the insole of the shoe of the affected leg, attached to a Gait Sensor pad. The transmitter is worn clamped to the inner rim of the shoe.

The Intelli-Sense Gait Sensor can be transferred to a different shoe, or additional Intelli-Sense Gait Sensors can be purchased for different shoes. There is no 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 may need to be replaced after approximately six months of use.

L300 Plus Control Unit

The L300 Plus Control Unit is used to:

- Turn on/off the NESS L300 Plus System.
- Test the position of the L300 and Thigh FS Cuffs.
- Select an operating mode (gait, training, standby, or clinician).
- Adjust stimulation intensity.
- Mute/un-mute system audio/visual alerts.
- Turn on/off audio feedback during stimulation.
- Monitor system status.

The L300 Plus Control Unit communicates wirelessly with the L300 RF Stim Unit, the Thigh RF Stim Unit, and the Intelli-Sense Gait Sensor. It is powered by a single rechargeable AAA NiMH battery that is easily replaced.

The NESS L300 Plus System Kit includes a system charger set for charging the L300 Plus Control Unit. It also includes a belt pouch, wrist strap, and neck strap for carrying the L300 Plus Control Unit.

Operating Buttons

The L300 Plus Control Unit operating buttons are illustrated in Figure 4-24 and described in Table 4-3.

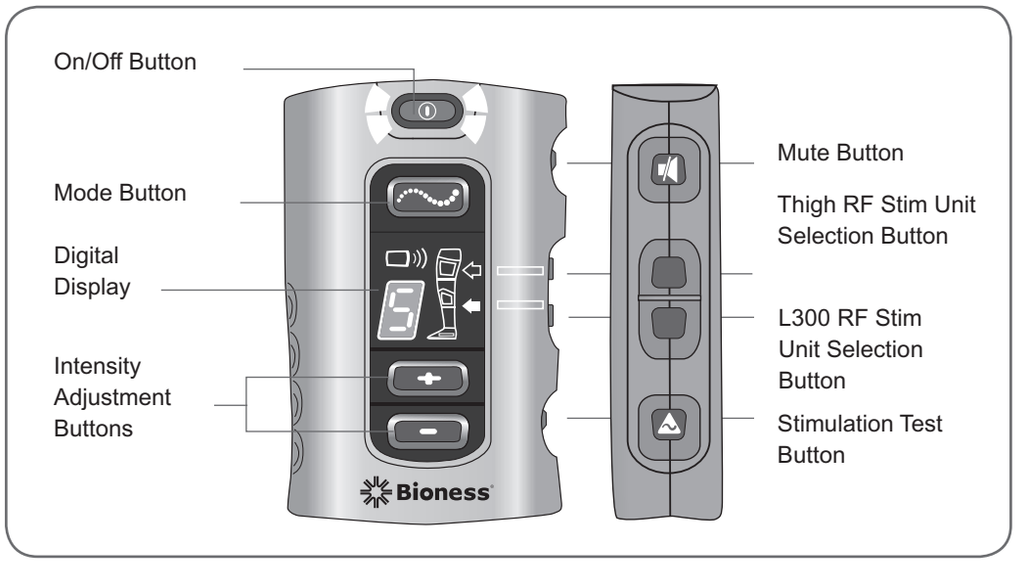


Figure 4-24: L300 Plus Control Unit.

Turning On/Off the NESS L300 Plus System

1. Press the on/off button on the L300 Plus Control Unit once.

The L300 Plus 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 then FLASH GREEN to indicate the system is on.

Testing the Position of the FS Cuffs

L300 FS Cuff

1. Place the L300 Plus Control Unit in standby mode.
2. Press the L300 RF Stim Unit selection button.
3. Press and hold the stimulation test button. The L300 RF Stim Unit will stimulate until the stimulation test button is released.

L300 Plus Control Unit	Operating Button	Description	Function
		On/Off	Turns On/Off the System
		Mode	Selects Standby, Gait, or Training Mode
		Intensity Adjustment	Increases Stimulation Intensity Decreases Stimulation Intensity
		RF Stim Unit Selection	Top: Selects the Thigh RF Stim Unit. Bottom: Selects the L300 RF Stim Unit
		Mute	Mutes/Un-Mutes the Control Unit Audio Alerts; Mutes the Audio/Visual Alerts in the Selected RF Stim Unit; Turns On/Off Audio Feedback During Stimulation
		Stimulation Test	Tests the Position of the FS Cuffs

Table 4-3: L300 Plus Control Unit operating buttons.

Thigh FS Cuff

1. Place the L300 Plus Control Unit in standby mode.
2. Press the Thigh RF Stim Unit selection button.
3. Press and hold the stimulation test button. The Thigh RF Stim Unit will stimulate until the stimulation test button is released.

Selecting an Operating Mode

The L300 Plus Control Unit has four operating modes: gait, training, standby, and clinician.

Gait Mode

Gait mode is used when walking. In gait mode, the Intelli-Sense Gait Sensor signals heel-off and heel-strike events to the L300 and Thigh RF Stim Units. Stimulation in the L300 and Thigh RF Stim Units responds as programmed.

To select gait mode:

1. Turn on the L300 Plus System.
2. Press the mode button *briefly.* The L300 Plus Control Unit will beep and the mode button will start FLASHING YELLOW SLOWLY (stimulation is off). When stimulation is on, the mode button will FLASH YELLOW RAPIDLY.

Training Mode

Training mode is used to train the muscles when not walking (for example, sitting or lying down). Training mode works independently of the Intelli-Sense Gait Sensor. Stimulation is delivered in cycles pre-set by the clinician.

Training mode is designed to:

- Facilitate muscle re-education.
- Prevent or retard disuse atrophy of the lower leg and thigh muscles.
- Maintain or improve range of motion of the ankle and knee joints.
- Improve local blood circulation.

To select training mode:

1. Turn on the L300 Plus System.
2. Press and *hold* the mode button until the L300 Plus Control Unit beeps, the mode button starts FLASHING YELLOW SLOWLY, 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

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

To return to standby mode from gait or training mode:

1. Press the  FLASHING YELLOW mode button briefly. The L300 Plus Control Unit will beep, and the  mode button will stop flashing.

Note: The L300 and Thigh FS Cuffs may be worn individually in training mode. When only one FS Cuff is worn, the NESS L300 Plus System will emit a faulty electrode contact alert. The visual and audio alerts can be turned off temporarily by pressing the RF Stim Unit selection button and then holding the mute button for three seconds. The visual and audio alerts will be restored with the system is turned on.

Clinician Mode

Clinician mode is used to manually start and stop stimulation in the Thigh RF Stim Unit and L300 RF Stim Unit simultaneously. Clinician mode uses the stimulation parameters set for gait mode.

To enter clinician mode:

1. Make sure the L300 Plus System is turned off.
2. Press and hold the  minus button
3. Press the  on/off button briefly. The L300 Plus Control Unit will beep twice and the  mode button will start FLASHING YELLOW SLOWLY. The digital display will alternately show  (“C” for Clinician) and the intensity level.

To apply stimulation in clinician mode:

1. Continuously press the mode button. While stimulation is on, the  mode button FLASHES YELLOW RAPIDLY.

To stop stimulation in clinician mode:

1. Release the mode button.

To exit clinician mode:

1. Press the  on/off button briefly.

Adjusting Stimulation Intensity

L300 FS Cuff

1. Press the L300 RF Stim Unit selection button.
2. Then press the plus or minus button to change the intensity level. The L300 Plus Control Unit will beep with each change in level. The new level will show in the digital display.

Thigh FS Cuff

1. Press the Thigh RF Stim Unit selection button.
2. Then press the plus or minus button to change the intensity level. The L300 Plus 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.

Note: The default stimulation intensity level will be restored when the L300 Plus System is turned on.

Muting/Un-Muting the Control Unit

The L300 Plus Control Unit beeps to indicate that the system is on, a button was pressed, low battery, or an error has occurred.

To mute the L300 Plus Control Unit:

1. Press the mute button briefly.

Muting the RF Stim Units

To communicate wirelessly, the NESS L300 Plus Control Unit, L300 RF Stim Unit, Thigh RF Stim Unit, and Intelli-Sense Gait Sensor must be within RF communication range of each other. If the components become separated, RF communication will be lost and the system will emit an RF communication failure alert.

If an RF Stim Unit is affected, the RF Stim Unit status light will FLASH RED and the RF Stim Unit will emit an audio alert. In addition, the L300 Plus Control Unit will emit an RF communication error alert.

To mute the alerts for the L300 RF Stim Unit:

1. Place the L300 Plus Control Unit in standby mode.
2. Press and release the L300 RF Stim Unit selection button.
3. Press and hold the mute button for three seconds.

To mute the alerts for the Thigh RF Stim Unit:

1. Place the L300 Plus Control Unit in standby mode.
2. Press and release the Thigh RF Stim Unit selection button.
3. Press and hold the mute button for three seconds.

Note: The default settings will be restored when the L300 Plus System is turned on.

Turning On Audio Feedback During Stimulation

L300 FS Cuff

1. Place the L300 Plus Control Unit in standby mode.
2. Press and hold the L300 RF Stim Unit selection button.
3. Press the mute button for three seconds.

Thigh FS Cuff

1. Place the L300 Plus Control Unit in standby mode.
2. Press and hold the Thigh RF Stim Unit selection button.
3. Press the mute button for three seconds.

Turning Off Audio Feedback During Stimulation

1. Select the RF Stim Unit and press the mute button
2. Or press the on/off button.

Digital Display and Indicator Lights

The L300 Plus Control Unit digital display and indicator lights indicate:

- Stimulation intensity level.
- Operating mode.
- RF Stim Unit selected.
- Component battery charge status.
- Electronic registration status.
- Error messages.

The L300 Plus Control Unit digital display and indicators are illustrated in Figure 4-25. The visual displays are described in Tables 4-4 to 4-9.

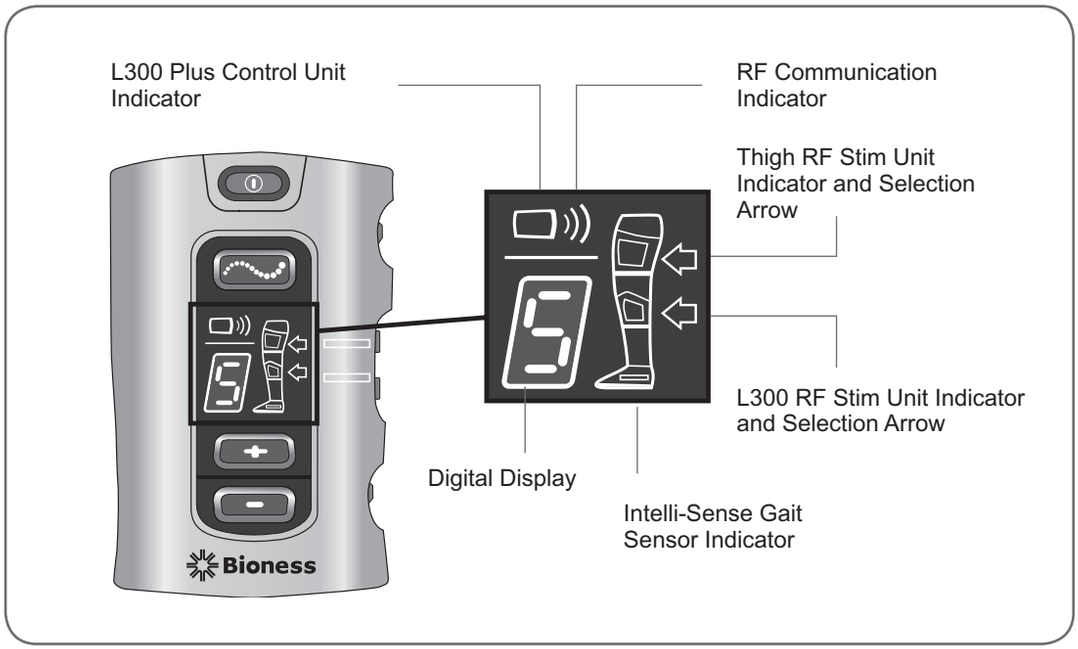


Figure 4-25: L300 Plus Control Unit digital display and indicators.

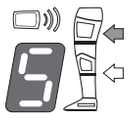
Display	Description	Definition
	On/Off Button FLASHES GREEN	System is On
	Mode Button FLASHES YELLOW SLOWLY	Stimulation is Off
	Mode Button FLASHES YELLOW RAPIDLY	Stimulation is On
	Displays 0–9	Stimulation Intensity Level
	Intensity Level and Letter “t” Alternate	Training Mode is On
	GREEN Arrow by Thigh RF Stim Unit	Thigh RF Stim Unit Selected
	GREEN Arrow by L300 RF Stim Unit	L300 RF Stim Unit Selected

Table 4-4: L300 Plus Control Unit operational displays.

Display	Description	Definition
	ROTATING GREEN Circle	L300 Plus Control Unit Charging
	Horizontal GREEN Line	L300 Plus Control Unit Fully Charged
	Letter "E" FLASHES while Charging	Charging Error

Table 4-5: L300 Plus Control Unit charging displays.

Display	Description	Definition
	Thigh RF Stim Unit Indicator FLASHES RED	Faulty Electrode Contact in Thigh FS Cuff
	L300 RF Stim Unit Indicator FLASHES RED	Faulty Electrode Contact in L300 FS Cuff
	Thigh RF Stim Unit Indicator is SOLID RED	Thigh RF Stim Unit Software or Hardware Malfunction
	L300 RF Stim Unit Indicator is SOLID RED	L300 RF Stim Unit Software or Hardware Malfunction
	L300 Plus Control Unit Indicator is SOLID RED	L300 Plus Control Unit Software or Hardware Malfunction
	Gait Sensor Indicator is SOLID RED	Intelli-Sense Gait Sensor Software or Hardware Malfunction

Table 4-6: L300 Plus Control Unit error displays.

Display	Description	Definition
	ALTERNATING GREEN Arches	Registration is in Process
	Letter "C"	Registration is Complete
	Letter "E"	Registration Error

Table 4-7: L300 Plus Control Unit electronic registration displays.

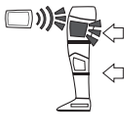
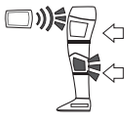
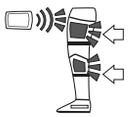
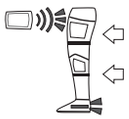
Display	Description	Definition
	Thigh RF Stim Unit Indicator and RF Communication Indicator ALTERNATELY FLASH RED	RF Communication Failure, Thigh RF Stim Unit
	L300 RF Stim Unit Indicator and RF Communication Indicator ALTERNATELY FLASH RED	RF Communication Failure, L300 RF Stim Unit
	Thigh RF Stim Unit, L300 RF Stim Unit, and RF Communication Indicators ALTERNATELY FLASH RED	RF Communication Failure, L300 and Thigh RF Stim Units
	Intelli-Sense Gait Sensor Indicator and RF Communication Indicator ALTERNATELY FLASH RED	RF Communication Failure, Intelli-Sense Gait Sensor

Table 4-8: L300 Plus Control Unit RF communication error displays.

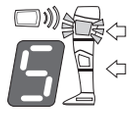
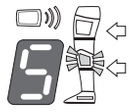
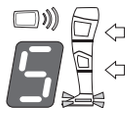
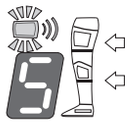
Display	Description	Definition
	Thigh RF Stim Unit Indicator FLASHES YELLOW	Thigh RF Stim Unit Low Battery
	L300 RF Stim Unit Indicator FLASHES YELLOW	L300 RF Stim Unit Low Battery
	Intelli-Sense Gait Sensor Indicator FLASHES YELLOW	Intelli-Sense Gait Sensor Low Battery
	L300 Plus Control Unit Indicator FLASHES YELLOW	L300 Plus Control Unit Low Battery

Table 4-9: L300 Plus Control Unit low battery displays.

Clinician’s Components and Accessories

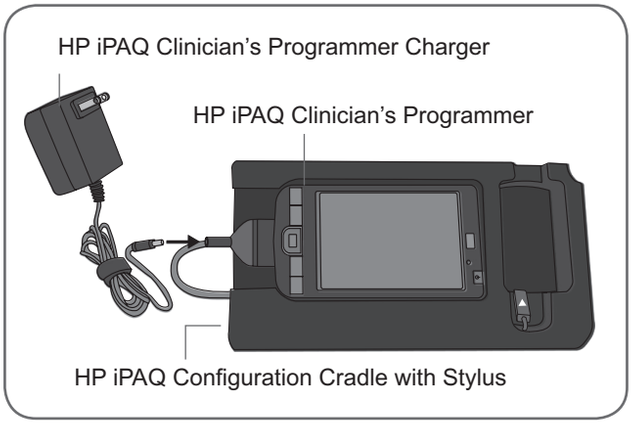
L300 Clinician’s Kit

PDA Components

- HP iPAQ Clinician’s Programmer
- HP iPAQ Configuration Cradle with Stylus
- HP iPAQ Clinician’s Programmer Charger

Accessories

- L300 FS Cuff Straps
- Personal Panels
- Personal Strap Covers
- L300 Hydrogel Electrodes and Bases
- L300 Cloth Electrodes and Bases
- Fitting Cable
- Tester, L300 systems
- Wire Concealers
- Replacement Battery, Gait Sensor
- Gait Sensor Pads
- Shoe Spacers
- Clinical Scissors
- Shoe Horn
- Tape Measure
- Phillips Screwdriver
- Marking Pen
- Personal Panel Storage System
- Bolster



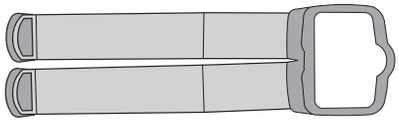
L300 Plus Clinician’s Pack w/ Software

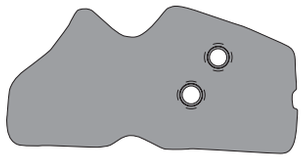
- L300 Plus Intelli-Gait Software*
- Thigh Clinic Strap Set
- Thigh Home Strap Set*
- Thigh Cloth Electrodes
- Thigh Cuff Buckles
- Thigh Elongation Bar Locks
- Thigh Electrode Marking Rings
- L300 Plus *Clinician’s Guide*
- Clinician’s Reference Card

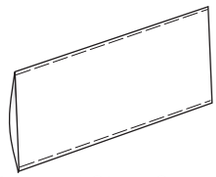
*Not illustrated.

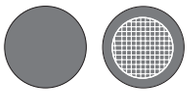
Note: The L300 Plus System is compatible with L300 Dell PDA components.

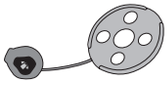
L300 Clinician's Kit

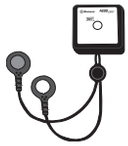

L300 FS Cuff Strap


Personal Panel

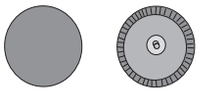

Personal Strap Cover

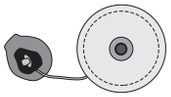

L300 Hydrogel Electrode

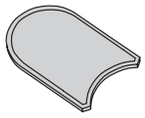

L300 Hydrogel Electrode Base


Tester, L300 Systems

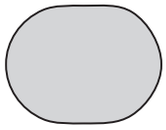

Fitting Cable

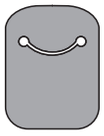

L300 Cloth Electrode


L300 Cloth Electrode Base


Wire Concealer

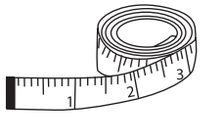
Replacement Battery, Gait Sensor


Gait Sensor Pad


Shoe Spacer


Clinical Scissors


Shoe Horn



Tape Measure

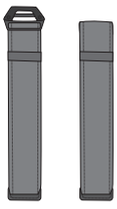

Phillips Screwdriver

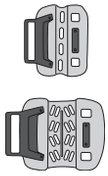

Marking Pen

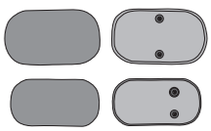

Personal Panel Storage System

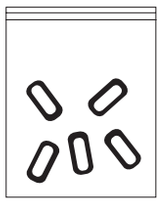
Bolster

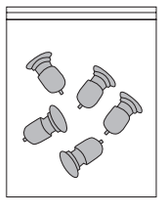
L300 Plus Clinician's Pack w/Software


Thigh Clinic Strap Set


Thigh Cuff Buckles


Thigh Cloth Electrodes


Thigh Electrode Marking Rings


Thigh Elongation Bar Locks

PDA Components and Setup

The descriptions in this section are for the L300 HP iPAQ clinician's programming components. The NESS L300 Plus System is also compatible with the L300 Dell clinician's programming components.

HP iPAQ Clinician’s Programmer

The HP iPAQ Clinician’s Programmer is a portable personal digital assistant (PDA) used to program the NESS L300 Plus System. When connected to the HP iPAQ Configuration Cradle and the L300 Plus Control Unit, the Clinician’s Programmer can wirelessly communicate with the L300 RF Stim Unit and the Thigh RF Stim Unit. See Figure 6-1.

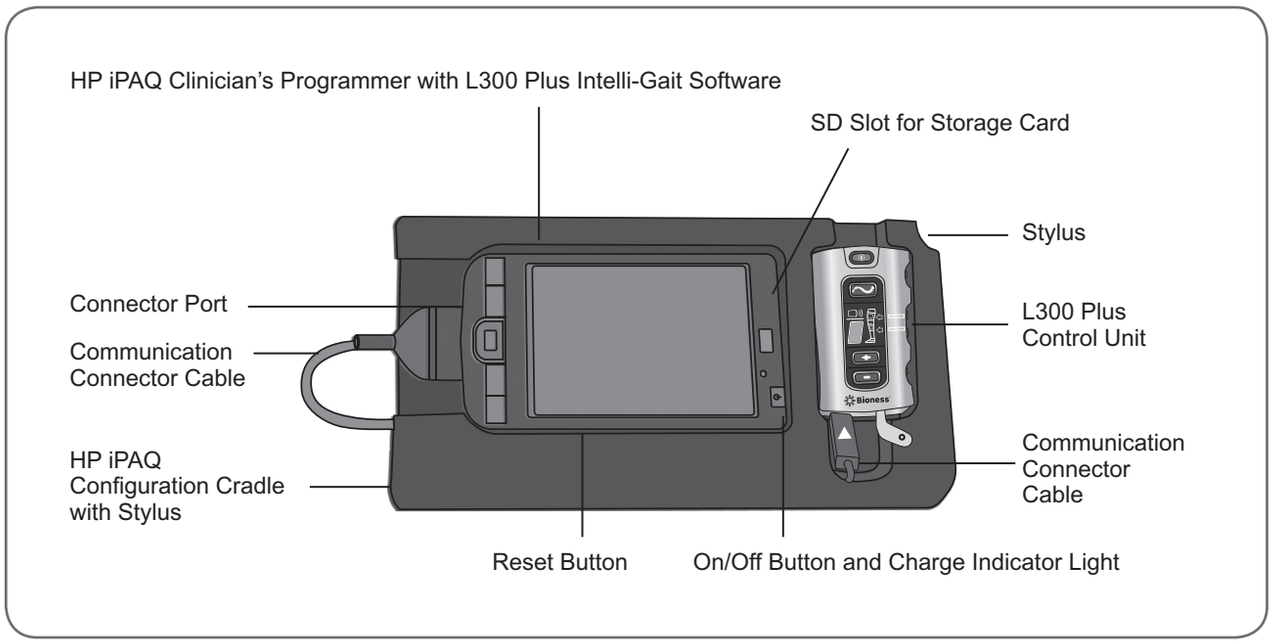


Figure 6-1: PDA components with L300 Plus Control Unit connected.

On/Off Button

The on/off button is used to turn on/off the Clinician's Programmer.

Reset Button

The reset button is used to soft reset the Clinician's Programmer.

Charge Indicator Light

The charge indicator light is AMBER when the Clinician's Programmer is charging and GREEN when the Clinician's Programmer battery charge is complete.

SD (Secure Digital) Slot

The SD slot is for an SD card, used to back up patient information.

Battery

The HP iPAQ Clinician's Programmer contains a removable/rechargeable 2200 mAh Lithium-Ion battery.

WARNING: Risk of explosion if battery is replaced with an incorrect type. Dispose of used batteries according to local regulation.

Touchscreen Display

The touchscreen display is used to navigate the NESS L300 Plus Intelli-Gait Software, display system status, and enter data. Use the pointed end of the stylus to make contact with the display screen. Use only the stylus.

Connector Port

The connector port is used to connect the HP iPAQ Clinician's Programmer with the communication connector cable on the HP iPAQ Configuration Cradle.

WARNING: The Clinician's Programmer should only contain the Windows Mobile® operating system and Bioness Inc proprietary software. Third-party software packages are not supported and may interfere with proper operation of the NESS L300 Plus System, thus voiding the warranty.

HP iPAQ Configuration Cradle with Stylus

The HP iPAQ Configuration Cradle with Stylus is used to connect the HP iPAQ Clinician's Programmer to the L300 Plus Control Unit and to the HP iPAQ Clinician's Programmer Charger. While the Clinician's Programmer is connected to the L300 Plus Control Unit, it communicates via the L300 Plus Control Unit with the L300 RF Stim Unit and the Thigh RF Stim Unit. The stylus is used for software navigation.

HP iPAQ Clinician's Programmer Charger

The HP iPAQ Clinician's Programmer Charger is used to recharge the HP iPAQ Clinician's Programmer battery. Use only the Clinician's Programmer Charger included in the NESS L300 Clinician's Kit. See Figure 6-2.

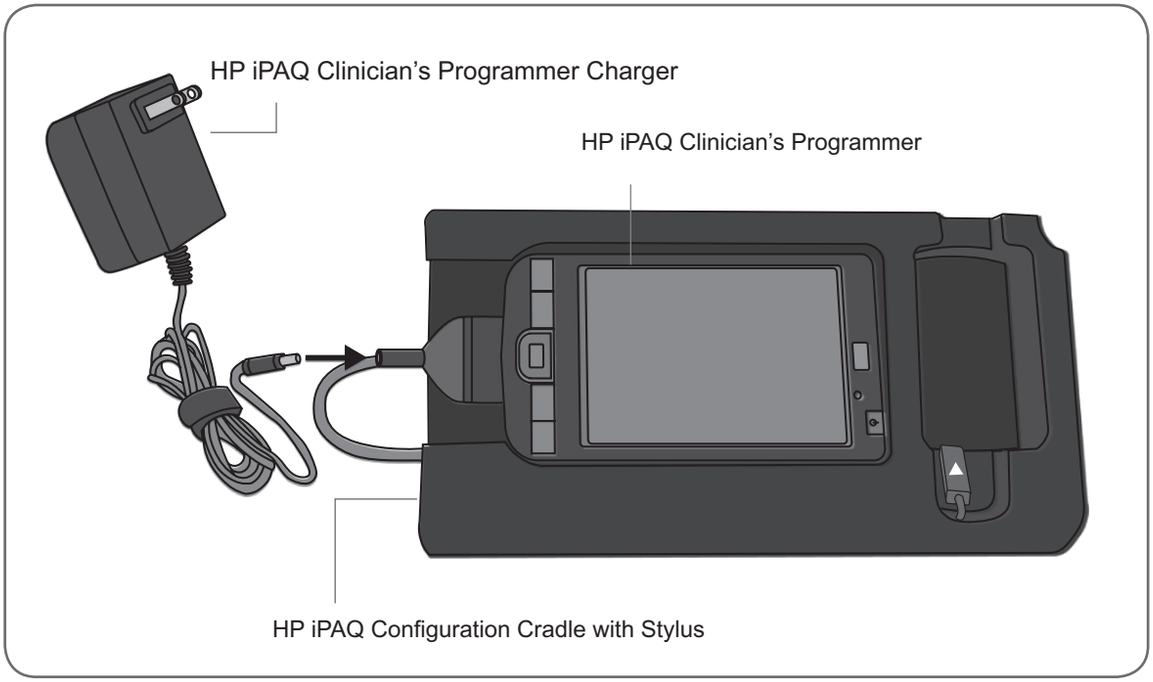


Figure 6-2: Connecting the HP iPAQ Clinician's Programmer Charger.

WARNING: Use only the Clinician's Programmer Charger included in the NESS L300 Clinician's Kit.

Programming Setup

Orient the Clinician's Programmer in the Configuration Cradle with the touchscreen facing up and the connector port facing left. See Figure 6-3.

1. Plug the communication connector cable with charger adapter into the connector port.

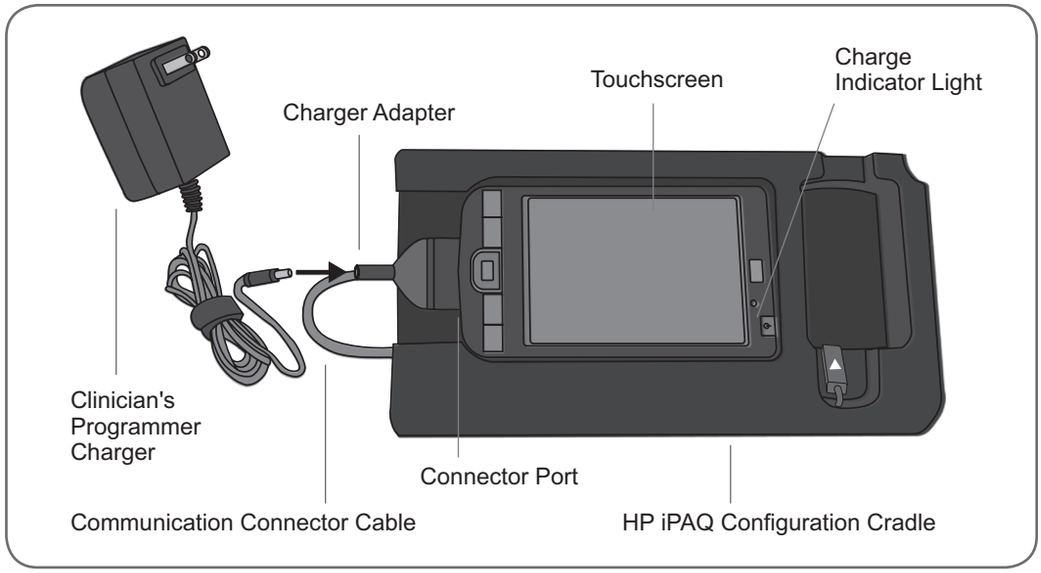


Figure 6-3: Clinician's Programmer setup and charging configuration.

To charge the Clinician's Programmer:

1. Connect the Clinician's Programmer Charger to the charger adapter. See Figure 6-3.
2. Plug the Clinician's Programmer Charger into a power socket.
3. Allow the Clinician's Programmer to charge. The Clinician's Programmer can take two to four hours to charge. When the Clinician's Programmer is fully charged, the charge indicator light will be GREEN.

To connect the L300 Plus Control Unit:

1. Turn off the L300 Plus Control Unit, or place it in standby mode.
2. Plug the communication connector cable into the connector port of the L300 Plus Control Unit. The white arrow should be facing up. See Figure 6-4.
3. Insert the L300 Plus Control Unit into the Configuration Cradle.

CAUTION: Turn off the L300 Plus Control Unit or place it in standby mode before connecting it to the Configuration Cradle.

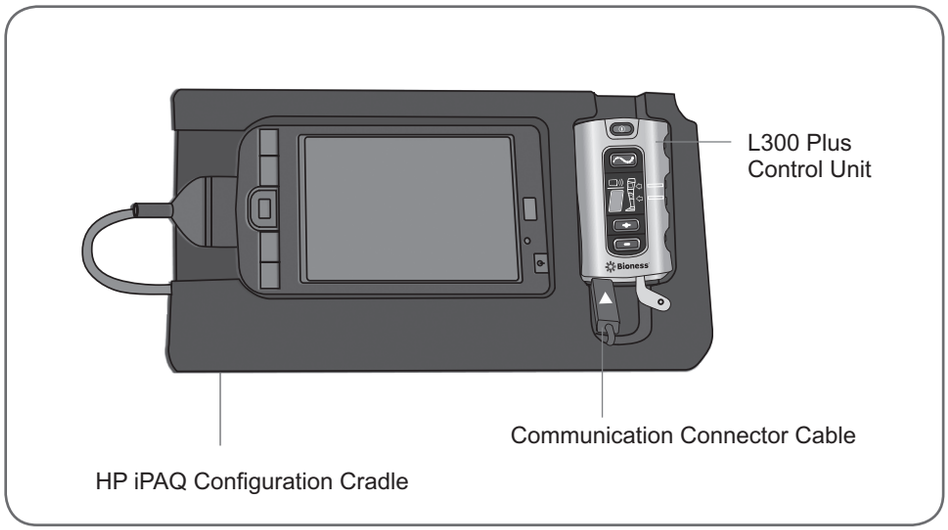


Figure 6-4: Connecting the L300 Plus Control Unit.

NESS L300 Plus Intelli-Gait Software

The NESS L300 Plus Intelli-Gait Software is used to program the NESS L300 Plus System.

Icons, Menus, Buttons, Tabs, and Data Entry

Information Icon

The information icon indicates system status and, when pressed, opens error messages and troubleshooting screens. The information icon is positioned in the top right corner of the screens. See Figure 7-1 and Table 7-1.

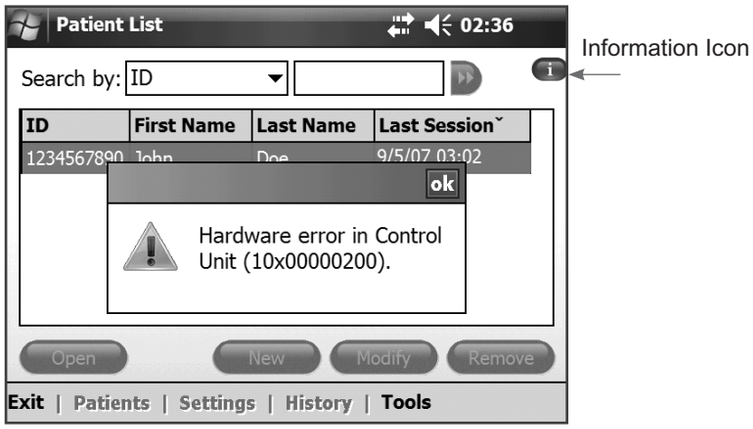


Figure 7-1: Information icon.

Information Icon	Display Description	Definition
	SOLID GREEN	L300 Plus Control Unit connected.
	SOLID GRAY	L300 Plus Control Unit disconnected.
	FLASHING YELLOW	Low battery in one or more of the components.
	FLASHING RED	Error: RF communication failure, faulty electrode contact.
	SOLID RED	Error: Software or hardware malfunction in one or more of the system components.

Table 7-1: Information icon displays.

Advanced Settings and Audio Feedback Icons

The advanced settings icon opens the advanced settings screen. The audio feedback icon turns on/off audio feedback during stimulation. See Figure 7-2.

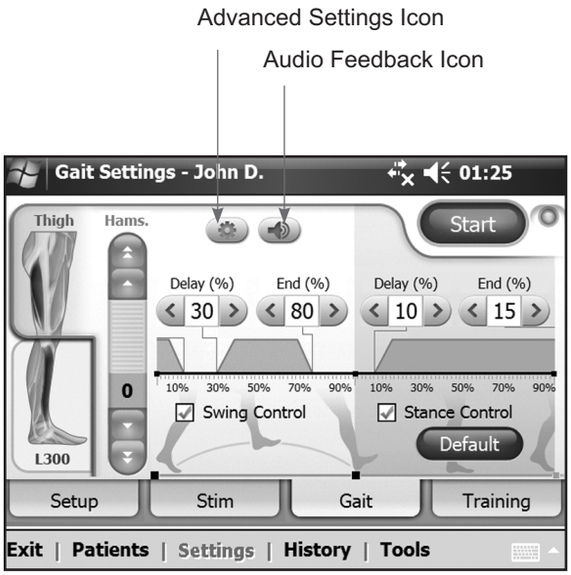


Figure 7-2: Advanced settings and audio feedback icons.

Back Icon

The back icon returns to the prior screen. See Figure 7-3.

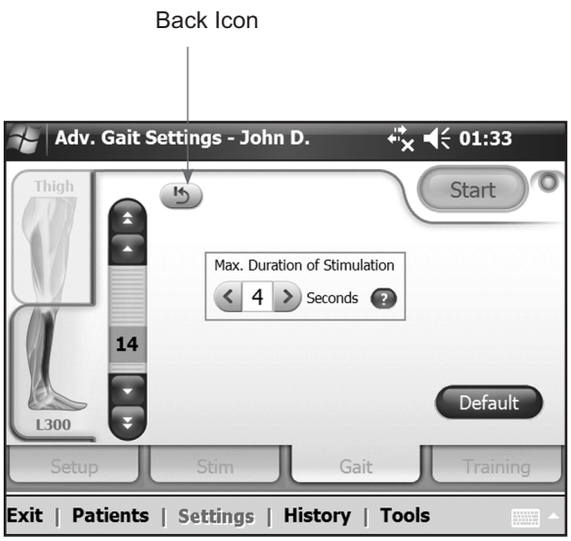


Figure 7-3: Back icon.

Menus

The L300 Plus Intelli-Gait Software has five menus at the bottom of each screen: **Exit, Patients, Settings, History,** and **Tools**. See Figure 7-4 and Table 7-2.

Figure 7-4: Menus.

Menu	Function
Exit	Exit or log off the L300 Plus Intelli-Gait Software.
Patients	Open the Patient List window to open, add, modify, or remove a patient record.
Settings	Open the Setup window to select a system configuration. Open the Stim, Gait, Training, and Advanced Settings windows for viewing and to program settings.
History	View the patient's gait log, training log, and session history.
Tools	View the System Information window. For administrators only: manage users and backup and restore the database.

Table 7-2: Menu functions.

Note: The **Settings** menu has four tabs: Setup, Stim, Gait, and Training. See Figure 7-5.

Figure 7-5: **Settings** menu, tabs.

Note: The **Tools** menu has four tabs: Info, Users, Backup, and Restore. Only Administrators have access to the Users, Backup, and Restore tabs. See Figure 7-6.

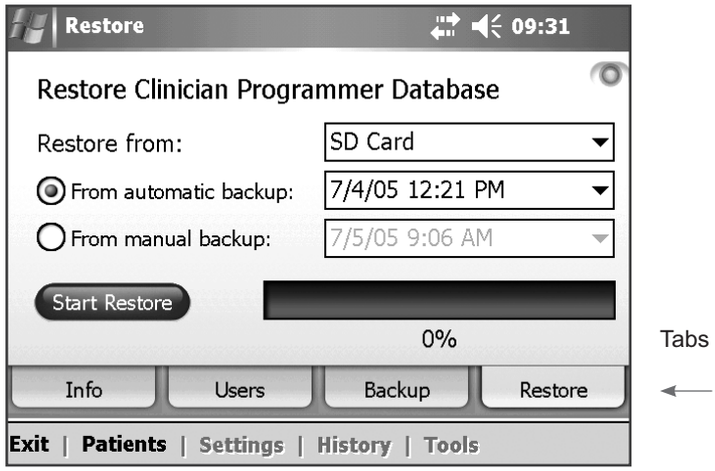


Figure 7-6: **Tools** menu, tabs.

Buttons

The buttons, when pressed, open a new screen or execute a command. See Figure 7-7.

Figure 7-7: Buttons.

Frequently used buttons on the **Settings** and **History** menus are described in Table 7-3.

Button	Function
Start/Stop	Starts/stops stimulation in both the L300 RF Stim Unit and the Thigh RF Stim Unit.
Test	Tests stimulation in the selected RF Stim Unit.
Session	From the **History** menu, opens the patient's session history.
Gait	From the **History** menu, opens the patient's gait log.
Training	From the **History** menu, opens the patient's training log.
Default	Restores the stimulation, gait, and training settings to their default values. **Note:** Pressing **Default** will restore the default settings in the open window and reduce the intensity level in the stimulation, gait, and training settings windows to zero.
?	Opens a help screen.

Table 7-3: Frequently used buttons.

L300 and Thigh Tabs

Press the **L300 tab** to program settings for the L300 FS Cuff. See Figure 7-8.

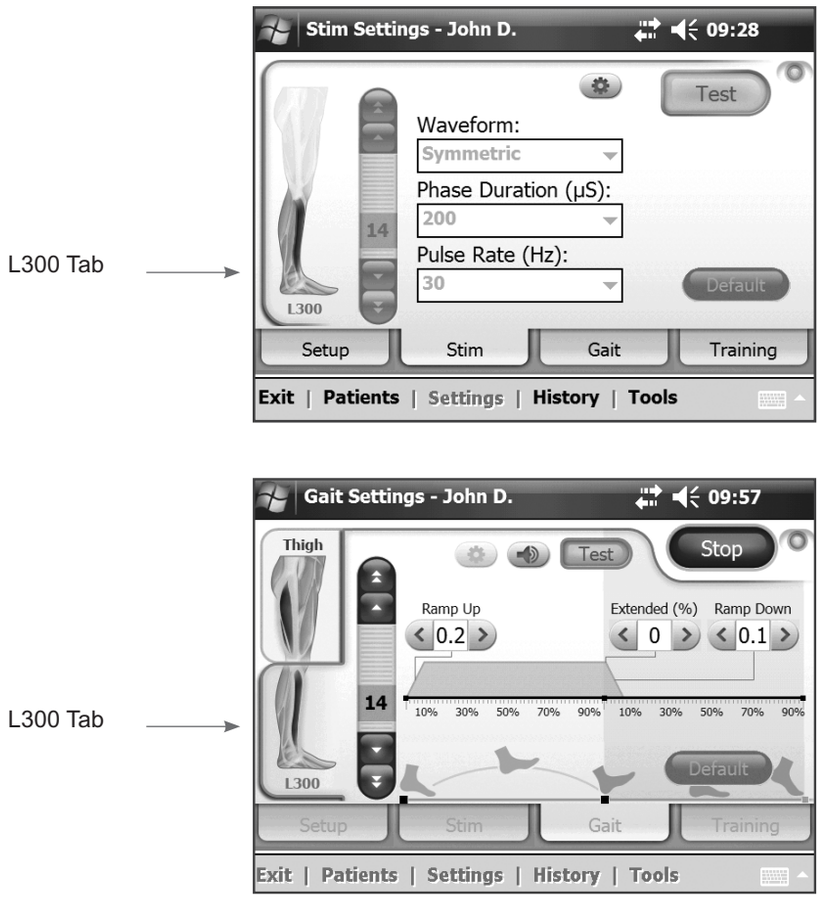


Figure 7-8: **L300 tab**. Top: L300 Only configuration. Bottom: L300 and Thigh configuration.

Press the **Thigh tab** to program settings for the Thigh FS Cuff. See Figure 7-9.

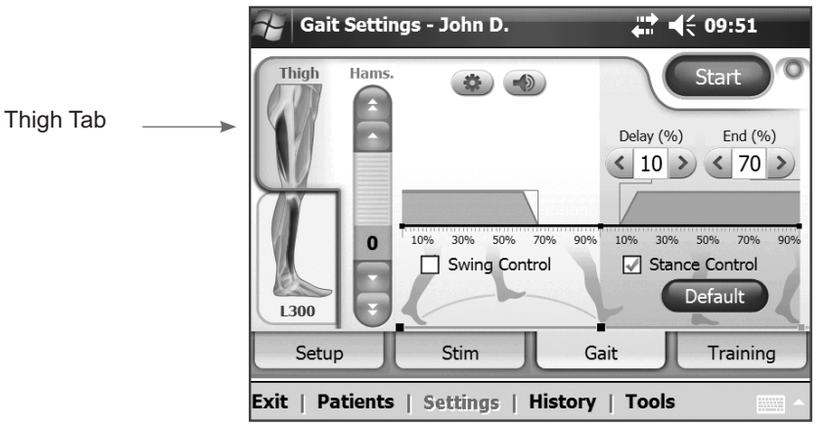


Figure 7-9: **Thigh tab**.

Scroll Bars

Press the arrows on a scroll bar to move through the selectable data set. See Figure 7-10.

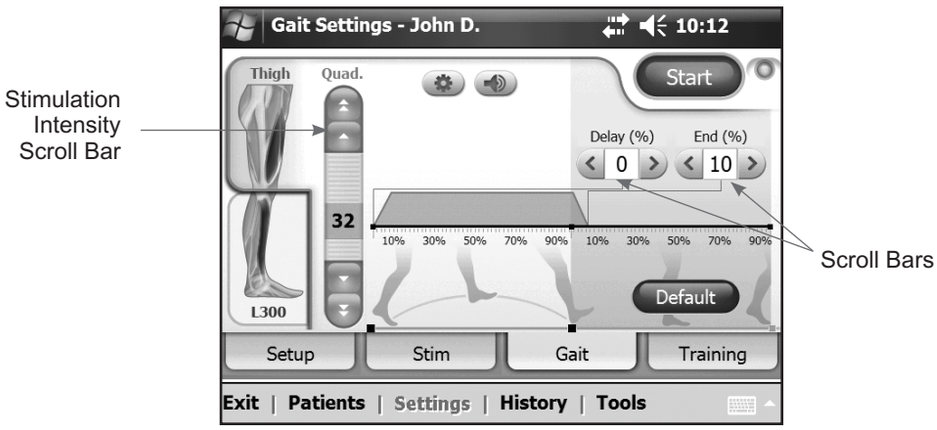


Figure 7-10: Scroll bars.

Keyboard

Use the on-screen keyboard to enter characters in a field that requires alphanumeric input. The keyboard appears collapsed at the bottom right of most screens. To enlarge or reduce the keyboard, touch the keyboard with the stylus. To enter data, select each character using the stylus. See Figure 7-11.

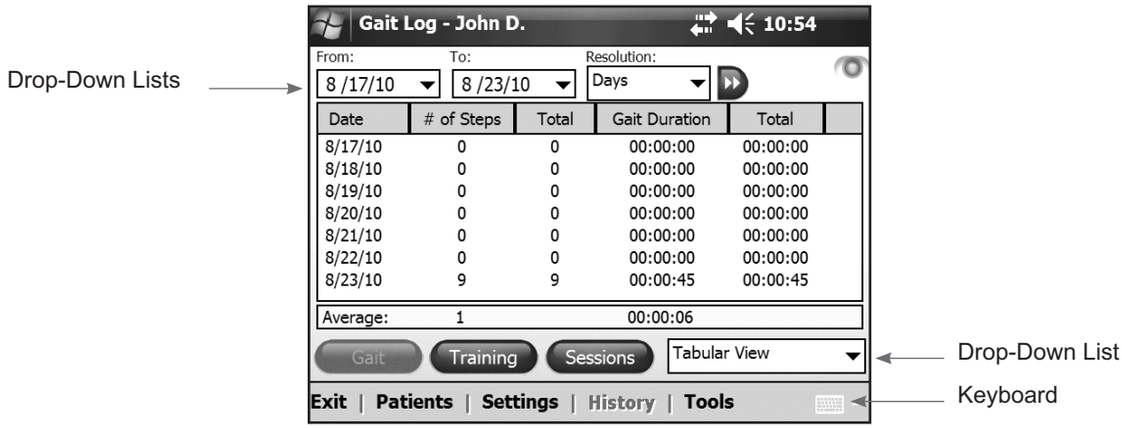


Figure 7-11: On-screen keyboard and drop-down lists.

Drop-Down Lists

Press the down arrow to display the values in a drop-down list. Use the stylus to select a value. See Figure 7-11.

Programming the NESS L300 Plus System

Logging In

1. Turn on the Clinician's Programmer and launch the NESS L300 Plus Intelli-Gait Software.
2. From the Login Screen, enter a user name and password, and then press **Login**. See Figure 7-12.

Figure 7-12: Login screen.

3. If the login is successful, the Patient List window will open. See Figure 7-13.

Figure 7-13: Patient List window.

4. Connect the L300 Plus Control Unit.

Connecting the L300 Plus Control Unit.

When an L300 Plus Control Unit is connected to the Clinician's Programmer, one of the following start-up message screens may appear.

New Patient Detected

Message appears when an L300 Plus Control Unit with patient data on it is connected to a Clinician's Programmer with no record of the data in the database. See Figure 7-14.

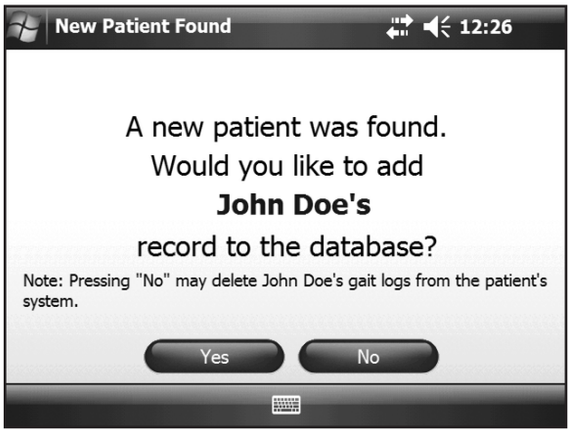


Figure 7-14: New patient message.

Do one of the following:

- Press **Yes** to add the patient's data to the Clinician's Programmer database.
- Press **No** and open an existing patient record**.**

Note: If you press **No** and open an existing patient record, the opened record will permanently overwrite all existing data on the NESS L300 Plus System.

Control Unit Unassigned

Message appears when a new, unassigned L300 Plus Control Unit (one with no patient data on it) is connected to the Clinician's Programmer. See Figure 7-15.

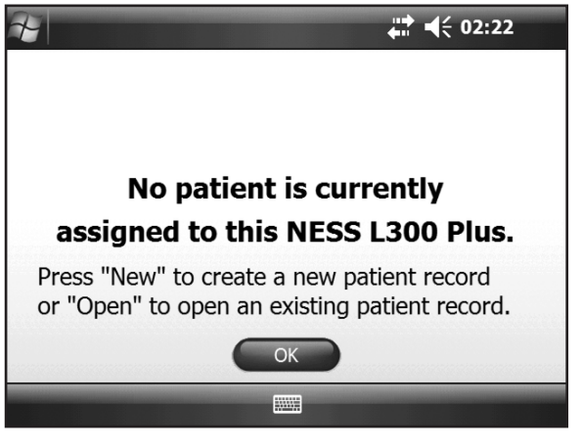


Figure 7-15: Unassigned Control Unit message.

Do one of the following:

- Press **OK** and then **NEW** to create a new patient record.
- Press **OK** and then select a patient record from the Patient List. Press **Open** to copy the parameters stored for that record from the Clinician's Programmer to the NESS L300 Plus System. (Choose this option for new-patient setup or for a replacement NESS L300 Plus System electronic family.)

L300 Plus Control Unit Not Registered

Message appears when the connected L300 Plus Control Unit is not registered to an L300 RF Stim Unit and/or Thigh RF Stim Unit. This may occur, for example, when a patient brings in a replacement L300 Plus Control Unit that has not been electronically registered. Disconnect the unregistered L300 Plus Control Unit and register it to the existing NESS L300 Plus System components.

Non-Supported System Detected

Message appears when a Control Unit that is not supported by the NESS L300 Plus Intelli-Gait Software is connected to the Clinician's Programmer (for example, an L300 Control Unit). Disconnect the Control Unit.

Thigh RF Stim Unit Not Detected

Message appears when the Clinician's Programmer does not detect the Thigh RF Stim Unit. This may occur, for example, when a patient forgets to bring the Thigh FS Cuff to a follow-up session, or the patient and clinician choose to discontinue use of the Thigh FS Cuff. The software will prompt: “Do you wish to deactivate the Thigh RF Stim Unit?"

Do one of the following:

- Press **Yes** to deactivate the Thigh RF Stim Unit and continue with the programming session. **Note:** The Thigh FS Cuff cannot be reactivated until communication with the Thigh RF Stim Unit is re-established.
- Press **No** to open the patient’s record without changing the setup, and continue the programming session.

Data Inconsistency

Message appears when the data stored in the Clinician’s Programmer database and on the NESS L300 Plus System differ. This may occur, for example, when two Clinician’s Programmers are used to program the system. See Figure 7-16.

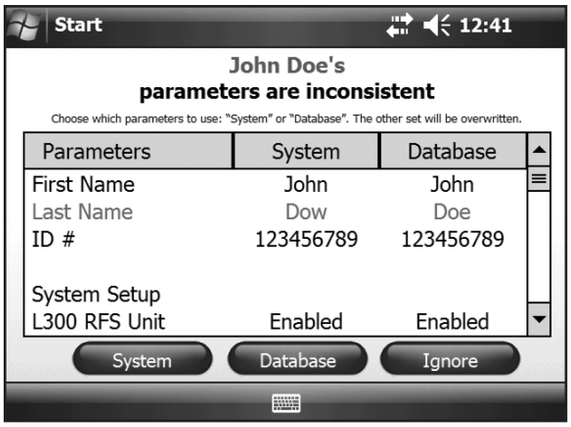


Figure 7-16: Data inconsistency message.

Do one of the following:

- Press **System** to overwrite the data in the Clinician’s Programmer database with that on the NESS L300 Plus System.
- Press **Database** to overwrite the data on the NESS L300 Plus System with that in the Clinician’s Programmer database.
- Press **Ignore** to make no changes to either data set.

Opening/Creating a Patient Record

1. Select a patient record from the patient list and press Open, or press **New** to create a new patient record. See Figure 7-17.

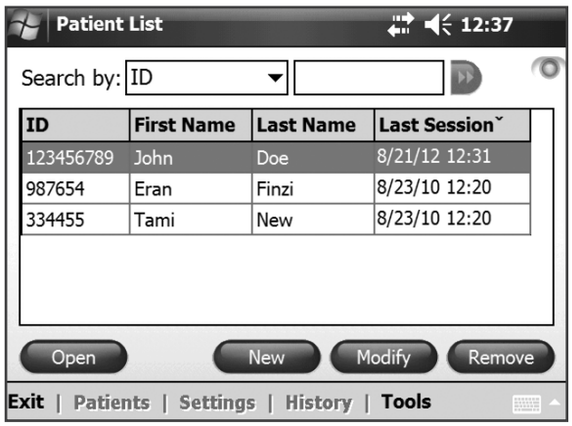


Figure 7-17: Patient List window.

2. For new patients, enter the patient's first and last name (alpha characters only) in the New Patient window, and assign a patient ID (1–14 characters). All fields must be completed. Then press **OK**. See Figure 7-18.

Figure 7-18: New Patient window.

Selecting a System Configuration

The L300 Plus System supports three system configurations:

- L300 Only.
- L300 and Thigh *Hamstrings*.
- L300 and Thigh *Quadriceps*.

To select a system configuration:

1. Press the **Setup tab**.
2. Select **L300 Only**, **L300 and Thigh** *Hamstrings*, or **L300 and Thigh** *Quadriceps*. See Figure 7-19.

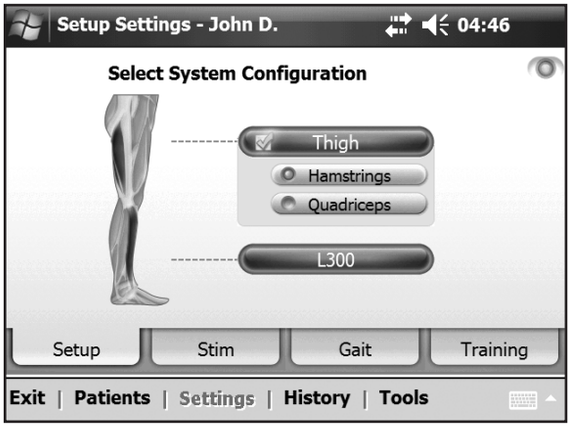


Figure 7-19: Selecting a system configuration.

Programming the L300

Stim Settings

1. Press the **Stim tab** and the **L300 Tab**. See Figure 7-20.

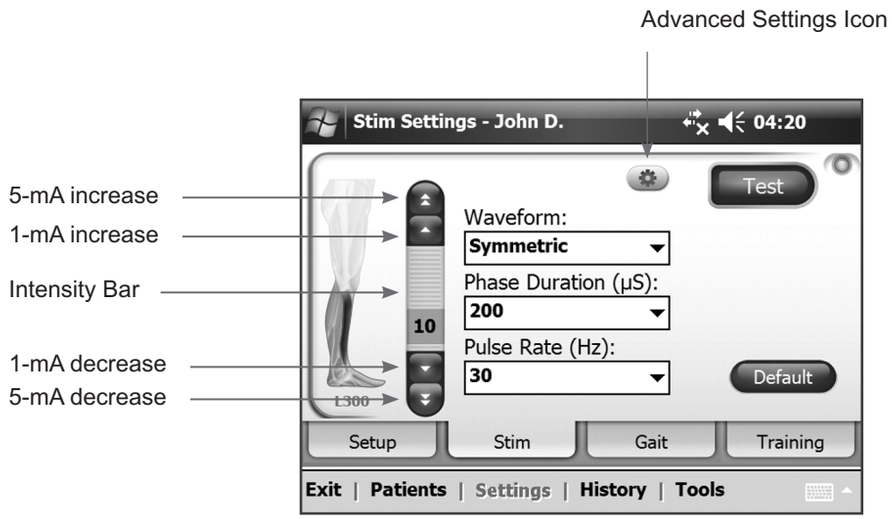


Figure 7-20: **L300 tab,** Stim Settings window (**L300 Only** configuration).

2. Adjust Intensity, Waveform, Phase Duration, and Pulse Rate using the intensity bar and drop-down lists. See Table 7-4.
3. Press **Test** to turn on stimulation in the L300 FS Cuff only.

Note: Stimulation will start with a ramp up time of 1.5 seconds unless previously adjusted to a different value. When stimulation is on, the muscle on the **L300 tab** will animate.

4. Gradually increase stimulation intensity to achieve the desired dorsiflexion.
5. Press **Stop** to stop stimulation.

Note: To restore the default settings in an open window, press **Default**.

Advanced Stim Settings

1. Press the advanced settings icon to open the Advanced Stim Settings window.
2. From the Advanced Stim Settings window, check the box next to **Increased Charge**. See Figure 7-21.

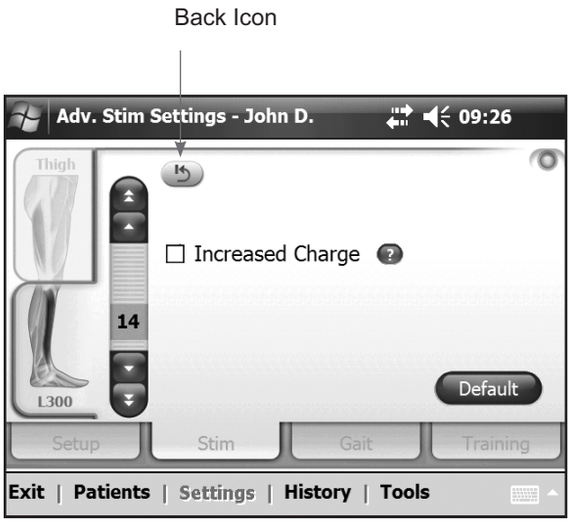


Figure 7-21: **L300 tab,** Advanced Stim Settings window.

3. Press the back icon to return to the Stim Settings window.

Note: If asymmetrical waveform is selected, **Increased Charge** cannot be selected.

Increased Charge

The **Increased Charge** feature optimizes the software algorithm that controls the pulse, to achieve better nerve recruitment in cases of high skin impedance. The **Increased Charge** feature is useful when an increase in intensity fails to produce sufficient dorsiflexion, despite good electrode placement.

Note: The **Increased Charge** feature is only available when using symmetric waveform.

Note: When the **Increased Charge** box is checked, the advanced settings icon in the Stim Settings window will be BLUE.

L300 Stim Parameter	Definition
Intensity	Strength of stimulation: 0 mA to 80 mA, in 1-mA steps and 5-mA steps
Waveform	Type of stimulation: Symmetric or Asymmetric
Phase Duration	Length of time of the pulse: 100, 200, or 300 µsec
Pulse Rate	Frequency of stimulation: 20 Hz to 45 Hz, in 5-Hz steps
L300 Gait Parameter	**Definition**
Ramp Up	The time, in seconds, that it takes for the stimulation to increase from zero to the maximum level set. • A gradual buildup of the current makes the stimulation more comfortable, helps avoid stretch reflexes, and delays the start of muscle contraction. • Values are from 0 to 2 seconds in 0.1-second increments.
Ramp Down	The time, in seconds, that it takes for the stimulation to decrease from the maximum level set to zero. • The current is reduced slowly to gradually reduce the muscle contraction. • Increase this setting to prevent foot slap. • Values are from 0 to 2 seconds in 0.1-second increments.
Extended (%)	The percentage of total time from heel on to heel off that the stimulation continues after heel contact with the ground. • This parameter determines the length of time before the stimulation starts to ramp down. • Increase this setting to prevent foot slap and genu recurvatum (knee hyperextension/knee snapping) or to increase ankle stability during stance.
Intensity	The strength of the electrical stimulation. • Values are from 0 to 80 mA. • The initial value appearing on the intensity bar will be the level established when configuring the stimulation settings. Changes can be made to the intensity level while in gait mode and will be maintained in training mode unless you have activated the “Enable specific intensity level” for training mode in the Training Settings window.

Table 7-4: L300 stim and gait parameters.

Gait Settings

The Intelli-Sense Gait Sensor must be in the patient's shoe to program and test the gait settings.

To program gait settings:

1. Press the **Gait tab** and the **L300 tab**. See Figure 7-22.

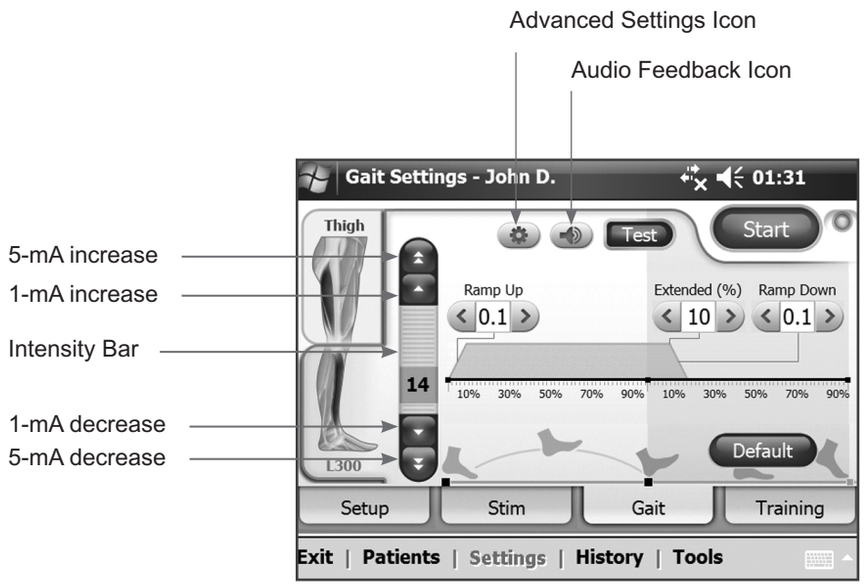


Figure 7-22: **L300 tab**, Gait Settings window.

2. Adjust Ramp Up, Ramp Down, Extended (%), and Intensity settings for the L300 using the scroll bars and intensity bar. See Table 7-4.
3. Press **Test** to turn on stimulation in the L300 RF Stim Unit only. Stimulation will respond to input from the Intelli-Sense Gait Sensor.
   - The L300 Plus Intelli-Gait Software will highlight heel off and heel contact in gait mode.
   - The muscle on the L300 tab will highlight when stimulation is on.
4. Adjust settings while the patient is walking.
5. Press **Stop** to stop stimulation.

Note: To minimize genu recurvatum (knee hyperextension/knee snapping) and foot slap, use the **Extended** option to create an eccentric contraction of the dorsiflexors after heel contact.

Note: To turn on audio feedback during stimulation, press the audio feedback icon.

Advanced Gait Settings

1. Press the advanced settings icon to open the L300 Advanced Gait Settings window.
2. Set the maximum duration of stimulation. See Figure 7-23.
3. Press the back icon to return to the Gait Settings window.

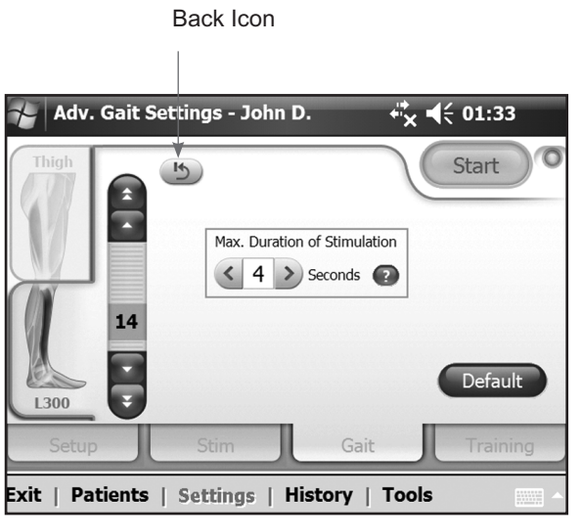


Figure 7-23: **L300 tab,** Advanced Gait Settings window.

Maximum Duration of Stimulation

To avoid excessive fatigue of the muscles that activate dorsiflexion, the NESS L300 Plus System is designed to automatically stop stimulation after a set number of seconds (the maximum duration of stimulation).

This safety feature is useful when a patient sits or lies down, the leg wearing the NESS L300 Plus System is in the air, and the system is in gait mode.

The clinician can increase or decrease the duration of stimulation.

For fast and stable users:

- This setting can be relatively low (the default setting is 4 seconds). The lowest setting should be the maximum time it takes the patient to lift the leg to climb a stair or avoid an obstacle.

For slow walkers or patients who are just beginning rehabilitation:

- This setting may need to be higher than 4 seconds for a patient who requires more time to advance the involved leg during the swing phase of gait.

Note: When the setting is changed from the default 4 seconds, the advanced settings icon in the Gait Settings window will be BLUE.

Programming the Thigh

Stim Settings

1. Press the **Stim tab** and the **Thigh tab** to open the Thigh Stim Settings window. See Figure 7-24.

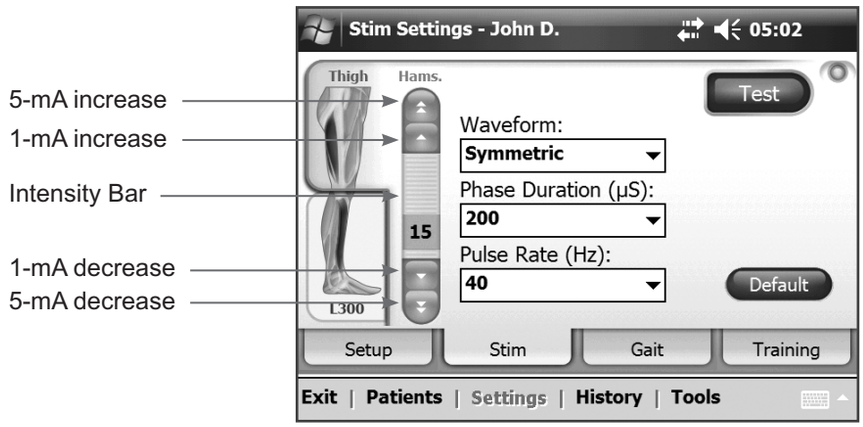


Figure 7-24: Stim Settings window, Thigh *Hamstrings*.

2. Adjust Intensity, Waveform, Phase Duration, and Pulse Rate using the intensity bar and drop-down lists. See Table 7-5.
3. Press **Test** to turn on stimulation in the Thigh FS Cuff only.

Note: Stimulation will start with a ramp up time of 1.5 seconds unless previously adjusted to a different value. When stimulation is on, the muscle on the **Thigh tab** will highlight.

4. Gradually increase stimulation intensity to achieve the desired knee flexion for the hamstrings or knee extension for the quadriceps.
5. Press **Stop** to stop stimulation.

Gait Settings, Thigh *Hamstrings*

The Intelli-Sense Gait Sensor must be in the patient's shoe to program and test the gait settings.

To program gait settings for the Thigh *Hamstrings:*

1. Press the **Gait tab** and the **Thigh tab** to open the Gait Settings window. See Figure 7-25.

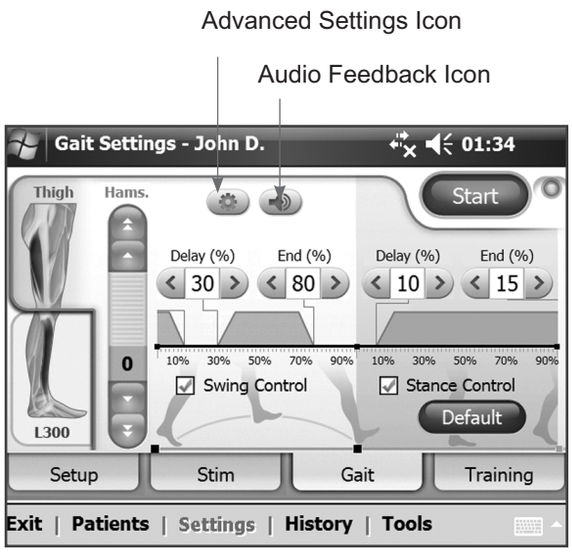


Figure 7-25: Gait Settings window, Thigh *Hamstrings*.

2. If appropriate, check the box next to Swing Control and adjust Delay (%) and End (%). See Table 7-5.

3. If appropriate, check the box next to Stance Control and adjust Delay (%) and End (%).

4. Press **Start** to turn on stimulation in both FS Cuffs. Stimulation will respond to input from the Intelli-Sense Gait Sensor.

Note: The L300 Plus Intelli-Gait Software will highlight heel off and heel contact in gait mode. The muscle on the **Thigh Tab** will highlight when stimulation is on.

5. Adjust settings with the patient walking.
6. Press **Stop** to stop stimulation.

Note: Stimulation cannot be tested in the Thigh FS Cuff alone in gait mode.

Stim Parameter	Definition
Intensity	Strength of stimulation: 0 mA to 100 mA, in 1-mA steps and 5-mA steps
Waveform	Type of stimulation: **Symmetric** or **Asymmetric**
Phase Duration	Length of time of the pulse: 100, 200, or 300 µsec
Pulse Rate	Frequency of stimulation: 20 Hz to 45 Hz, in 5-Hz steps
Gait Parameter	**Definition**
Swing Control	The stimulation burst/sequence triggered by heel off.
Swing Control Delay (%)	Determines when the stimulation starts to ramp up after heel off. • Presented as a percentage of the average swing. • Increase to start the stimulation at a point in the gait cycle. • Decrease to start the stimulation earlier in the gait cycle.
Swing Control End (%)	Determines when the stimulation finishes ramp down. • Presented as a percentage of the average swing. • Increase to stop the stimulation at a point in the gait cycle. • Decrease it to stop the stimulation earlier in the gait cycle.
Stance Control	The stimulation burst/sequence triggered by heel contact.
Stance Control Delay (%)	Determines when the stimulation starts to ramp up after heel contact. • Presented as a percentage of the average stance. • Increase to start the stimulation at a point in the gait cycle. • Decrease it to start the stimulation earlier in the gait cycle.
Stance Control End (%)	Determines when the stimulation finishes ramp down. • Presented as a percentage of the average stance. • Increase to stop the stimulation a point in the gait cycle. • Decrease it to stop the stimulation earlier in the gait cycle.
Ramp Up	The time, in seconds, that it takes for the stimulation to increase from zero to the maximum level set. • A gradual buildup of the current makes the stimulation more comfortable, helps avoid stretch reflexes, and delays the start of muscle contraction. • Values are from 0 to 2 seconds in 0.1-second increments.
Ramp Down	The time, in seconds, that it takes for the stimulation to decrease from the maximum level set to zero. • The current is reduced slowly to gradually reduce the muscle contraction. • Values are from 0 to 2 seconds in 0.1-second increments.

Table 7-5: Thigh stim and gait parameters.

Advanced Gait Settings, Thigh *Hamstrings*

1. Press the advanced settings icon to open the Advanced Gait Settings window.
2. Adjust the maximum duration of stimulation. See Figure 7-26.

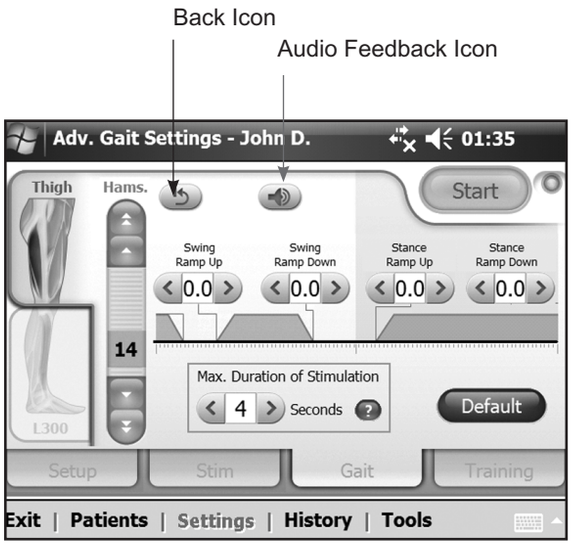


Figure 7-26: Advanced Gait Settings window, Thigh *Hamstrings.*

3. Adjust Swing Ramp Up, Swing Ramp Down, Stance Ramp Up, and Stance Ramp Down.
4. Press **Start** to turn on stimulation in both FS Cuffs. Stimulation will respond to input from the Intelli-Sense Gait Sensor.

Note: The L300 Plus Intelli-Gait Software will highlight heel off and heel contact in gait mode. The muscle on the **Thigh tab** will highlight when stimulation is on.

Note: Stimulation cannot be tested in the Thigh FS Cuff alone in gait mode.

5. Adjust settings with the patient walking.
6. Press **Stop** to stop stimulation.
7. Press the back icon to return to the Gait Settings window.

Note: To turn on audio feedback during stimulation, press the audio feedback icon.

Maximum Duration of Stimulation

To avoid excessive fatigue of the muscles that activate dorsiflexion, the NESS L300 Plus System is designed to automatically stop stimulation after a set number of seconds (the maximum duration of stimulation).

This safety feature is useful when a patient sits or lies down, the leg wearing the NESS L300 Plus System is in the air, and the system is in gait mode.

The clinician can increase or decrease the duration of stimulation.

For fast and stable users:

- This setting can be relatively low (the default setting is 4 seconds). The lowest setting should be the maximum time it takes the patient to lift the leg to climb a stair or avoid an obstacle.

For slow walkers or patients who are just beginning rehabilitation:

- This setting may need to be higher than 4 seconds for a patient who requires more time to advance the involved leg during the swing phase of gait.

Note: When the setting is changed from the default 4 seconds, the advanced settings icon in the Gait Settings window will be BLUE.

Gait Settings, Thigh *Quadriceps*

The Intelli-Sense Gait Sensor must be in the patient's shoe to program and test the gait settings.

To program gait settings for the Thigh *Quadriceps*:

1. Press the **Gait tab** and the **Thigh tab** to open the Gait Settings window. See Figure 7-27.

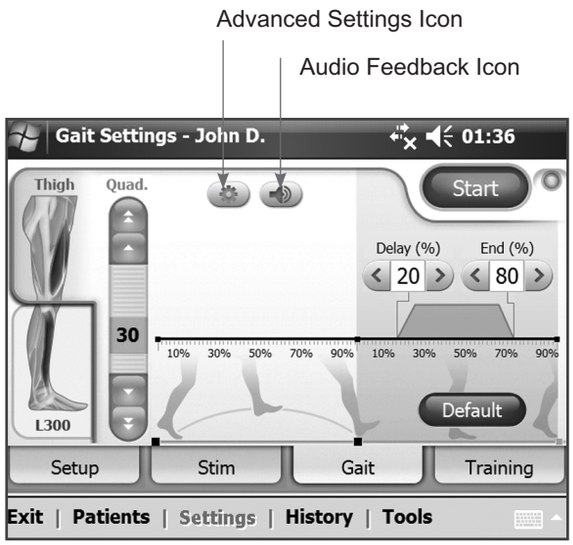


Figure 7-27: Gait Settings window, Thigh *Quadriceps*.

2. From the Gait Settings window, adjust Delay (%) and End (%). See Table 7-5.
3. Press **Start** to turn on stimulation in both FS Cuffs. Stimulation will respond to input from the Intelli-Sense Gait Sensor.

Note: The L300 Plus Intelli-Gait Software will highlight heel off and heel contact in gait mode. The muscle on the **Thigh tab** will highlight when stimulation is on.

4. Adjust settings with the patient walking.
5. Press **Stop** to stop stimulation.

Note: To turn on audio feedback during stimulation, press the audio feedback icon.

Note: Stimulation cannot be tested in the Thigh FS Cuff alone in gait mode.

Advanced Gait Settings, Thigh *Quadriceps*

1. Press the advanced settings icon to open the Advanced Gait Settings window.
2. Set the maximum duration of stimulation. See Figure 7-28.

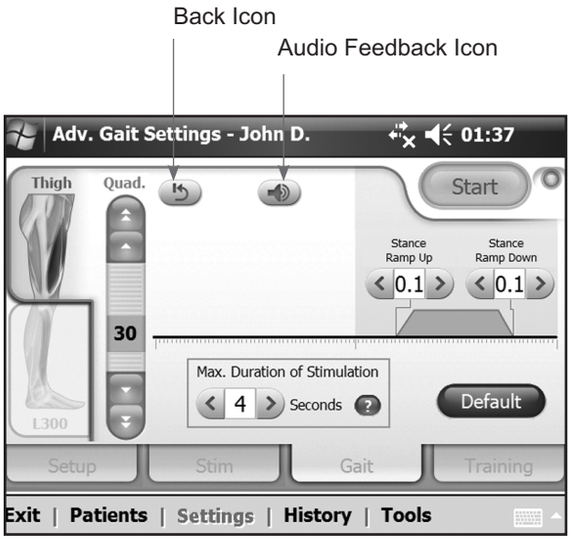


Figure 7-28: Advanced Gait Settings window, Thigh *Quadriceps.*

3. Adjust Stance Ramp Up and Stance Ramp Down.
4. Press **Start** to turn on stimulation in both the L300 and Thigh RF Stim Units. Stimulation will respond to input from the Intelli-Sense Gait Sensor.
   - The L300 Plus Intelli-Gait Software will highlight heel off and heel contact in gait mode.
   - The muscle on the Thigh Tab will highlight when stimulation is on.

Note: Stimulation cannot be tested in the Thigh RF Stim Unit alone in gait mode.

5. Adjust settings while the patient is walking.
6. Press **Stop** to stop stimulation.
7. Press the back icon to return to the Gait Settings window.

Note: To turn on audio feedback during stimulation, press the audio feedback icon.

Programming Training Settings

1. Press the **Training tab** to open the Training Settings window. See Figure 7-29.

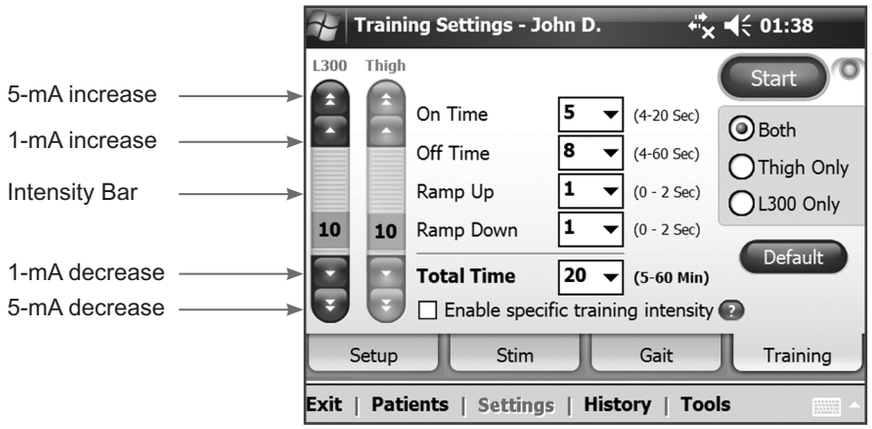


Figure 7-29: Training Settings window.

2. Choose a training configuration: **Both**, **Thigh Only**, or **L300 Only.**
3. Adjust On Time, Off Time, Ramp Up, Ramp Down, Total Time, and Stimulation Intensity. See Table 7-6.
4. Enable specific training intensity, if desired. (Check the box next to “Enable specific training intensity.” The default setting is unchecked.)

Note: Some patients may require a lower or higher intensity level in training mode than in gait mode. To adjust the intensity level in training mode independently of the intensity level set for stimulation and gait settings**,** enable specific training intensity.

5. Press **Start** to turn on stimulation in the selected FS Cuff(s).
6. Adjust stimulation intensity.
7. Press **Stop** to turn off stimulation.

Training Parameter	Definition
On Time	The amount of time that stimulation is applied.
Off Time	The amount of rest time between stimulations.
Ramp Up	The time, in seconds, that it takes for the stimulation to increase from zero to the maximum level set. • A gradual buildup of the current makes the stimulation more comfortable, helps avoid stretch reflexes, and delays the start of muscle contraction. • Values are from 0 to 2 seconds in 0.1-second increments.
Ramp Down	The time, in seconds, that it takes for the stimulation to decrease from the maximum level set to zero. • The current is reduced slowly to gradually reduce the muscle contraction. • Values are from 0 to 2 seconds in 0.1-second increments.
Total Time	The total time for the training period. • The training period consists of repeated cycles of the Ramp Up, On Time, Ramp Down, and Off Time parameters, until the total session time expires.

Table 7-6: Training parameters and definitions.

Viewing a Patient's History

Session History

A patient session begins when an L300 Plus Control Unit is connected to the Clinician's Programmer and the patient's record is opened. A patient session ends when session data are saved and the L300 Plus Control Unit is disconnected from the Clinician's Programmer. If the L300 Plus Control Unit is disconnected and then reconnected within one hour, the most recent session reopens.

To view a patient's Session History:

1. Open the patient's record, and then press **History**.
2. Press **Sessions**. The Sessions List window will open, showing the date, time, and programming clinician for each saved session. See Figure 7-20.

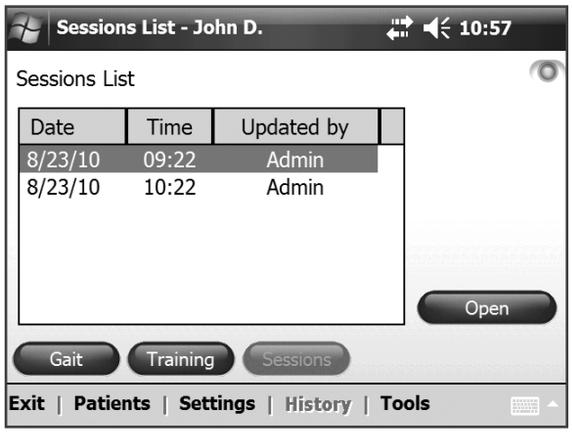


Figure 7-30: Sessions List window.

3. Select a session from the Sessions List and press **Open**.
4. The Session Details window will open, showing the parameters saved for that session. See Figure 7-31.

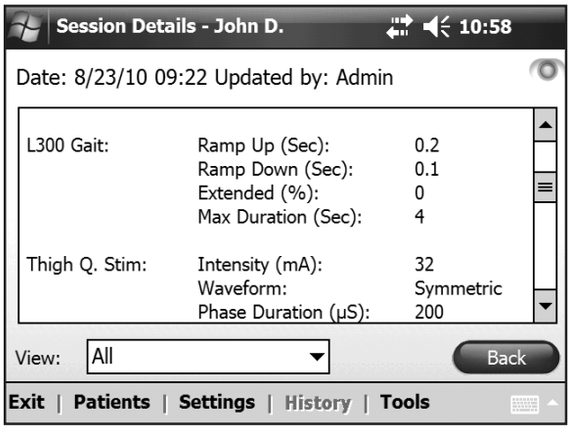


Figure 7-31: Session Details window.

5. From the View drop-down list, select “All” to view all the session details, or narrow the search by selecting one of the following:
   - L300 Stim
   - L300 Gait
   - Thigh Stim
   - Thigh Gait
   - Training
6. Press **Back** to return to the Sessions List window.

Gait Log

The Gait Log is a record of the patient's NESS L300 Plus System usage history. The Gait Log can be filtered by date and time frame, and displayed as a table or graph.

To view a patient's Gait Log:

1. Open the patient's record and press **History**.
2. Press **Gait**. The Gait Log will open in tabular view. See Figure 7-32.

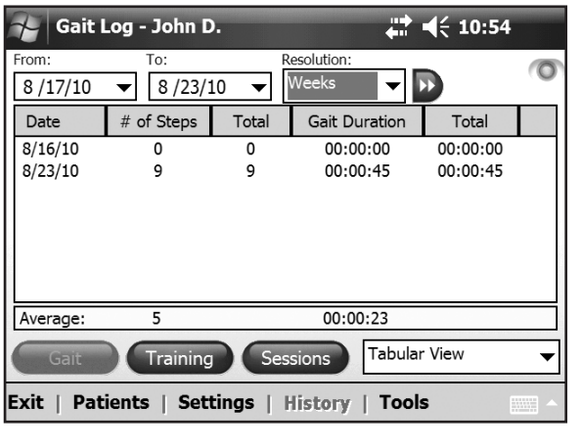


Figure 7-32: Gait Log, Tabular View.

3. From the drop-down list at the bottom right of the screen, select **Tabular View, # of Steps Graph,** or **Gait Duration Graph.**
   - **Tabular View** displays:
     - » Date.
     - » Number of steps recorded for a given date.
     - » Cumulative number of steps recorded to date.
     - » Average number of steps recorded to date.
     - » Total time spent using the NESS L300 Plus System for a given date.
     - » Cumulative time spent using the NESS L300 Plus System to date.
     - » Average time spent using the NESS L300 Plus System to date.
   - The **# of Steps Graph** displays the date and the number of steps for each date in a bar graph. See Figure 7-33. Each column represents a day, week, month, or year, per the specified resolution.

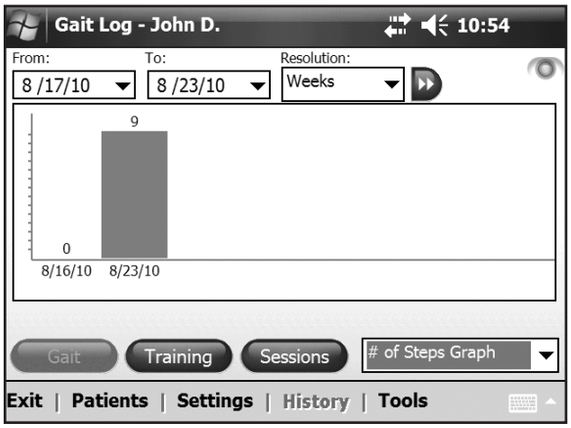


Figure 7-33: Gait Log, # of Steps Graph.

   - The **Gait Duration Graph** displays the date and total time spent using the NESS L300 Plus System in a bar graph. Each column represents a day, week, month, or year, per the specified resolution.
4. From the drop-down lists at the top of the screen, enter the filtering dates and resolution (days, weeks, months, or years.).
5. Press the double arrow to perform the search.

Training Log

The Training Log is a record of the patient's NESS L300 Plus System training history. The Training Log can be filtered by date and resolution, and displayed as a table or graph.

To view a patient's Training Log:

1. Open the patient's record and press **History**.
2. Press **Training**. The Training Log will open in tabular view. See Figure 7-34.

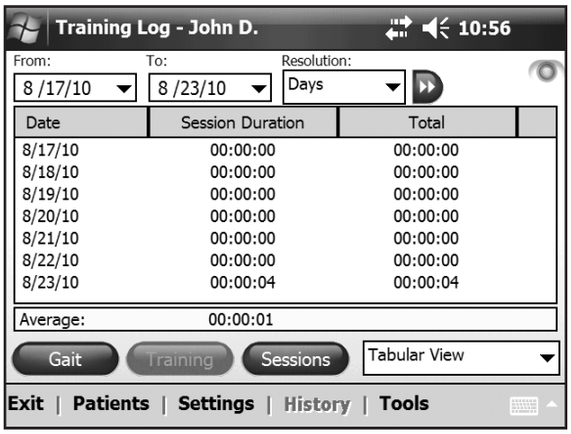


Figure 7-34: Training Log, Tabular View.

3. From the drop-down list at the bottom right of the screen, select **Tabular View** or **Graph View.**
   - **Tabular View** displays:
     - » The session date.
     - » Session duration (time in training mode).
     - » Total (cumulative) time in training mode.
     - » Average time in training mode.
   - **Graph View** displays the session date and the session duration for each date in a bar graph. See Figure 7-35. Each column represents a day, week, month, or year, per the specified resolution.

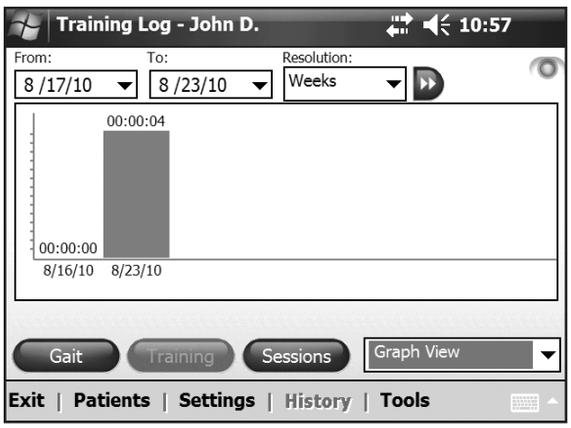


Figure 7-35: Training Log, Graph View.

4. From the drop-down lists at the top of the screen, enter the filtering dates and resolution (days, weeks, months, or years.). Press the double arrow to begin the search.

Managing Patient Records

Modifying a Patient Name

1. Select a patient from the Patient List, and then press **Modify**.
2. The Modify Patient window will open. See Figure 7-36.

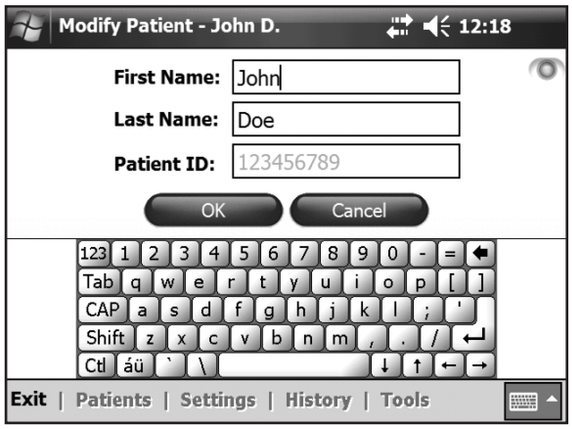


Figure 7-36: Modify Patient window.

3. Modify the name and press **OK.**

Note: Patient ID cannot be modified.

Removing a Patient Record

1. Select a patient from the Patient List.
2. Press **Remove**.
3. The Remove Patient confirmation window will open. See Figure 7-37.
4. Press **Yes**.

Figure 7-37: Remove Patient confirmation window.

Viewing the System Information

1. Connect an L300 Plus Control Unit to the Clinician's Programmer.
2. Press the **Tools** Menu and the **Info tab**. See Figure 7-38.

Note: If an L300 Plus Control Unit is not connected, no system information will be displayed.

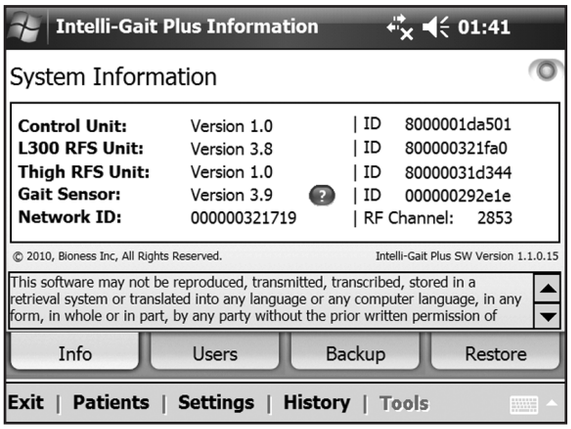


Figure 7-38: **System** Information window, L300 Plus Control Unit connected.

Managing Users

From the **Tools** menu, administrators can add or remove users, change user passwords, and back up and restore the database.

Adding a User

1. Press the **Users tab** to view the User Administration window. See Figure 7-39.

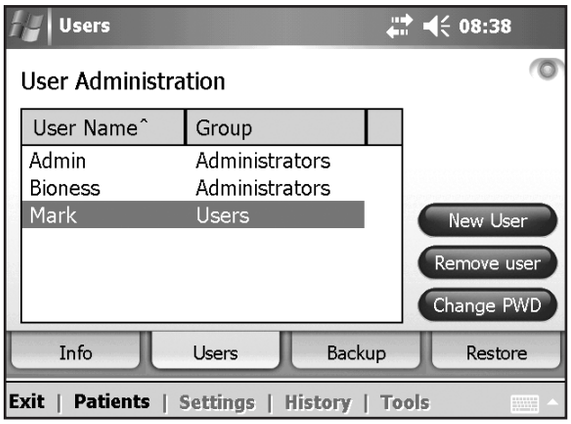


Figure 7-39: User Administration window.

2. Press **New User**. The Add New User window will open. See Figure 7-40.

Figure 7-40: Add New User window.

3. Enter a user name and password, and confirm the password.
4. From the **Group** drop-down list, select **Administrators** or **Users,** and then press **Add**.

Removing a User

1. From the User Administration window, select a user.
2. Press **Remove User.**
3. A confirmation message will appear. See Figure 7-41. Press **Yes**.

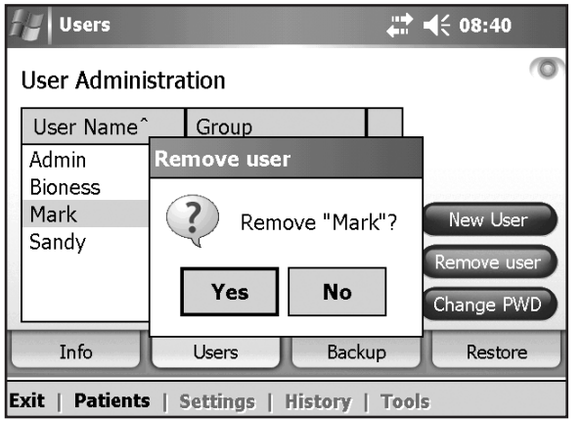


Figure 7-41: Remove User confirmation window.

Note: The last remaining administrator cannot be removed.

Changing a User Password

1. From the User Administration window, select a user.
2. Press **Change PWD.** The Change User's Password window will open. See Figure 7-42.
3. Enter and confirm the new password. Press **OK**.

Figure 7-42: Change User's Password window.

Backing Up and Restoring the Database

Automatic Backup

The L300 Intelli-Gait Software will automatically back up the database whenever the application is exited. If a storage card is not in the SD slot, upon exiting the application a warning will appear.

Note: Users should exit the L300 Plus Intelli-Gait Software at the end of each day.

To disable automatic backup:

1. Press **Tools** and then the **Backup tab**.
2. Uncheck the box next to “Enable automatic database backup.” See Figure 7-43.

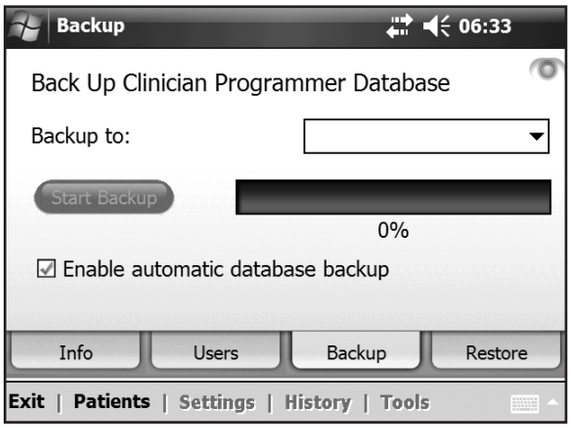


Figure 7-43: Backup window.

Manual Backup

Administrators can manually back up the Clinician’s Programmer database to the storage (SD) card at any time.

To manually back up the database:

1. Ensure that a storage card is in the Clinician’s Programmer SD slot.
2. Press **Tools** and then the **Backup tab**.
3. Press **Start Backup**. A file will be created on the storage card. The file name will be the date and time the file was created.
4. Monitor the progress bar until the backup is successful, and then press **ok**.

Restore

Administrators can restore the database when the Clinician's Programmer is replaced or the database is corrupted. Do not enter new patient information before restoring the database.

To restore the database:

1. If a new storage card is in the Clinician's Programmer, remove it.
2. Make sure the backup storage card lock switch is in the unlocked position, and insert the storage card with the backup files into the Clinician's Programmer.
3. Open the L300 Plus Intelli-Gait Software, and log in using an administrator's user name and password.
4. Press **Tools** and then the **Restore tab**. The Restore window will open. See Figure 7-44.

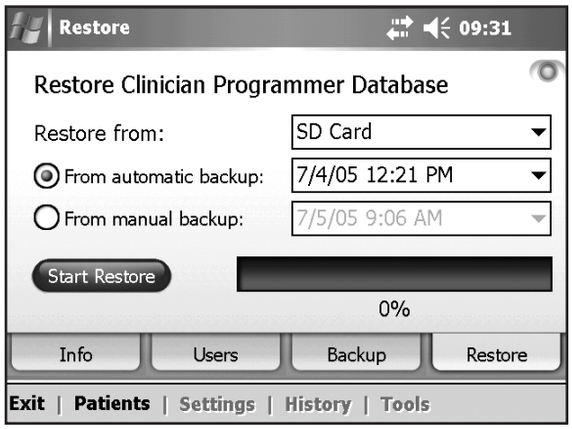


Figure 7-44: Restore window.

5. Select "From automatic backup" or "From manual backup," select a file name from the drop down list, and press **Start Restore**.
6. A message will appear: "Restoring a database will overwrite the current database. Are you sure?" Press **Yes**.
7. Wait until the progress bar shows 100% and a "Restore successful" message appears. Then press **ok**.
8. Press **Patients** to return to the Patient List window, and then verify that the database was restored.

Fitting the NESS L300 Plus System

Before fitting, check all components and accessories for signs of wear or damage. If any component is damaged, contact your local distributor. If the electrodes are old, replace them. Make sure the component batteries are charged.

Also before fitting, the components in a NESS L300 Plus System Upgrade Kit must be electronically registered to the existing L300 components for the L300 Plus System to operate. The clinician will need to electronically register the system components. See the Maintenance Chapter of this guide.

Skin Preparation

1. Clean the skin where the electrodes will touch with a wet washcloth. If any 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 an electric shaver or scissors. Do not use a razor. A razor can irritate the skin.
3. Check the skin for signs of irritation. If any irritation is present, wait for complete healing before using the NESS L300 Plus System.

L300 FS Cuff

Measuring for FS Cuff Strap Size

1. Measure the circumference of the patient's leg at its broadest point (the gastrocnemius muscle belly). Depending on the measurement, select the small, medium, or large L300 FS Cuff strap. Refer to Table 8-1.
2. Remove the existing strap from the L300 FS Cuff, if required.

L300 FS Cuff Strap Size	Leg Circumference
Small	29–36 cm
Medium	36–42 cm
Large	42–51 cm

Table 8-1: L300 FS Cuff strap fitting chart.

CAUTION: Remove the L300 FS Cuff from the skin every 3 to 4 hours for 15 minutes to allow the skin to breathe.

3. Orient the selected L300 FS Cuff strap with the hook and loop fasteners facing away from the L300 FS Cuff.
4. Insert the selected strap through the strap leads and buckles on the L300 FS Cuff. See Figure 8-1.
5. Press on the hook and loop fasteners to secure the L300 FS Cuff strap.

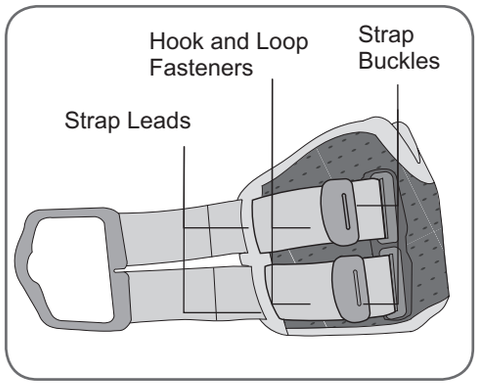


Figure 8-1: L300 FS Cuff strap fitted to the L300 FS Cuff.

Attaching the Personal Strap Cover

The personal strap cover is used as an hygienic cover for the L300 FS Cuff strap when an L300 FS Cuff is used by multiple patients. The personal strap cover slides over the L300 FS Cuff strap. See Figure 8-2.

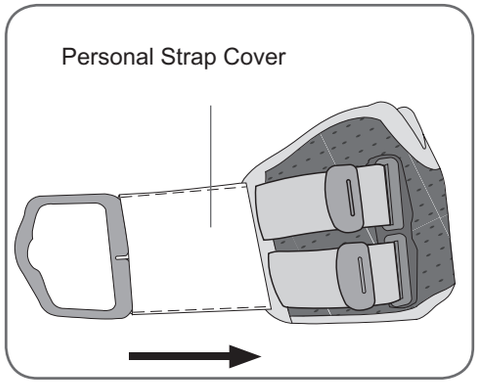


Figure 8-2: Sliding the personal strap cover over the L300 FS Cuff strap.

Attaching the Personal Panel

The personal panel is used as an hygienic liner for the L300 FS Cuff. It is also used to preserve the placement of the L300 electrode bases and/or L300 electrode(s) when an L300 FS Cuff is used by multiple patients. The personal panel is available in right and left configurations.

To attach the personal panel:

1. Attach the personal panel buttonholes to the L300 FS Cuff plug holes. See Figure 8-3.

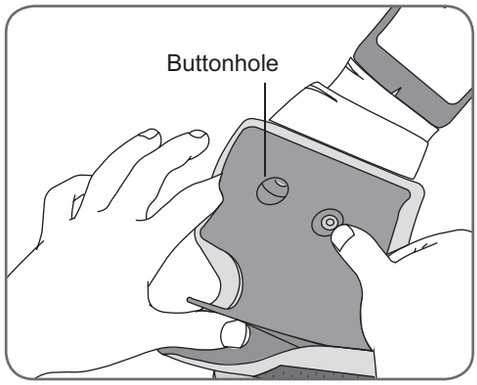


Figure 8-3: Attaching the personal panel to the L300 FS Cuff.

Attaching the Large Cloth Electrode, L300 Systems

The L300 FS Cuff uses one large cloth electrode. The large cloth electrode snaps to the L300 FS Cuff plug holes. No electrode base is required.

To attach the large cloth electrode:

1. Turn off the L300 Plus System.
2. Wet the entire large cloth electrode with water. See Figure 8-4.

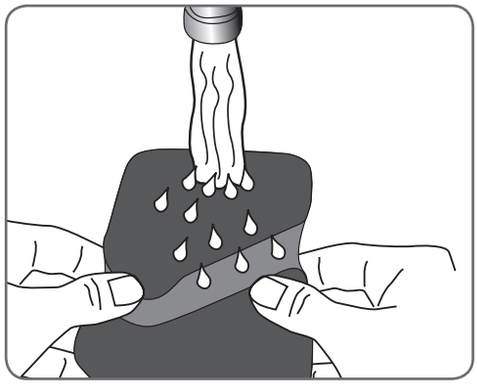


Figure 8-4: Wetting the large cloth electrode.

3. Remove excess water from the large cloth electrode. See Figure 8-5.

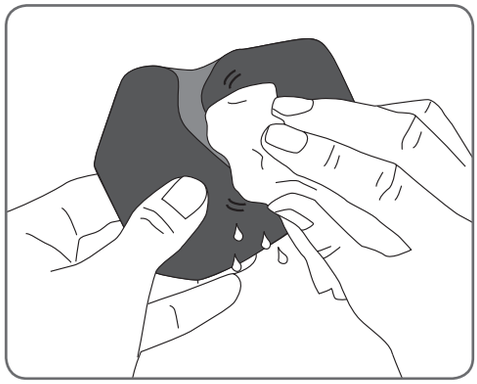


Figure 8-5: Blotting the large cloth electrode.

4. Align the orange and blue snaps on the large cloth electrode with the orange and blue plug holes on the L300 FS Cuff. See Figure 8-6.

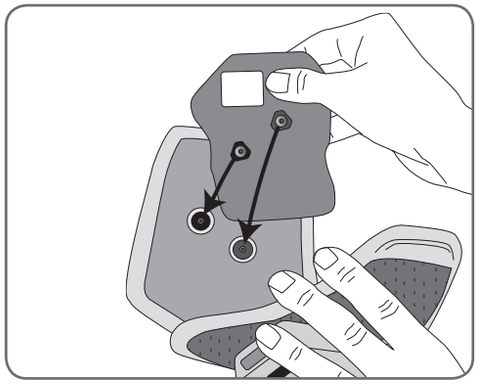


Figure 8-6: Aligning the large cloth electrode.

CAUTION: Only use electrodes provided by Bioness Inc.

CAUTION: Do not fold or twist the large cloth electrode.

CAUTION: The electrodes are for single patient use.

5. Press firmly to snap the large cloth electrode to the L300 FS Cuff. See Figure 8-7.

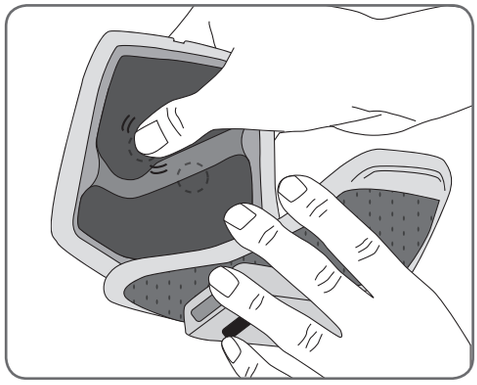


Figure 8-7: Snapping the large cloth electrode.

6. Gently remove and rewet the large cloth electrode after every three to four hours of use. See Figure 8-8.

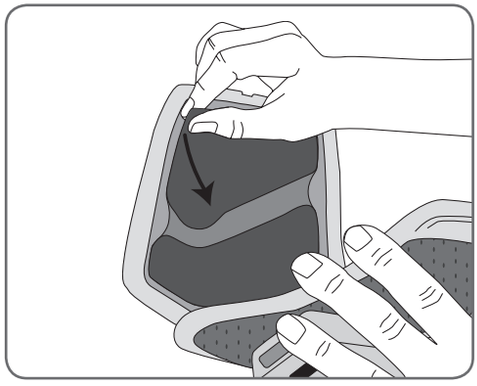


Figure 8-8: Removing the large cloth electrode.

Note: Wet the cloth electrodes before use. After every three to four hours of use, remove and rewet the cloth electrodes. If the L300 FS Cuff is removed for more than one hour, then wet the cloth electrodes again before use. If the L300 cloth electrodes dry out, the response to the stimulation may change. If stimulation intensity needs to be adjusted more often than usual, try rewetting the cloth electrodes.

CAUTION: Change the electrodes every two weeks.

Attaching the L300 Hydrogel Electrodes and Bases

The L300 hydrogel electrodes are an alternative to the large cloth electrode. The L300 FS Cuff uses two L300 hydrogel electrodes and two L300 hydrogel electrode bases. The electrode bases snap to the L300 FS Cuff plug holes. The electrodes adhere to the electrode bases. The grid side of the hydrogel electrode faces the hydrogel electrode base. See Figure 8-9.

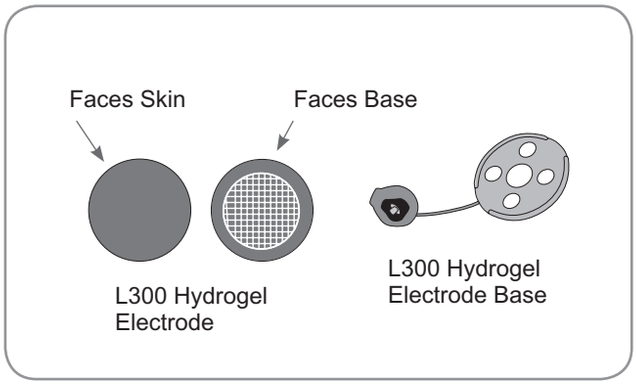


Figure 8-9: L300 hydrogel electrode and hydrogel electrode base.

The L300 hydrogel electrode bases snap to the L300 FS Cuff plug holes. The bases are used to elevate the hydrogel electrodes from the liner of the L300 FS Cuff to achieve optimal electrode contact.

The L300 hydrogel electrode bases also:

- Provide a secure location for the L300 hydrogel electrodes.
- Allow the L300 hydrogel electrodes to be repositioned easily and accurately, if needed.

Placing the Hydrogel Electrodes and Bases on the Leg

1. Separate two new hydrogel electrodes along the perforation. See Figure 8-10.

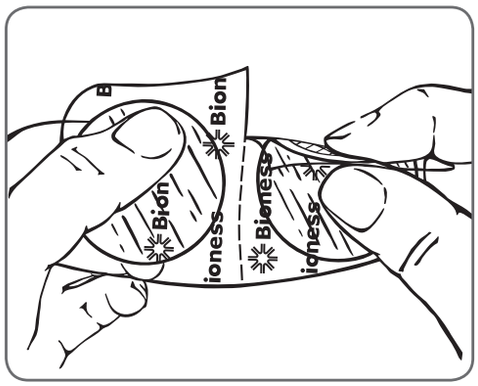


Figure 8-10: Separating the L300 hydrogel electrodes.

2. Split the two-piece covers on each electrode and discard them. See Figure 8-11.

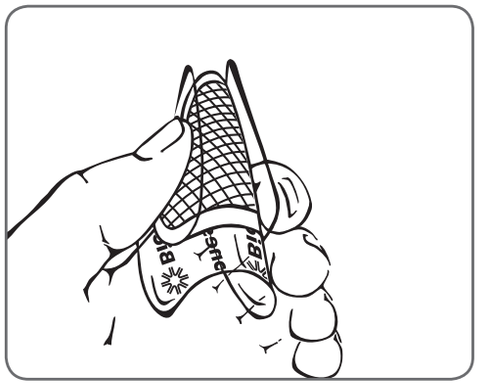


Figure 8-11: Splitting the two-piece covers.

3. Attach the grid side of the electrodes to the electrode bases and then press firmly.
4. Remove the larger covers (with the Bioness logo) from the electrodes and save them. *(*Always cover the hydrogel electrodes between uses.)
5. Have the patient sit and extend the lower leg straight out, then flex the knee between 15 and 20 degrees. (The patient should maintain this position throughout the fitting process.) The heel should be elevated (on the bolster), if possible.
6. Place one L300 hydrogel electrode (the nerve electrode) over the common peroneal nerve, distal and slightly posterior to the fibular head. See Figure 8-12.

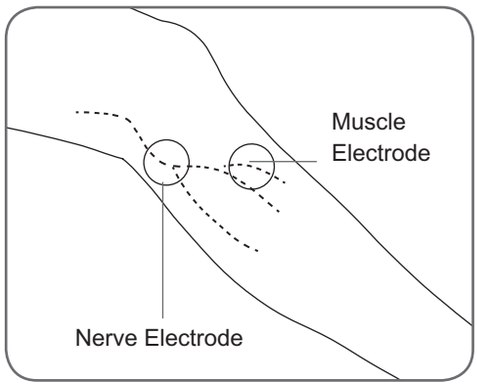


Figure 8-12: Placement of the L300 hydrogel electrodes on the leg.

7. Place the other L300 hydrogel electrode (the muscle electrode) approximately 5 cm distal and anterior to the nerve electrode, over the belly of the tibialis anterior muscle. See Figure 8-12.

Connecting the Fitting Cable

The fitting cable is used to connect the L300 hydrogel electrode base snaps to the L300 FS Cuff plug holes, for aid in determining optimal placement of the L300 hydrogel electrodes on the leg.

To connect the fitting cable:

1. Make sure the L300 RF Stim Unit is connected to the cradle on the L300 FS Cuff.
2. Connect the fitting cable to the L300 electrode bases and to the L300 FS Cuff plug holes.
   - Connect the ORANGE ends of the fitting cable to the muscle electrode base and the ORANGE L300 FS Cuff plug hole.
   - Connect the BLUE ends of the fitting cable to the nerve electrode base and the BLUE L300 FS Cuff plug hole.
3. Place the L300 FS Cuff close by. See Figure 8-13.

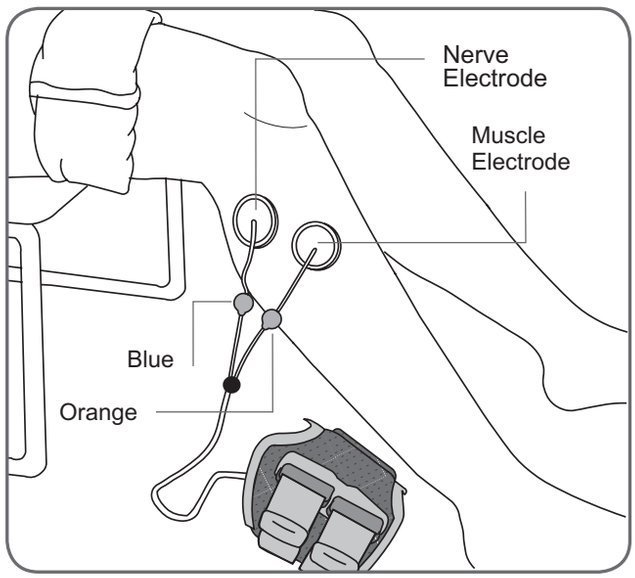


Figure 8-13: The fitting cable connected to the L300 FS Cuff and L300 electrode bases.

Adjusting the Position of the Electrodes: Patient Seated

1. Connect the patient's L300 Plus Control Unit to the Clinician's Programmer.
2. Log into the L300 Plus Intelli-Gait Software and open the patient's record.
3. Press the **Stim tab** and the **L300 tab**.
4. Adjust waveform and phase duration, if necessary.
5. Set the stimulation intensity to "0" and press **Test** to turn on stimulation in the L300 FS Cuff only.
6. While applying stimulation, observe the patient's foot for proper dorsiflexion.
7. Gradually increase the stimulation intensity to achieve dorsiflexion with a small amount of eversion.
8. With stimulation on, gently move the electrode and skin as a unit over the common peroneal nerve area. (Do not leave stimulation on for long. Fatigue may result.)

If inversion is excessive—move the nerve electrode posterolaterally to increase eversion.

If eversion is excessive—move the nerve electrode slightly anteriorly to decrease eversion.

Note: The muscle electrode can also be moved to balance dorsiflexion. Bring the muscle electrode anteriorly to decrease eversion of the foot or posterolaterally to increase eversion. Avoid stimulation directly over the tibial shaft. It can be uncomfortable and less effective.

Note: Press gently on the electrode bases while testing to simulate pressure from the L300 FS Cuff.

Adjusting the Position of the Electrodes: Patient Standing

After proper dorsiflexion is achieved with the patient seated, if possible, retest with the patient standing and the foot in the air. If necessary, adjust the stimulation or electrode position to achieve proper dorsiflexion in this position.

Transferring the Electrodes to the L300 FS Cuff

1. Stop stimulation.
2. Using a marking pen, make four small, evenly spaced marks on the patient's leg around the electrode bases for reference.
3. Disconnect the fitting cable from the electrode bases and the L300 FS Cuff, making sure not to move the electrodes.
4. Grasp the L300 FS Cuff on each side to flare the L300 FS Cuff slightly open. Then tilt the bottom of the L300 FS Cuff away from the leg about 30 degrees.
5. Position the locator of the L300 FS Cuff below the patella, over the tibial plateau. See Figure 8-14.

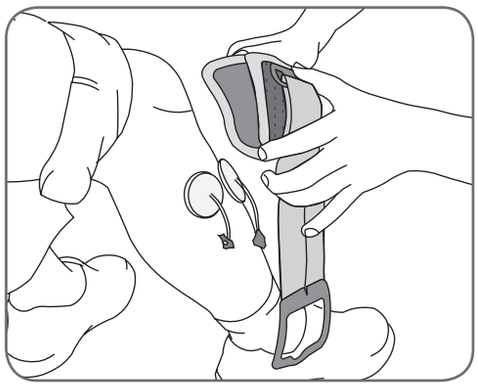


Figure 8-14: Positioning the L300 FS Cuff locator below the patella.

6. Make sure the L300 FS Cuff does not touch the electrode bases. The locator should fit snugly but comfortably under the inferior pole of the patella.
7. Keeping the L300 FS Cuff open, lower the bottom of the cuff, allowing only the front to contact the anterior surface of the tibia. Then wrap the ends of the L300 FS Cuff around the leg to "capture" the electrode bases. See Figure 8-15.

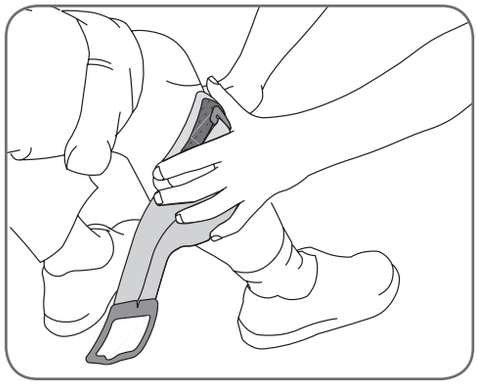


Figure 8-15: Capturing the L300 electrode bases.

8. Gently remove the L300 FS Cuff from the leg. See Figure 8-16.

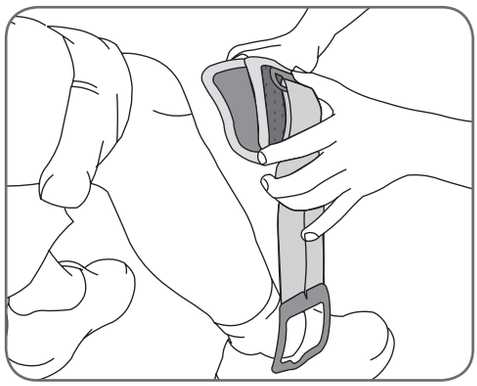


Figure 8-16: Removing the L300 FS Cuff with the captured electrode bases.

9. Press firmly on the L300 electrode bases to secure them to the L300 FS Cuff. Plug the L300 electrode base snaps into the L300 FS Cuff plug holes.

Donning the L300 FS Cuff

Turn off stimulation before donning the L300 FS Cuff.

To don the L300 FS Cuff:

1. Have the patient tilt the top of the L300 FS Cuff toward the leg, and slide the locator up the leg until it rests just under the patella. See Figure 8-17.

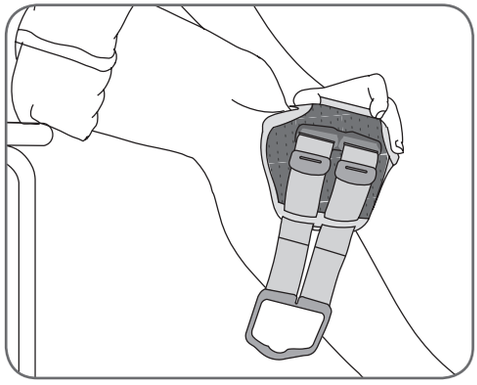


Figure 8-17: Tilting the L300 FS Cuff.

2. While holding the locator in place, have the patient lower the L300 FS Cuff until it rests flush against the leg. The L300 FS Cuff should gently grip the leg.

3. Have the patient grasp the handle of the L300 FS Cuff strap. With the thumb on the L300 RF Stim Unit cradle, have the patient fasten the L300 FS Cuff strap handle around the cradle. See Figure 8-18.

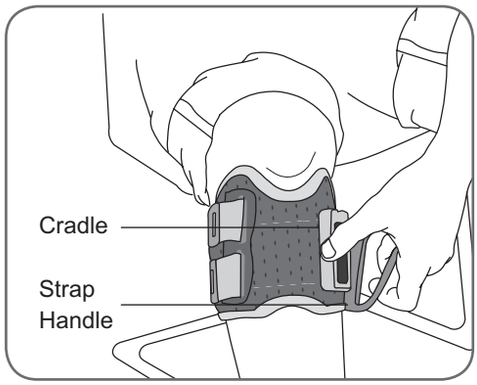


Figure 8-18: Fastening the L300 FS Cuff strap.

4. Make sure the L300 FS Cuff fits comfortably, with the locator below the patella and the strap handle around the cradle. The L300 RF Stim Unit should be on the medial side of the leg. See Figure 8-19.

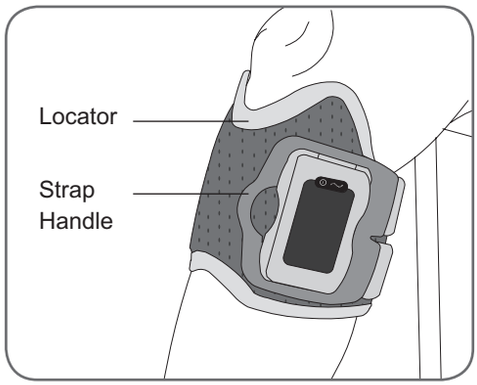


Figure 8-19: L300 FS Cuff on the right leg.

Note: Always recover the L300 hydrogel electrodes with the plastic covers after use, so that the hydrogel does not dry out.

CAUTION: Replace the electrodes every two weeks.

Retesting Electrode Placement: Patient Sitting and Standing

1. Press the **Stim tab** and the **L300 tab.**
2. Press **Test** to turn on stimulation in the L300 only.
3. Press **Stop** to turn off stimulation.
4. If patient response is not accurate or is inconsistent with the original response, reposition the L300 FS Cuff and assess the response to stimulation.

Attaching the L300 Cloth Electrodes and Bases

The L300 cloth electrodes are designed to provide an alternative for individuals who prefer to not use the standard L300 hydrogel electrodes or have skin sensitivities (for example, allergy or skin sensitivity to tape/adhesive). Fit standard L300 hydrogel electrodes first before fitting the L300 cloth electrodes.

The L300 FS Cuff uses two L300 cloth electrodes and two L300 cloth electrode bases. See Figure 8-20.

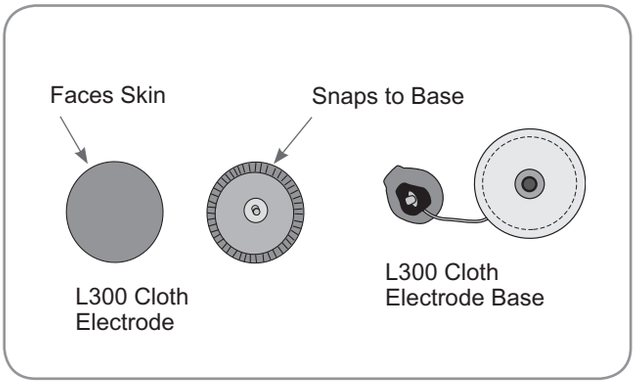


Figure 8-20: L300 cloth electrode and cloth electrode base.

Note: Wet the cloth electrodes before use. After every three to four hours of use, remove and rewet the cloth electrodes. If the L300 FS Cuff is removed for more than one hour, then wet the cloth electrodes again before use. If the L300 cloth electrodes dry out, the response to the stimulation may change. If stimulation intensity needs to be adjusted more often than usual, try rewetting the cloth electrodes.

CAUTION: The electrodes are for single patient use.

L300 Cloth Electrode Bases

1. Turn off the L300 Plus System.
2. Using the marking pen, mark the position of the L300 hydrogel electrode bases on the L300 FS Cuff liner. See Figure 8-21.

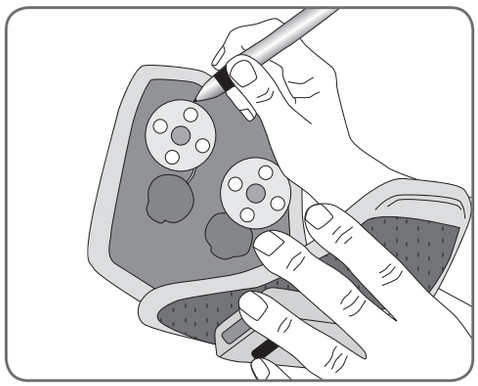


Figure 8-21: Marking the position of the L300 hydrogel electrode bases on the L300 FS Cuff liner.

3. Unsnap the L300 hydrogel electrode bases from the L300 FS Cuff plug holes. See Figure 8-22.

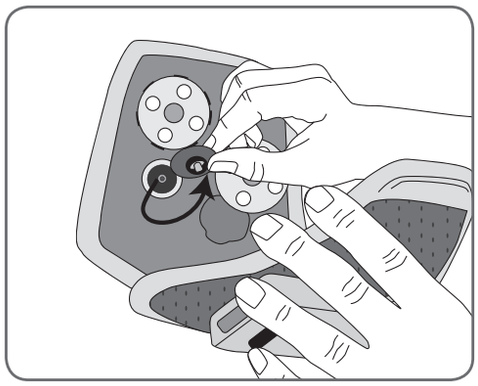


Figure 8-22: Unsnapping the L300 hydrogel electrode bases.

4. Remove the L300 hydrogel electrode bases from the L300 FS Cuff liner. See Figure 8-23.

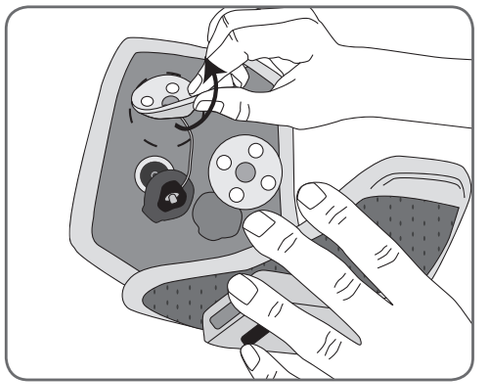


Figure 8-23: Removing the L300 hydrogel electrode bases.

5. Attach the L300 cloth electrode bases to the L300 FS Cuff where the L300 hydrogel electrode bases were attached. See Figure 8-24.

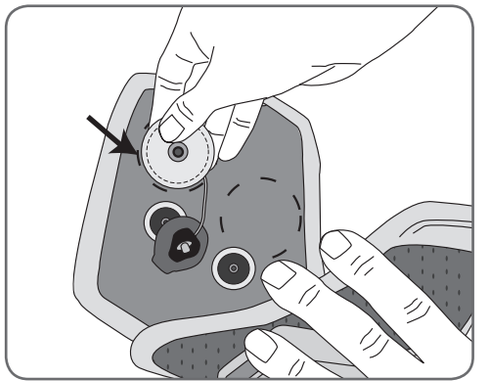


Figure 8-24. Attaching the L300 cloth electrode bases.

6. Snap the L300 cloth electrode bases to the plug holes of the L300 FS Cuff. See Figure 8-25.

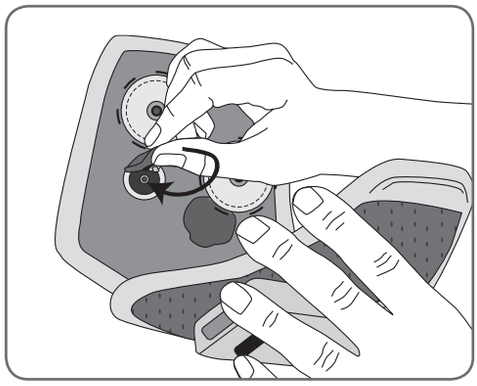


Figure 8-25: Snapping the L300 cloth electrode bases to the L300 FS Cuff plug holes.

Note: The L300 cloth electrode base is 2 mm smaller in diameter than the L300 hydrogel electrode base.

L300 Cloth Electrodes

1. Make sure the L300 Plus System is turned off.
2. Wet the L300 cloth electrodes with tap water until saturated. See Figure 8-26.

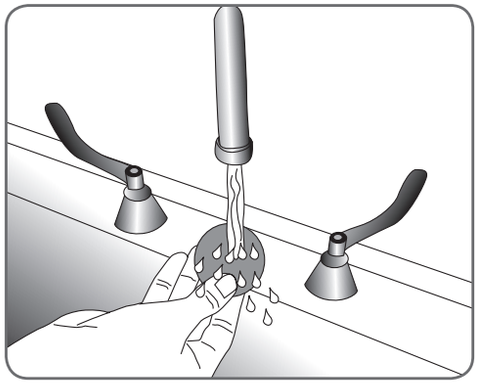


Figure 8-26: Wetting the L300 cloth electrodes.

3. With a soft cloth, gently wipe or blot excess water from the snap side of the L300 cloth electrodes. See Figure 8-27.

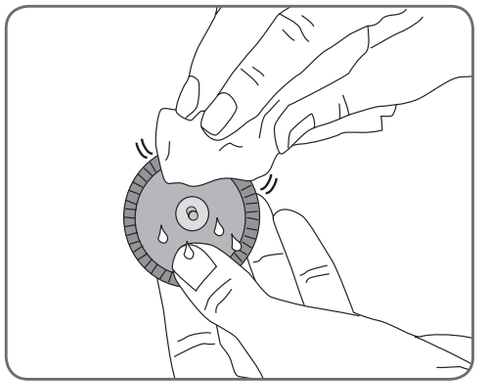


Figure 8-27: Blotting the snap side of the L300 cloth electrodes.

4. Snap the L300 cloth electrodes to the cloth electrode bases in the L300 FS Cuff. See Figure 8-28.

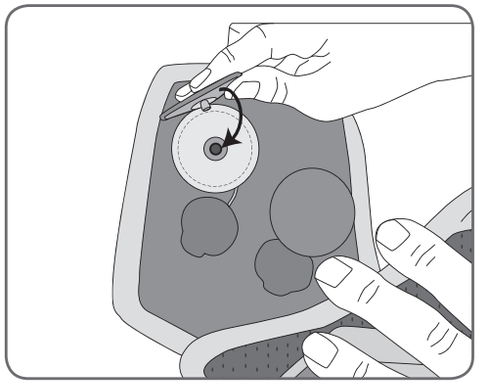


Figure 8-28: Snapping the L300 cloth electrodes to the L300 cloth electrode bases.

5. Don the L300 FS Cuff and verify that the desired dorsiflexion response is produced. If needed, optimize the stimulation settings and the position of the cloth electrodes.

CAUTION: Replace the electrodes every two weeks.

Attaching the Wire Concealers

The wire concealers may be used to cover the wires and snaps of the L300 electrode bases on the L300 FS Cuff. See Figure 8-29. Press on the wire concealers to attach them to the liner of the L300 FS Cuff.

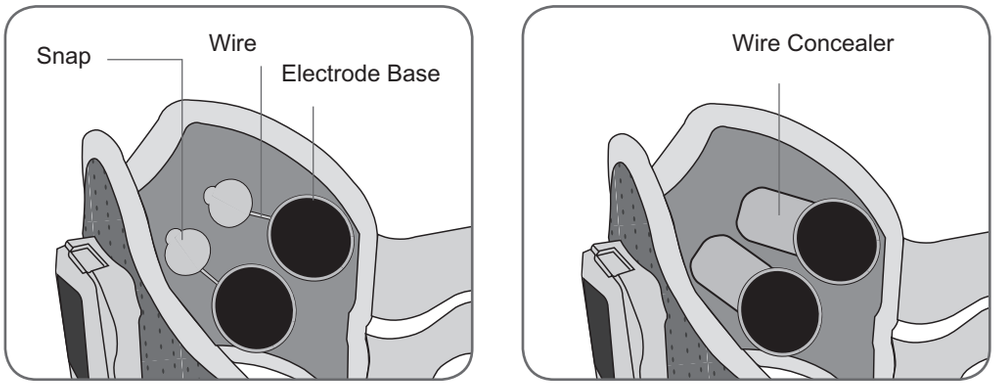


Figure 8-29: L300 FS Cuff without (left) and with (right) wire concealers.

Thigh FS Cuff

The Thigh FS Cuff is available in two sizes: regular and large.

Measuring for Thigh FS Cuff Size

1. Have the patient sit at the edge of a chair.
2. Using the tape measure, determine the thigh circumference three finger widths proximal from the patella. See Figure 8-30.

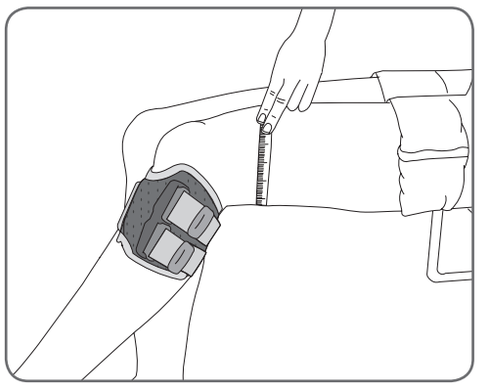


Figure 8-30: Measuring for the Thigh FS Cuff.

3. Refer to Table 8-2 to select the Thigh FS Cuff size.

Thigh FS Cuff Size	Leg Circumference
Regular	< 51 cm
Large	≥ 51 cm

Table 8-2: Thigh FS Cuff fitting chart.

CAUTION: Remove the Thigh FS Cuff from the skin every 3 to 4 hours for 15 minutes to allow the skin to breathe.

Adjusting the Elongation Bar

The Thigh elongation bar is used to adjust the distance between the Thigh FS Cuff proximal and distal panels, to accommodate different leg sizes. The elongation bar has six adjustment holes. The default elongation bar position is the #3 adjustment hole.

To adjust the Thigh FS Cuff elongation bar:

1. Open the flap on the elongation bar. See Figure 8-31.

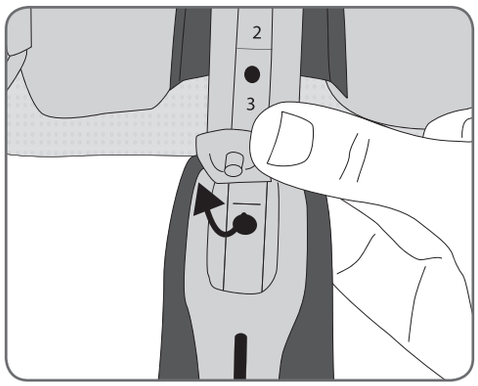


Figure 8-31: Opening the flap on the elongation bar.

2. Center the elongation bar on the thigh. Position the Thigh FS Cuff locator three finger widths proximal from the patella if stimulating the quadriceps or from the popliteal fossa if stimulating the hamstrings.
3. Slide the Thigh FS Cuff proximal and distal panels together or apart as required to achieve optimal stimulation. See Figure 8-32.

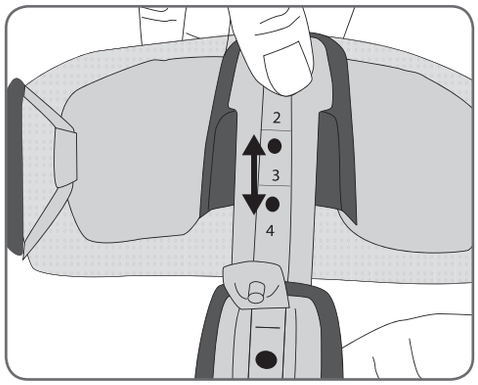


Figure 8-32: Sliding the elongation bar.

4. Close the flap on the Thigh elongation bar.

Attaching the Thigh Cloth Electrodes

The Thigh FS Cuff uses two cloth electrodes. The proximal Thigh electrode snaps to the Thigh FS Cuff proximal panel and the distal Thigh electrode snaps to the Thigh FS Cuff distal panel. The distal Thigh electrode is smaller and has a marking around one of the snaps. See Figure 8-33.

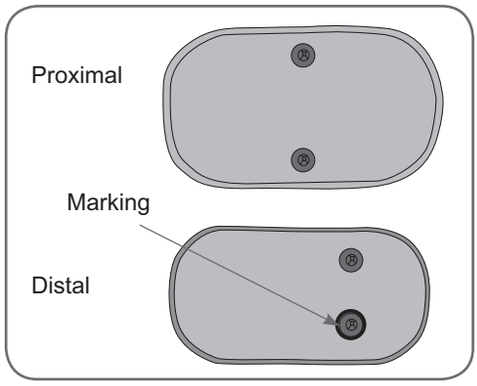


Figure 8-33: Thigh cloth electrodes.

The marking is for determining which electrode orientation the distal Thigh cloth electrode should be positioned in for home users: centered or off-centered. See Figure 8-34, Figure 8-35, and Figure 8-36.

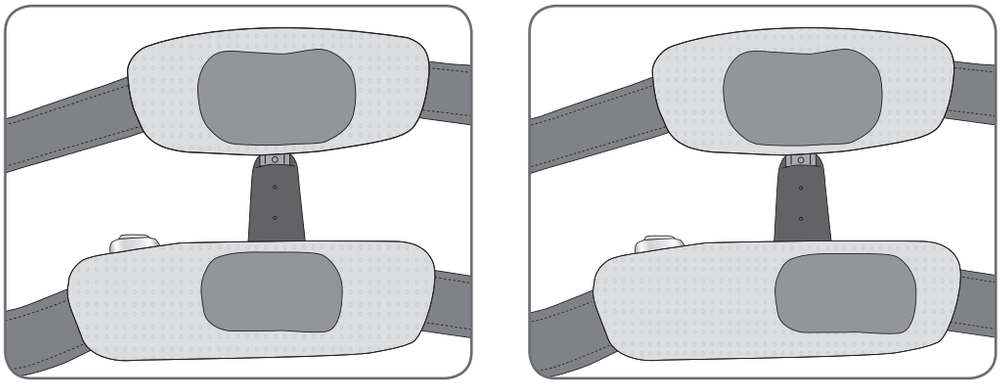


Figure 8-34: The distal cloth electrode centered (left) and off-centered (right).

CAUTION: Replace the electrodes every two weeks.

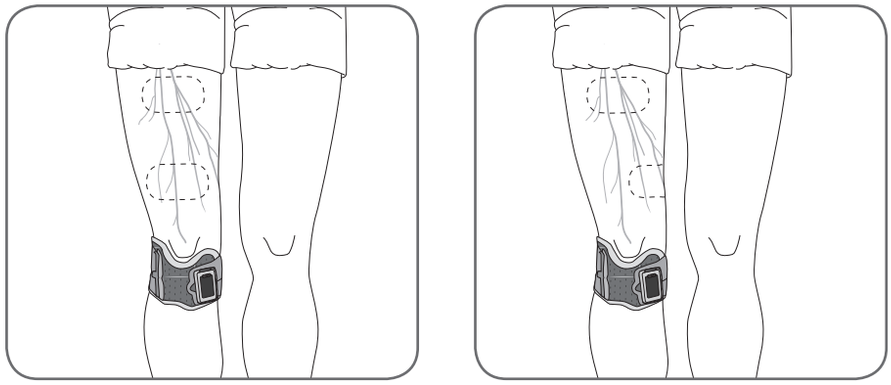


Figure 4-35: Electrode positioning on the quadriceps: centered (left) and off-centered (right) position.

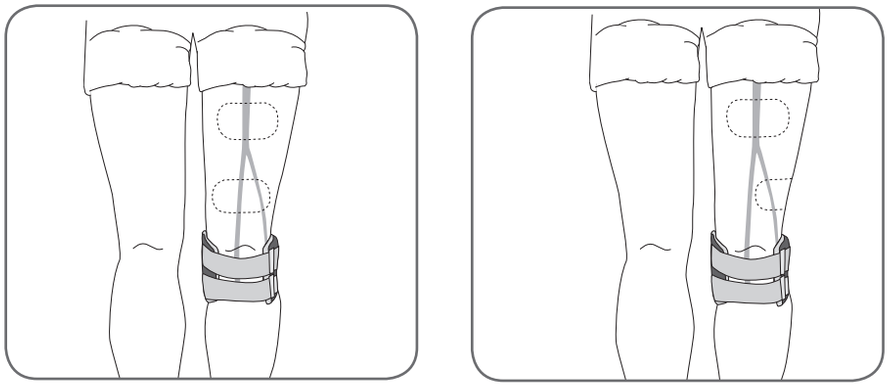


Figure 4-36: Electrode positioning on the hamstrings: centered (left) and off-centered (right) position.

Note:

- Wet the Thigh cloth electrodes before use. After every three to four hours of use, remove and rewet the Thigh cloth electrodes. If the Thigh FS Cuff is removed for more than one hour, wet the cloth electrodes again before use. If the Thigh cloth electrodes dry out, the response to the stimulation may change. If stimulation intensity needs to be adjusted more often than usual, try rewetting the cloth electrodes.
- Store the Thigh cloth electrodes where they can air dry.

To attach the Thigh cloth electrodes:

1. Wet the Thigh cloth electrodes with water until saturated. See Figure 8-37.

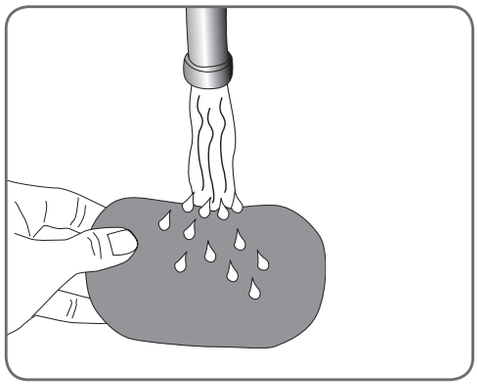


Figure 8-37: Wetting the Thigh cloth electrodes.

2. Press the electrodes together and gently squeeze out excess water. Then, with a soft cloth, gently wipe or blot excess water from snap side. See Figure 8-38.

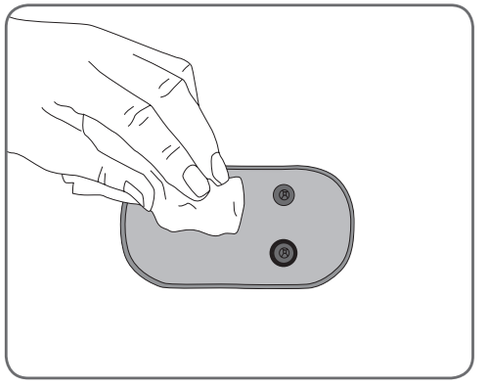


Figure 8-38: Blotting the Thigh cloth electrodes.

3. Snap the proximal Thigh cloth electrode to the proximal panel. See Figure 8-39.

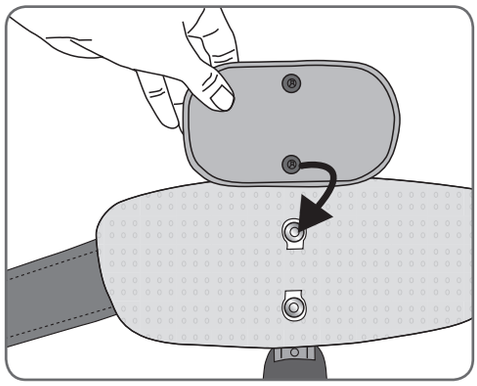


Figure 8-39: Snapping the proximal Thigh cloth electrode.

4. Snap the distal Thigh cloth electrode to the distal panel. See Figure 8-40.

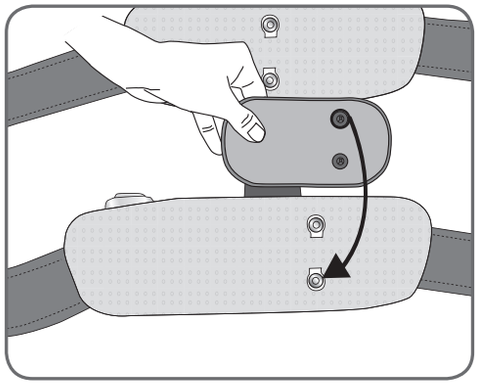


Figure 8-40: Snapping the distal cloth electrode.

Donning the Thigh FS Cuff

Turn off stimulation before donning the Thigh FS Cuff.

To don the Thigh FS Cuff:

1. Center the Thigh elongation bar on the thigh.
2. Position the Thigh FS Cuff locator approximately three finger widths proximal from the patella if stimulating the quadriceps or from the popliteal fossa if stimulating the hamstrings. See Figure 8-41.

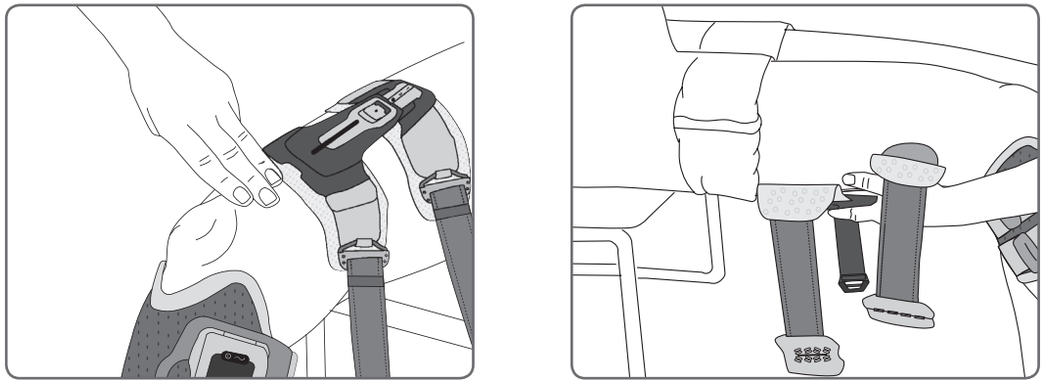


Figure 8-41: Donning the Thigh FS Cuff.

3. Fasten and tighten the straps. See Figure 8-42.

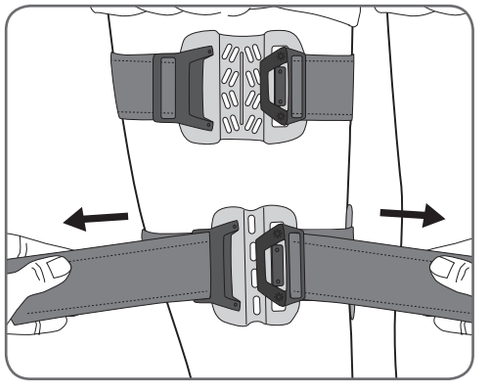


Figure 8-42: Tightening the straps.

Checking the Position of the Thigh Cloth Electrodes: Patient Seated

Stimulation can be tested in the Thigh FS Cuff only by way of the stimulation setting screen. Stimulation cannot be tested in the Thigh FS Cuff alone by way of the gait setting screen.

To check the position of the Thigh electrodes:

1. Have the patient sit with the lower leg dangling unobstructed. See Figure 8-43.
2. Press the **Stim tab** and the **Thigh tab** to view the Stim Settings window.

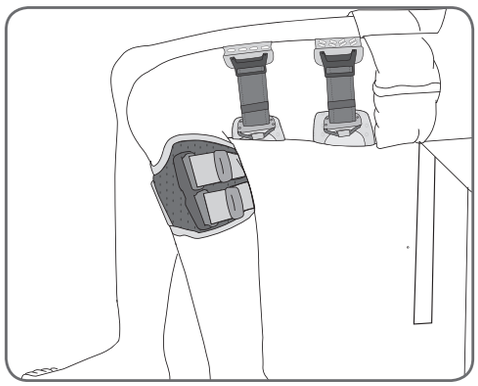


Figure 8-43: Test stimulation with the patient seated and the legs dangling.

3. Adjust waveform and phase duration, if necessary.
4. Set stimulation intensity to “0,” and press **Test** to test stimulation in the Thigh FS Cuff.
5. Gradually increase stimulation intensity to achieve the desired extension or flexion at the knee.
6. If the desired knee extension or flexion is not achieved, adjust stimulation or consider the off-centered electrode position.

Note: Do not rotate the Thigh FS Cuff on the leg while it is fastened.

Checking the Position of the Thigh Cloth Electrodes: Patient Standing

After proper extension or flexion is achieved with the patient seated, if possible, retest with the patient standing, the knee at an adjustable angle, and the foot in the air. If necessary, adjust the stimulation settings and/or the position of the Thigh FS Cuff.

Programming Gait Settings

The clinician will need to assess the patient walking and make gait setting adjustments as needed. To test in gait mode, the Intelli-Sense Gait Sensor must be placed in the patient's shoe.

Placing the Gait Sensor in the Shoe

1. Lift the shoe insole
2. Attach a Gait Sensor pad to the heel of the shoe. The Gait Sensor pad secures the Intelli-Sense Gait Sensor pressure sensor to the inside of the shoe. The Gait Sensor pad is placed under the insole of the shoe. See Figure 8-13.
3. With the wire of the pressure sensor pointing toward the toe of the shoe, attach the pressure sensor to the Gait Sensor pad. (Refer to the foot image on the pressure sensor for alignment.) See Figure 8-44.

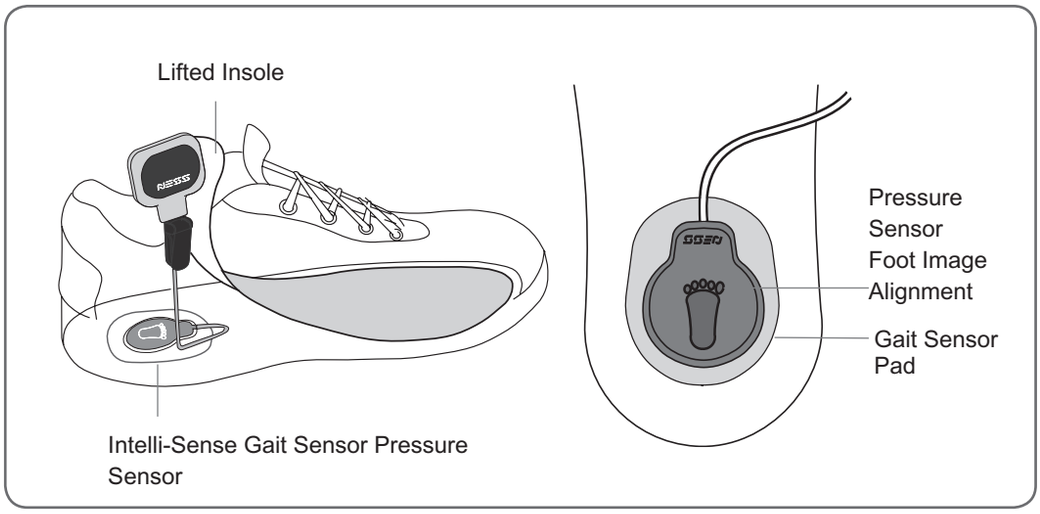


Figure 8-44: Intelli-Sense Gait Sensor in a left shoe.

4. Attach a shoe spacer to the inner clamp of the Intelli-Sense Gait Sensor. The shoe spacer stabilizes the Intelli-Sense Gait Sensor in the shoe. It also protects the rim of the shoe from the clamp on the Intelli-Sense Gait Sensor. The shoe spacer fits between the inner clamp and the outside of the shoe.
   - Open the clamp.
   - Slide the shoe spacer over the inner clamp See Figure 8-45.

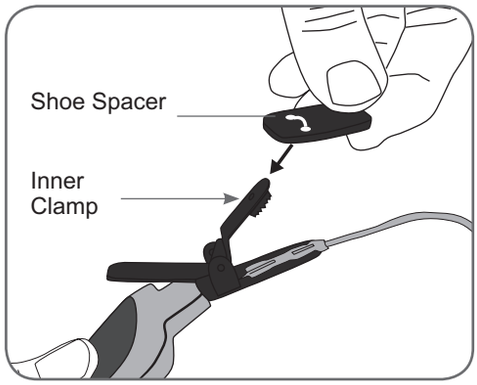


Figure 8-45: Attaching the shoe spacer.

5. Clamp the transmitter to the inner rim of the shoe. Face the NESS logo on the transmitter away from the ankle.
6. Lower the insole over the pressure sensor, tucking any excess wire under the insole.

Note: If the shoe does not have a detachable insole, place the Gait Sensor pad and pressure sensor on top of the insole. Then, place a soft, thin (one layer versus two) generic insole over them. Generic insoles can be purchased from drugstores, shoe stores, or Bioness Inc.

CAUTION: The Intelli-Sense Gait Sensor has not been validated for use by individuals weighing more than 136 kilograms.

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

Programming Training Settings

Training settings should be adjusted with the patient seated.

Doffing the NESS L300 Plus System

1. If the L300 FS Cuff is for clinic use, remove the patient's personal strap cover and personal panel, with the L300 electrode(s) and electrode bases attached, from the L300 FS Cuff. See Figure 8-46. Store the personal panel and personal strap cover in the Personal Panel Storage System until the patient’s next session.

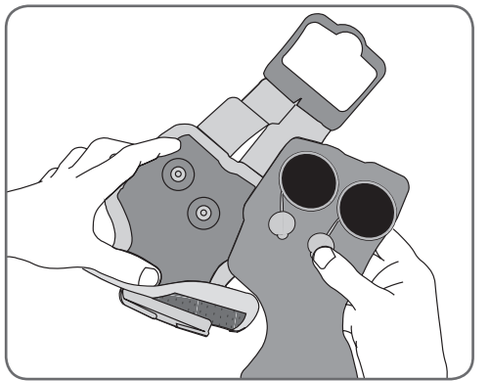


Figure 8-46: Removing the personal panel from the L300 FS Cuff.

Note: When the patient returns for a follow-up session, attach the personal panel, with the L300 electrode bases and/or L300 electrode(s) attached, to the L300 FS Cuff plug holes, and reattach the personal strap cover to the L300 FS Cuff strap.

2. If using the L300 hydrogel electrodes, re-adhere the covers to the L300 hydrogel electrodes. Do not allow the hydrogel to dry out.
3. Store the cloth electrodes where they can air dry.
4. Note the orientation of the distal Thigh cloth electrode.
5. Note the adjustment hole selected for the Thigh elongation bar.
6. For home users, attach the Thigh electrode marking ring to the appropriate snap.
7. Clean and disinfect the Thigh FS Cuff, if appropriate.

Attaching the Thigh Electrode Marking Ring

1. Check the orientation of the distal thigh cloth electrode, and attach the Thigh electrode marking ring to the appropriate snap. See Figure 8-47.

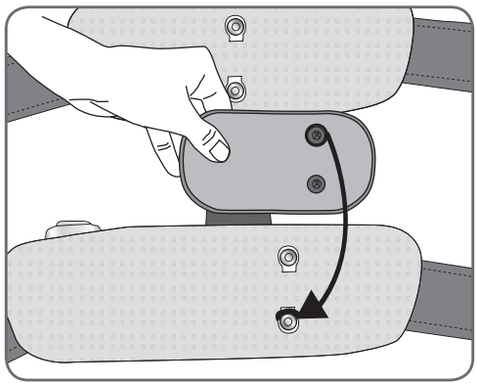


Figure 8-47: Thigh electrode marking ring on the Thigh distal panel snap.

2. The thigh electrode marking ring slides over the snap. See Figure 8-48.

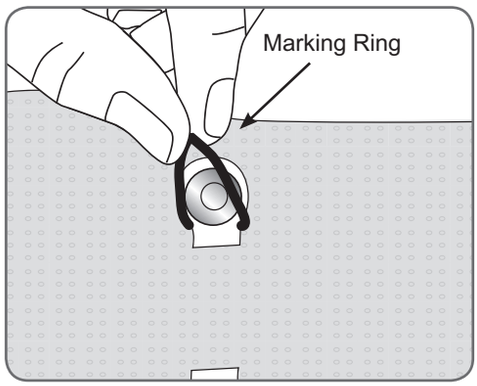


Figure 8-48: Attaching the Thigh electrode marking ring.

CAUTION: Store the Thigh cloth electrodes where they can air dry.

Patient Training and Follow-Up

Clinicians and patients should know the limitations, warnings, and precautions associated with the NESS L300 Plus System. Clinicians should review the safety information with patients, and train patients on system set-up, operation, and maintenance. Patients should understand the system displays and indicators, and the troubleshooting solutions. Clinicians and patients should know whom to contact for clinical and technical support.

A training program should cover the following topics:

- A review of the general safety information, including the Skin Care Guidelines.
- An overview of the NESS L300 Plus System.
- Donning and doffing the L300 FS Cuff and the Thigh FS Cuff.
- Replacing the L300 electrodes and the Thigh cloth electrodes.
- Placing the Intelli-Sense Gait Sensor in a shoe.
- Transferring the Intelli-Sense Gait Sensor to a different shoe.
- Understanding the L300 Plus Control Unit and RF Stim Unit audio and visual alerts.
- Operating the L300 Plus Control Unit:
  - Testing the position of each FS Cuff.
  - Selecting gait and training modes.
  - Adjusting stimulation intensity for each RF Stim Unit.
  - Muting the audio alerts.
  - Turning off the alerts in an FS Cuff.
- Conditioning protocol: using gait and training modes.
- Maintenance and cleaning instructions:
  - Changing and replacing the batteries.
  - Registering replacement components.
  - Cleaning and disinfecting the system components.
  - Replacing damaged components.
- Troubleshooting.
- Contacting a local distributor.

The NESS L300 Plus program should be supervised by a qualified clinician to monitor clinical progress, maximize clinical effectiveness and safety, and provide clinical and technical support.

Note: The above topics are described in this manual and in the NESS L300 Plus *User's Guide.*

A suggested follow-up agenda would include:

- Check out the system for wear and function.
- Programming adjustments: stimulation, gait, and training parameters.
- Gait training, including advanced training as appropriate (for example, stair negotiation).
- Review of training topics as necessary:
  - A review of the general safety information, including the Skin Care Guidelines.
  - An overview of the NESS L300 Plus System.
  - Donning and doffing the L300 FS Cuff and the Thigh FS Cuff.
  - Replacing the L300 electrodes and the Thigh cloth electrodes.
  - Placing the Intelli-Sense Gait Sensor in a shoe.
  - Transferring the Intelli-Sense Gait Sensor to a different shoe.
  - Understanding the L300 Plus Control Unit and RF Stim Unit audio and visual alerts.
  - Operating the L300 Plus Control Unit:
    - » Testing the position of each FS Cuff.
    - » Selecting gait and training modes.
    - » Adjusting stimulation intensity for each RF Stim Unit.
    - » Muting the audio alerts.
    - » Turning off the alerts in an FS Cuff.
  - Conditioning protocol: using gait and training modes.
  - Maintenance and cleaning instructions:
    - » Changing and replacing the batteries.
    - » Registering replacement components.
    - » Cleaning and disinfecting the system components.
    - » Replacing damaged components.
  - Troubleshooting.
  - Contacting a local distributor.
- Skin evaluation (under the FS Cuffs and around the Intelli-Sense Gait Sensor).
- Troubleshooting.

Maintenance and Cleaning

Registering an L300 Plus System Upgrade Kit

The components in a NESS L300 Plus System Upgrade Kit must be electronically registered to the existing L300 components for the L300 Plus System to operate. The clinician will need to electronically register the system components.

Registration Setup

1. Turn off the L300 Plus System.
2. Place the L300 RF Stim Unit, Thigh RF Stim Unit, L300 Plus Control Unit, and Intelli-Sense Gait Sensor close together on a table but not touching. See Figure 10-1.

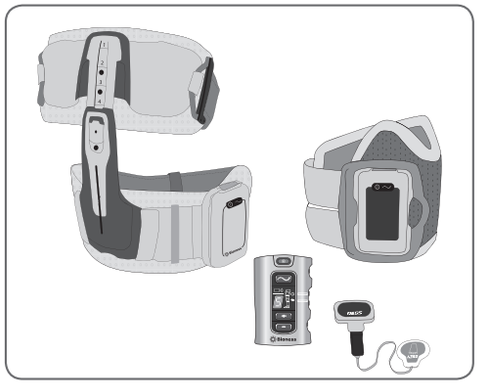


Figure 10-1: Registration setup.

3. Connect the L300 Plus Control Unit and both RF Stim Units to the L300 Plus system charger set during registration.
4. Make sure all other NESS L300 and NESS L300 Plus System components are at least 30 feet from the components to be registered.

Registration

The registration procedure must be performed twice: once for the L300 Plus Control Unit and once for the Thigh RF Stim Unit.

Note: The existing Intelli-Sense Gait Sensor does not need to be registered. Only a new Intelli-Sense Gait Sensor needs to be registered.

To register the L300 Plus Control Unit:

1. Simultaneously press and hold for three seconds the mode and minus buttons on the L300 Plus Control Unit. The L300 Plus Control Unit will beep when registration begins.
2. The L300 Plus Control Unit digital display will show two ALTERNATING GREEN arches while registration is in process. See Table 10-1. Registration may take up to five minutes to complete.

Display	Description	Definition
	ALTERNATING GREEN Arches	Registration in Process
	Letter "C"	Registration Complete
	Letter "E"	Registration Error

Table 10-1: L300 Plus Control Unit electronic registration displays.

3. When registration is complete, (“C” for complete) will appear in the digital display and the L300 Plus Control Unit indicator will turn GREEN for a few seconds. The L300 Plus Control Unit will beep.

Note: If (“E” for error) appears in the digital display, an error has occurred. Repeat the registration procedure.

4. After registration is complete, turn on the L300 Plus Control Unit. If the L300 Plus Control Unit is registered, it will turn on the L300 RF Stim Unit. If you see an RF communication failure indication, then repeat the registration procedure.

To register the Thigh RF Stim Unit:

1. Simultaneously press and hold for three seconds the mode and minus buttons on the L300 Plus Control Unit. The L300 Plus Control Unit will beep when registration begins.
2. The L300 Plus Control Unit digital display will show two ALTERNATING GREEN arches while registration is in process. Registration should take several seconds to complete.
3. When registration is complete, ("C" for complete) will appear in the digital display and the Thigh RF Stim Unit indicator will turn GREEN for a few seconds. The L300 Plus Control Unit will beep.

Note: If ("E" for error) appears in the digital display, an error has occurred. Repeat the registration procedure.

4. After registration is complete, turn on the L300 Plus Control Unit. If the Thigh RF Stim Unit is registered, it will turn on. If you see an RF communication failure indication, then repeat the registration procedure.

Following a successful registration:

1. Locate the System ID Number (for example, A334) on the label on the back of the L300 RF Stim Unit and the Intelli-Sense Gait Sensor.
2. Write the System ID Number on the label on the outside of the L300 Plus System Upgrade Kit carrying case and on the label on the back of the L300 Plus Control Unit and the Thigh RF Stim Unit, and on the Thigh FS Cuff.

Note: The System ID Number identifies which NESS L300 Plus System a component is registered to. The System ID Number on each component of a NESS L300 Plus System must match.

Charging

Charge the HP iPAQ Clinician's Programmer and the NESS L300 Plus System daily.

PDA Battery Storage

During extended periods of nonuse, remove the battery from the HP iPAQ Clinician's Programmer. Refer to the PDA manufacturer's instructions for information on battery removal and replacement.

Battery Replacement

Refer to the NESS L300 Plus *User's Guide* for battery replacement instructions for the NESS L300 Plus System components.

CAUTION: Only use batteries supplied by Bioness Inc.

Electrodes

Replace the L300 Plus System electrodes every two weeks, even if they appear to be in good condition.

CAUTION: Do not use the L300 Plus System without electrodes.

CAUTION: Only use electrodes supplied by Bioness Inc.

Cover the L300 hydrogel electrodes when not in use. Do not allow the hydrogel to dry out. If the electrode gel becomes dry, rehydrate it with 1–2 drops of water.

Wet the L300 and Thigh cloth electrodes:

- Before use
- After three to four hours of use.
- Every time the FS Cuffs are removed from the leg for more than one hour.

When wetting the cloth electrodes, remove them from the FS Cuffs. Wet the cloth electrodes with water until they are saturated.

Note: If the cloth electrodes dry out, the response to the stimulation may change. If stimulation intensity needs to be adjusted more often than usual, try rewetting the cloth electrodes.

Electrode Bases

The L300 electrode bases are reusable. When a patient discontinues use of the NESS L300 Plus System, remove the L300 electrode bases from the personal panel or the L300 FS Cuff, and remove the L300 electrodes from the L300 electrode bases. Clean the L300 electrode bases with cool water to remove any residue. Then disinfect the electrode bases before reuse.

If the L300 electrode bases become torn or cracked, they may need to be replaced. Refer to the L300 Plus *User's Guide* for replacement instructions.

CAUTION: Patients may replace the electrode bases, but only a clinician should reposition the electrode bases.

FS Cuffs

Replacement FS Cuffs need to be refit.

To replace an FS Cuff:

1. Transfer the RF Stim Unit to the new FS Cuff.
2. Transfer the Thigh cloth electrodes and orange marking ring to the new Thigh FS Cuff, if appropriate.
3. Transfer the L300 electrode(s) and bases to the new L300 FS Cuff, if appropriate.*
4. Place the new FS Cuff on the patient, and test for fit and functionality.
5. Record the L300 Plus System ID Number (for example, A334) on the blank label on the new FS Cuff.
6. Record the serial number of the new FS Cuff on the label on the outside of the System Kit carrying case.

***If using the large cloth electrode, L300 systems:**

1. Unsnap the large cloth electrode from the L300 FS Cuff.
2. Snap the large cloth electrode to the new L300 FS Cuff.
3. Place the new L300 FS Cuff on the patient. Test for fit and functionality.

***If using L300 hydrogel electrodes and bases:**

1. Place the old L300 FS Cuff on the leg.
2. Use a marking pen to mark the position of the L300 FS Cuff locator on the leg. (Mark a few small dots.)
3. Remove the L300 FS Cuff from the leg. (The leg should show impressions where the electrodes were touching.)
4. Remove the electrodes and bases from the L300 FS Cuff.
5. Place the electrodes and bases on the leg, using the impressions left by the electrodes for reference.
6. With the new L300 FS Cuff, capture the L300 electrodes from the leg.
7. Connect the L300 electrode base snaps to the L300 FS Cuff plug holes.
8. Cover the L300 electrode base wires and snaps with the wire concealers, if desired.
9. Place the new L300 FS Cuff on the patient. Test for fit and functionality.

If using L300 cloth electrodes and bases:

1. Fit the L300 hydrogel electrodes and bases first.
2. Then fit the cloth electrodes and bases.
3. Place the new L300 FS Cuff on the patient. Test for fit and functionality.

Thigh Cuff Buckles

The Thigh cuff buckles are for the Thigh clinic straps. The large buckle fastens the proximal straps. The regular buckle fastens the distal straps. See Figure 10-2.

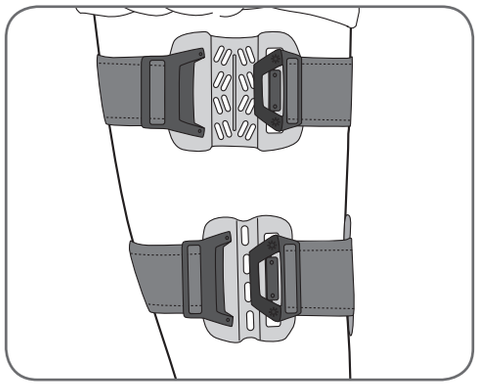


Figure 10-2: Thigh cuff buckles.

Thigh Clinic Straps

The Thigh clinic strap set includes two straps and one handle. The Thigh clinic straps slide in and out of the Thigh FS Cuff distal and proximal panels.

To replace the Thigh clinic straps:

1. Note the orientation of the buckle and handle on the old straps.
2. Remove the loops, handle, and buckle from the old straps.
3. Remove the straps from the Thigh FS Cuff. See Figure 10-3.

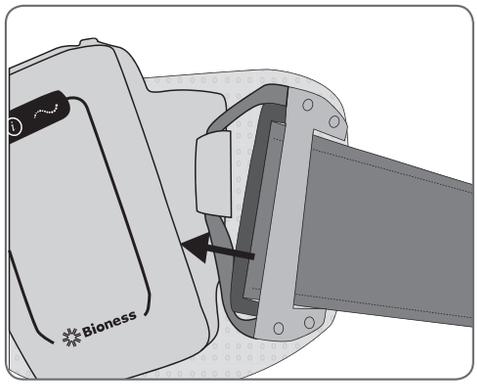


Figure 10-3: Removing the Thigh clinic straps.

4. Remove the loops and handle from the new strap set.
5. Attach the new straps to the Thigh FS Cuff.
6. Attach the loops, handle, and buckle to the new straps.

Thigh Silicone Panels

If the Thigh silicone panels need to be replaced, refer to the L300 Plus *User's Guide* for replacement instructions.

Thigh Elongation Bar Lock

The Thigh elongation bar lock is used to lock the position of the elongation bar on home-use systems. To adjust the elongation bar, the thigh elongation bar lock must be removed.

Note: Only clinicians should remove the Thigh elongation bar lock.

To remove the Thigh elongation bar lock:

1. Position the Thigh FS Cuff with the inside of the panels facing up.
2. Using the Phillips screwdriver, push the Thigh elongation bar lock through the elongation bar. See Figure 10-4.

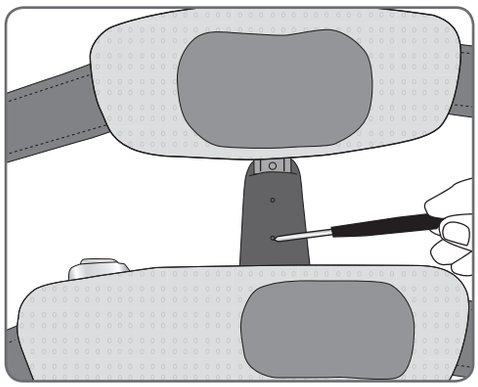


Figure 10-4: Removing the Thigh elongation bar lock.

3. Adjust the elongation bar.
4. Reinsert the Thigh elongation bar lock in the elongation bar. See Figure 10-5.

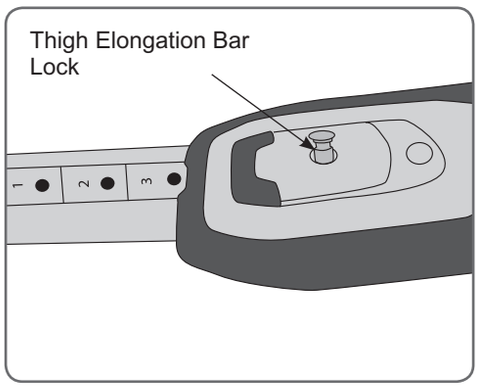


Figure 10-5: Inserting the Thigh elongation bar lock.

Cleaning

All L300 Plus components may be cleaned by carefully wiping them with a damp cloth. The electrical components are not waterproof. **Do not immerse them in water.**

If necessary, clean the L300 electrode bases with a damp cloth. Do not use a chemical-based cleaning substance.

The L300 FS Cuff is the only component that can be immersed in water to clean. Refer to the L300 Plus *User's Guide* for instructions on cleaning the L300 FS Cuff.

Disinfecting

To prevent patient cross-contamination, attach the L300 personal panels and personal strap covers to the L300 FS Cuff.

All NESS L300 Plus System components excluding the L300 FS Cuff and the outer surface of the Thigh clinic straps may be disinfected using CaviWipes™ (Metrex, Orange, CA USA). Metrex products are sold through authorized dealers worldwide. If you have difficulty locating Metrex CaviWipes, please call your local distributor.

To disinfect the L300 Plus System components:

1. Clean the surface that faces the skin with a wet CaviWipes disinfection wipe.

Note: Read and follow the Metrex precautions for personal protection as appropriate.

2. Using one or more new CaviWipes, wipe the surface again, thoroughly, for three minutes. The surface should be visibly wet.

Troubleshooting

Using the Tester

The Tester is used to troubleshoot if there is a disconnection in one of the FS Cuffs or a faulty RF Stim Unit. The Tester provides audio feedback when connected to the NESS L300 Plus System and stimulation is applied.

Testing the L300 FS Cuff in Training Mode

1. Connect the Tester to the L300 FS Cuff plug holes. See Figure 11-1.

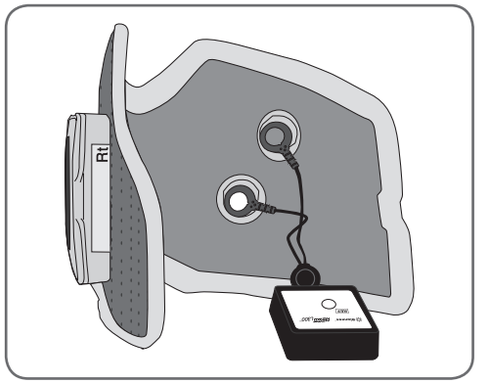


Figure 11-1: Tester connected to the L300 FS Cuff.

2. Press the L300 Plus Control Unit on/off button to turn on the system.
3. Press and hold the mode button until the L300 Plus Control Unit beeps, the mode button starts FLASHING YELLOW SLOWLY, and (“t” for training) alternates with the intensity level in the digital display. When stimulation is on, the mode button will FLASH YELLOW RAPIDLY.
4. You should hear a buzzing when stimulation is on and no buzzing when stimulation is off.

Testing the L300 FS Cuff in Gait Mode

1. Connect the Tester to the L300 FS Cuff.
2. Press the L300 Plus Control Unit on/off button to turn on the system.
3. Press the mode button briefly to enter gait mode. The L300 Plus Control Unit will beep and the mode button will FLASH YELLOW SLOWLY (indicating that stimulation is off). When stimulation is on, the mode button will FLASH YELLOW RAPIDLY.
4. Press and release the pressure sensor on the Intelli-Sense Gait Sensor. You should hear a buzzing when you release pressure from the pressure sensor and no buzzing when you press on the pressure sensor.

If either of the above tests elicits an error indication, test using the advanced testing procedures.

Advanced Testing

If stimulation is not delivered to the patient's leg, a "faulty electrode contact" error may appear. Recheck that the electrode base snaps are secured to the plug holes of the L300 FS Cuff and that the L300 RF Stim Unit is fully snapped into the L300 FS Cuff cradle. Then use the Tester to differentiate among problems in the L300 RF Stim Unit, L300 FS Cuff, and L300 electrode bases. Follow the steps below:

Step 1: Test the L300 FS Cuff:

1. Connect the Tester to the L300 FS Cuff.
2. Apply stimulation using the stimulation test button or the Clinician's Programmer. The minimum intensity required to produce a sound is 10 mA.
3. If the circuit is intact in the L300 FS Cuff and the L300 RF Stim Unit is working properly, the Tester will buzz.
4. If the Tester buzzes but the patient was not feeling stimulation while the L300 FS Cuff was donned, the problem may be in the L300 electrode bases. Replace the L300 electrode bases and L300 electrodes.
5. If the Tester does not buzz, then proceed to Step 2.

Step 2: Test the L300 RF Stim Unit:

1. Remove the L300 RF Stim Unit from the cradle. See Figure 11-2.

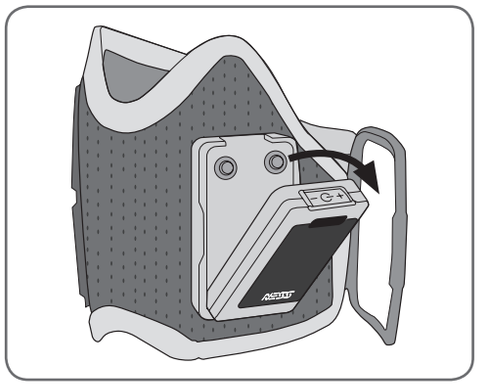


Figure 11-2: Removing the L300 RF Stim Unit.

2. Connect the Tester to the electrical sockets on the back of the L300 RF Stim Unit. See Figure 11-3. The connectors on the Tester and the sockets on the L300 RF Stim Unit are color coded.

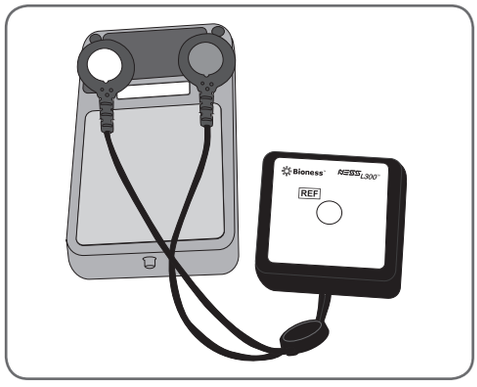


Figure 11-3: Tester connected to the L300 RF Stim Unit.

3. Apply stimulation using the stimulation test button or the Clinician's Programmer. The minimum intensity required to produce a sound is 10 mA.
4. If the Tester buzzes, the L300 RF Stim Unit is working. The problem may be in the L300 FS Cuff. Replace the L300 FS Cuff and connect the L300 RF Stim Unit to the new L300 FS Cuff. Retest the L300 FS Cuff.
5. If the Tester does not buzz, the L300 RF Stim Unit may be faulty. Replace the L300 RF Stim Unit or contact the your local distributor.

Testing the Thigh FS Cuff in Training Mode

1. Connect the Tester to the proximal snap on the Thigh FS Cuff proximal panel and to the proximal snap on the Thigh FS Cuff distal panel. See Figure 11-4.

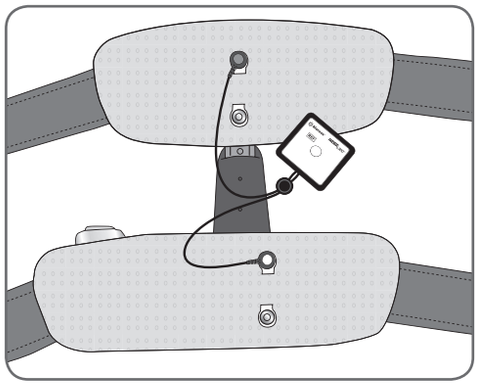


Figure 11-4: Tester connected to the Thigh FS Cuff.

2. Press the L300 Plus Control Unit on/off button to turn on the system.
3. Press and hold the mode button until the L300 Plus Control Unit beeps, the mode button starts FLASHING YELLOW SLOWLY, and (“t” for training) alternates with the intensity level in the digital display. When stimulation is on, the mode button will FLASH YELLOW RAPIDLY.
4. You should hear a buzzing when stimulation is on and no buzzing when stimulation is off.

Testing the Thigh FS Cuff in Gait Mode

1. Connect the Tester to the proximal snap on the Thigh FS Cuff proximal panel and to the proximal snap on the Thigh FS Cuff distal panel. See Figure 11-4.
2. Press the L300 Plus Control Unit on/off button to turn on the system.
3. Press the mode button briefly to enter gait mode. The L300 Plus Control Unit will beep and the mode button will FLASH YELLOW SLOWLY (indicating that stimulation is off). When stimulation is on, the mode button will FLASH YELLOW RAPIDLY.
4. Press and release the pressure sensor on the Intelli-Sense Gait Sensor. You should hear a buzzing when you release pressure from the pressure sensor and no buzzing when you press on the pressure sensor.

If either of the above tests elicits an error indication, test using the advanced testing procedures.

Advanced Testing

If stimulation is not delivered to the patient's leg, a "faulty electrode contact" error may appear. Recheck that the Thigh RF Stim Unit is fully snapped into the cradle of the Thigh FS Cuff. Then follow the steps below:

Step 1: Test the Thigh FS Cuff:

1. Connect the Tester to the Thigh FS Cuff. See Figure 11-4.
2. Apply stimulation using the stimulation test button or the Clinician's Programmer. The minimum intensity required to produce a sound is 10 mA.
3. If the circuit is intact in the Thigh FS Cuff and the Thigh RF Stim Unit is working properly, the Tester will buzz.
4. If the Tester buzzes but the patient was not feeling stimulation while the Thigh FS Cuff was donned, the problem may be in the electrodes. Replace the electrodes.
5. If the Tester does not buzz, then proceed to Step 2.

Step 2: Test the Thigh RF Stim Unit:

1. Remove the Thigh RF Stim Unit from the Thigh FS Cuff cradle. See Figure 11-5.

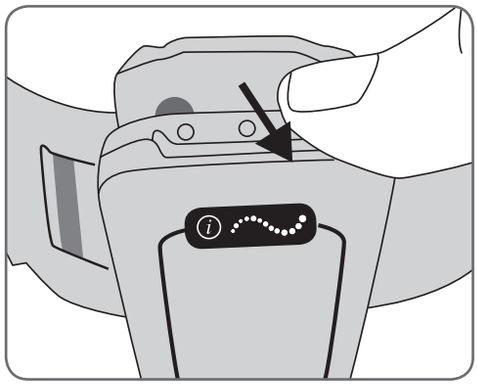


Figure 11-5: Removing the Thigh RF Stim Unit.

2. Connect the Tester to the electrical sockets on the back of the Thigh RF Stim Unit. See Figure 11-6. The connectors on the Tester and the electrical sockets on the Thigh RF Stim Unit are color coded.

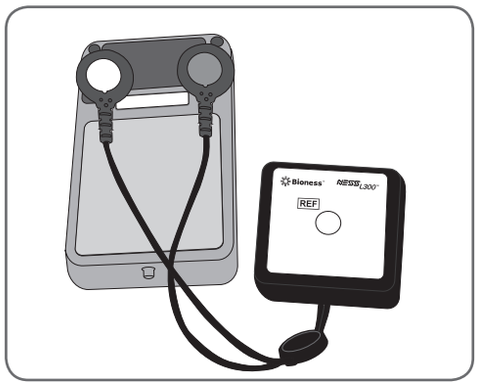


Figure 11-6: Tester connected to the Thigh RF Stim Unit.

3. Apply stimulation using the L300 Plus Control Unit in clinician mode or by using the Clinician's Programmer. The minimum intensity required to produce a sound is 10 mA.
4. If the Tester buzzes, the Thigh RF Stim Unit is working. The problem may be in the Thigh FS Cuff. Replace the Thigh FS Cuff. Then connect the Thigh RF Stim Unit to the new Thigh FS Cuff, and retest the Thigh FS Cuff.
5. If the Tester does not buzz, the Thigh RF Stim Unit may be faulty. Replace the Thigh RF Stim Unit or contact your local distributor.

Frequently Asked Questions

If you have any questions or concerns, please call your local distributor, or visit the Bioness website: www.bioness.com /Landing.php?reset.

Our clinic owns multiple NESS L300 Plus Systems. How can we identify which components belong to which system?

- Each NESS L300 Plus System has an alphanumeric System Identification (ID) Number (for example, A123) printed on the back of the L300 Plus Control Unit, L300 RF Stim Unit, Thigh RF Stim Unit, and Intelli-Sense Gait Sensor. The System ID Numbers on all four components must match for the system to work. Check the ID numbers before use to see if they match.

The buttons in the L300 Plus Intelli-Gait Software used to create a new patient record or adjust the settings for a current patient are grayed out and nonfunctional.

- The Clinician's Programmer and the L300 Plus Control Unit are not communicating. Both must be connected to the Configuration Cradle to communicate. Turn off the L300 Plus Control Unit or place it in standby mode. Then reconnect the Configuration Cradle communication connector cable to the L300 Plus Control Unit and the Clinician's Programmer.

I connected the L300 Plus Control Unit to the Configuration Cradle and a message appeared on the Clinician's Programmer. The message says that the date and time in the L300 Plus Control Unit differ from those in the Clinician's Programmer.

- The clocks on the L300 Plus Control Unit and Clinician's Programmer must be synchronized for the Gait Log and Training Log to record accurately.
  - If the date and time settings of the Clinician's Programmer are correct, update the L300 Plus System clock.
  - If the date and time settings of the Clinician's Programmer are not correct, press **Exit** to close the L300 Plus Intelli-Gait Software and open the PDA settings screen. (See the PDA manufacturer's instructions.) Use the stylus to adjust the Clinician's Programmer time zone, clock, and date. Press **Ok** to save the settings. Log back into the L300 Plus Intelli-Gait Software, reconnect the L300 Plus Control Unit, and update the L300 Plus System clock to match the Clinician's Programmer clock.

I connected the L300 Plus Control Unit to the Configuration Cradle. A message appeared on the Clinician's Programmer. The message says that a new patient was found and asks if I would like to add the patient record to the database.

- Select **Yes**, if you want to add that patient record to the database so that you may review or make changes to the patient's settings. If not, select **No** to return to the Patient List. If you want to copy a different patient record onto the L300 Plus Control Unit, then, with the L300 Plus Control Unit still connected to the Configuration Cradle, open another patient record or set up a new patient record for use with the L300 Plus Control Unit. **Note: If you open another patient record while the L300 Plus Control Unit is connected, the data on the L300 Plus System will be permanently overwritten by the record that is opened.**

When I connected the L300 Plus Control Unit to the Configuration Cradle, a message appeared on the Clinician's Programmer saying that the parameters are inconsistent.

- A different Clinician's Programmer was last used to update the patient's system.
  - Press **System** to overwrite the data on the Clinician's Programmer with the data on the L300 Plus Control Unit (preferred when patients have been using the L300 Plus Control Unit settings and are returning for a follow-up evaluation).
  - Press **Database** to overwrite the parameters on the L300 Plus Control Unit with the parameters on the Clinician's Programmer.
  - Press **Ignore** to leave the parameters on the Clinician's Programmer and the L300 Plus Control Unit unchanged.

When charging the L300 Plus System, how will I know when the batteries are fully charged?

- When the L300 Plus Control Unit is fully charged, a  horizontal GREEN line will appear in the L300 Plus Control Unit digital display.
- When the L300 and Thigh RF Stim Units are fully charged, the  status light on the RF Stim Units will be SOLID GREEN.
- Charging takes approximately three hours. After the components are fully charged, keep the components connected to the system charger set until ready to use.

After I fully charged the L300 Plus Control Unit and RF Stim Units, I disconnected the system charger set and then immediately reconnected it. The charging icons displayed again on the L300 Plus Control Unit and RF Stim Units. Do I need to repeat the charging process?

- If you recently 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.

If I charge the L300 Plus System 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 the L300 Plus Control Unit and RF Stim Units, "E" appears in the digital display.

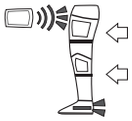
- An error occurred while charging. Reconnect the system charger set. If the problem persists, contact your local distributor.

The L300 Plus Control Unit (or one of the RF Stim Units) does not light up when the system is turned on.

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

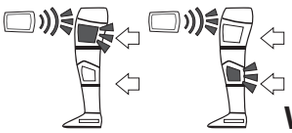
How will I know when the Intelli-Sense Gait Sensor battery charge level is low?

- An Intelli-Sense Gait Sensor battery will last for approximately six months, and then it will need to be replaced. When the battery charge level is low, the Intelli-Sense Gait Sensor indicator on the L300 Plus Control Unit will FLASH YELLOW and the L300 Plus Control Unit will emit an audio alert. The audio alert will become more persistent as the battery weakens.



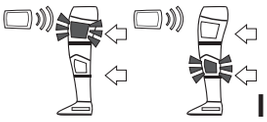
Stimulation works in training mode but not in gait mode. When I turn on gait mode I hear a beep. The Intelli-Sense Gait Sensor and the RF communication indicators on the L300 Plus Control Unit FLASH RED.

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



When I turn on the L300 Plus Control Unit, it beeps. One of the RF Stim Unit indicators and the RF communication indicator on the L300 Plus Control Unit is FLASHING RED. The RF Stim Unit indicators are not lit.

- The RF Stim Unit battery is likely discharged, preventing the L300 Plus Control Unit and the RF Stim Unit from communicating. Turn off the L300 Plus Control Unit, and charge the system fully. Then, disconnect the system charger set and turn on the L300 Plus Control Unit. The L300 Plus Control Unit on/off button and the status light on both RF Stim Units should FLASH GREEN. Communication should be restored.

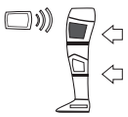


I hear a beep, and one of the RF Stim Unit indicators on the L300 Plus Control Unit is FLASHING RED.

- If the patient feels stimulation but the intensity level seems weaker than usual and knee or ankle movement is unsatisfactory, electrode contact may be compromised.
  - Turn off the L300 Plus Control Unit and remove the affected FS Cuff.
  - Thoroughly cleanse the skin where the electrode(s) touch.
  - Remove and replace any worn L300 hydrogel electrodes. Press firmly on the new L300 hydrogel electrodes until they are securely attached to the L300 hydrogel electrode bases. Then, remove the covers.
  - Remove and rewet any cloth electrodes. Saturate them with water, and then blot the snap side before reattaching them.
  - Replace the electrodes every two weeks.
- If the patient does not feel stimulation:
  - Turn off the L300 Plus Control Unit and remove the affected FS Cuff.
  - Make sure the L300 electrode bases or large cloth electrode, if appropriate, is snapped into the plug holes of the L300 FS Cuff, especially if using a personal panel.
  - If L300 hydrogel electrodes are being used, confirm that the covers have been removed.
  - Remove and rewet any cloth electrodes, if they are dry.
  - Make sure the RF Stim Unit is properly snapped into the cradle of the FS Cuff. Press firmly near the upper edges of the RF Stim Unit until it is flush with the cradle.
  - If using a fitting cable, check that the cable is correctly connected to both plug holes of the L300 FS Cuff and to both L300 electrode bases.
  - Use the Tester to test the electrical flow.

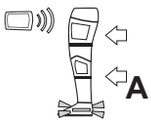
An electrode or base is frayed, peeling, damaged, or falling off the FS Cuff.

- Replace any worn or damaged electrodes or electrode bases.



A component indicator is SOLID RED and the L300 Plus Control Unit is beeping.

- The component is malfunctioning. Turn off the L300 Plus Control Unit and turn it back on. If the problem persists, then stop using the NESS L300 Plus System and contact your local distributor.



A component indicator is FLASHING YELLOW.

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

The patient's ankle or knee is not moving satisfactorily, and the L300 Plus System is not indicating any errors.

- Turn off the L300 Plus Control Unit and reposition the appropriate FS Cuff. Test the new position using the stimulation test button on the L300 Plus Control Unit. Make sure the FS Cuff strap(s) is snug and the FS Cuff is secure.

Stimulation is inconsistent when the patient is walking, but the L300 Plus System is not indicating any errors.

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

The skin is irritated or has a skin reaction where the electrodes or FS Cuff adheres.

- Stop using the NESS L300 Plus System immediately and contact your local distributor. Resume use only when the skin is completely healed. Give patients the NESS L300 Plus Skin Care Guidelines and 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 L300 Plus Control Unit, L300 RF Stim Unit, Thigh RF Stim Unit, or Intelli-Sense Gait Sensor needs to be electronically registered to the existing L300 Plus System components to communicate wirelessly. To electronically register a replacement component, see the L300 Plus *User's Guide*.

I tried the registration procedure and saw a  immediately, but I never saw the ALTERNATING GREEN arches in the digital display. The replacement component is not working.

- Clinician mode may have been started instead of the registration process. Clinician mode is started by pressing the minus  and  on/off buttons on the L300 Plus Control Unit. Registration is started with the L300 Plus Control Unit off, and by pressing the minus  and mode  buttons on the L300 Plus Control Unit. Turn off the L300 Plus Control Unit, and press the  minus and  mode buttons to restart the registration process.

How can I verify that current is flowing through the L300 Plus System?

- Connect the Tester to the L300 RF Stim Unit and the L300 FS Cuff plug holes, or the ends of the fitting cable, depending on the setup. The Tester will buzz when stimulation intensity is at least 10 mA. Repeat for the Thigh RF Stim Unit and Thigh FS Cuff.

What else can I use the Tester for?

- The Tester can be used as an educational tool, to demonstrate when stimulation is on in the various stimulation modes.

Troubleshooting Quick Reference Table

L300 Plus Control Unit	Solution
Will not turn on.	• Charge the L300 Plus Control Unit. • Change the battery, and charge the L300 Plus Control Unit. • Replace the L300 Plus Control Unit.
Component malfunction.	Replace the L300 Plus Control Unit.
L300 and Thigh RF Stim Units	**Solution**
Will not turn on.	• Charge the RF Stim Unit. • Contact your local distributor to replace the battery. • Replace the RF Stim Unit.
Component malfunction.	Replace the RF Stim Unit.
Intelli-Sense Gait Sensor	**Solution**
RF communication error.	• Press and release the pressure sensor while in gait mode to activate the Intelli-Sense Gait Sensor. • Change the battery, and press the pressure sensor to activate the Intelli-Sense Gait Sensor. • Replace the Intelli-Sense Gait Sensor and register it.
Will not function.	• Change the battery, and press the pressure sensor to activate the Intelli-Sense Gait Sensor. • Replace the Intelli-Sense Gait Sensor and register it.
Functioning but not reliably.	• Relocate the pressure sensor to the correct placement under the heel. • Replace the Gait Sensor pad, if it appears worn. • Replace the Intelli-Sense Gait Sensor and register it.
L300 and Thigh FS Cuffs	**Solution**

If you need technical or clinical assistance, please call your local distributor, or visit the Bioness website: www.bioness.com /Landing.php?reset.

The L300 Plus Control Unit is displaying a faulty electrode connection.	• Ensure good contact of the electrodes to the skin (and L300 electrode bases). • Ensure that the FS Cuff connections are intact.
An electrode is damaged or peeling off.	Replace the electrode.
An L300 electrode base is damaged.	Replace the L300 electrode base.
An FS Cuff strap is frayed or damaged.	Replace the FS Cuff strap.
An FS Cuff is damaged.	Replace the FS Cuff.
Stimulation is not as effective as usual.	• Try repositioning the FS Cuff. • Wet the cloth electrodes, if they are dry. • Change the electrodes.
Clinician's Programmer	**Solution**
Will not turn on.	• Charge the Clinician's Programmer. • Change the battery, and charge the Clinician's Programmer. • Press the Clinician's Programmer reset button. • Replace the Clinician's Programmer.
Lost the L300 Plus Intelli-Gait Software application/data.	Contact your local distributor.
Will not communicate with the L300 Plus Control Unit.	• Reconnect the Configuration Cradle to the Clinician's Programmer and L300 Plus Control Unit. • Contact your local distributor.

Technical Specifications

L300 Plus Control Unit Specifications	
Classification	Internally powered, continuous operation
Operation Modes	Gait, Training, Clinician, and Standby
Battery Type	Rechargeable AAA NiMH 1.2 V, 900–1100 mAh
Controls	• On/Off illuminated button • Mode illuminated button to change operating modes • Intensity +/- buttons to fine-tune intensity level • Mute button to mute audio and visual alerts • RF Stim Unit selection buttons • Stimulation test button
Indications	• Seven status LEDs: L300 Plus Control Unit, L300 RF Stim Unit, Thigh RF Stim Unit, Intelli-Sense Gait Sensor, L300 RF Stim Unit and Thigh RF Stim Unit Arrow Indicators, and RF Communication • Numerical display designates relative stimulation intensity • Illuminated buttons designate system operating mode • “Beeps” for audio alerts
Carrying Options	In pocket, neck strap, wrist strap, or belt pouch
Dimensions	Length: 73 mm; Width: 46 mm; Height: 18 mm
Weight	45 grams
Environmental Ranges	• Transport and storage temperature: -25°C to +55°C • Operating conditions temperature: 5°C to 40°C • Charging temperature: 5°C to 40°C • Relative humidity: 25% to 85% • Atmospheric pressure: 700 hPa to 1060 hPa

L300 RF Stim Unit Specifications	
Classification	Internally powered, continuous operation with type BF applied parts
Operating Voltage	3.7 V
Battery Type	Proprietary rechargeable Li-Ion (Lithium Ion) 3.7 V, 750 mAh
Indications	• Status (fault, battery, charging) and Stimulation LEDs • "Beeps" for audio alerts
Dimensions	• Length: 74 mm • Width: 43 mm • Height: 15 mm
Weight	50 grams
Environmental Ranges	• Transport and storage temperature: -25°C to +55°C • Operating conditions temperature: 5°C to 40°C • Charging temperature: 5°C to 40°C • Relative humidity: 25% to 85% • Atmospheric pressure: 700 hPa to 1060 hPa

Pulse Parameters						
Pulse	Balanced Biphasic					
Waveform	Symmetric or Asymmetric					
Intensity (Peak)	0–80 mA,1-mA resolution (positive phase)					
Maximum Intensity (rms)	13.2 mA (rms)					
Max Voltage	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
Extended (%)	0–100% of stance time, 10% resolution
Max Duration	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

L300 FS Cuff Specifications	
Material	Fabric-Polymer
Limb Circumference	29–51 cm
Dimensions	• Height: 160 mm • Width: 100 mm • Depth: 125 mm
Weight	Approximately 150 grams

L300 Electrode and Electrode Base Specifications	
Hydrogel Electrodes	Two, 45-mm diameter hydrogel electrodes **Note:** Use only electrodes provided by Bioness Inc.
Hydrogel Electrode Bases	Two relocatable polymer electrode bases for individual fitting
Cloth Electrodes	Two 45-mm diameter non-woven fabric/cloth electrodes **Note:** Use only electrodes provided by Bioness Inc.
Cloth Electrode Bases	Two relocatable polymer electrode bases for individual fitting

Thigh RF Stim Unit Specifications	
Classification	Internally powered, continuous operation with type BF applied parts
Operating Voltage	3.7 V
Battery Type	Proprietary rechargeable Li-Ion (Lithium Ion) 3.7 V, 750 mAh
Indications	• Status (fault, battery, charging) and Stimulation LEDs • "Beeps" for audio alerts
Dimensions	• Length: 74 mm • Width: 43 mm • Height: 15 mm
Weight	50 grams
Environmental Ranges	• Transport and storage temperature: -25°C to +55°C • Operating conditions temperature: 5°C to 40°C • Charging temperature: 5°C to 40°C • Relative humidity: 25% to 85% • Atmospheric pressure: 700 hPa to 1060 hPa

Pulse Parameters						
Pulse	Balanced Biphasic					
Waveform	Symmetric or Asymmetric					
Intensity (Peak)	0–100 mA,1-mA resolution (positive phase)					
Maximum Intensity (rms)	16.5 mA (rms					
Max Voltage	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	
Swing Control Delay (%)	0–100% of phase* time, 5% resolution
Swing Control End (%)	0–100% of phase* time, 5% resolution
Stance Control Delay (%)	0–100% of phase* time, 5% resolution
Stance Control End (%)	0–100% of phase* time, 5% resolution
Ramp Up	0–2 seconds, 0.1-second resolution
Ramp Down	0–2 seconds, 0.1-second resolution
Extended	0–100% of stance time, 10% resolution
Max Duration	2–10 seconds, 1-second resolution
* Stimulation burst can start either on swing or stance phase.	
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	5–60 minutes, 5-minutes resolution

Thigh FS Cuff Specifications	
Material	Skeleton–TPU; Panel Assemblies and Buckles–Silicone
Fits Limb Circumference	• Upper thigh circumference: 53 cm–85 cm • Knee circumference: 33 cm–50 cm • Thigh length: 24 cm–35 cm

Dimensions	• Length: 17 cm–26 cm
	• Circumference (minimal):
	  • Proximal panel: 42 cm
	  • Distal panel, regular: 45 cm
	  • Distal panel, large: 51 cm

Weight	Approximately 420 grams

Thigh Cloth Electrode Specifications	
Material	Non-woven cloth **Note**: Use only electrodes provided by Bioness Inc.
Dimensions	Proximal: Oval, 130 x 75 mm Distal: Oval, 120 x 63 mm

Intelli-Sense Gait Sensor Specifications	
Classification	Internally powered, continuous operation with type BF applied part(s)
Battery Type	Lithium coin cell, CR2430, 280 mAh
Dimensions of the Transmitter	• Length: 80 mm • Width: 50 mm • Height: 10 mm
Weight	35 grams
Environmental Ranges	• Transport and storage temperature: -25°C to +55°C • Operating conditions temperature: 5°C to 40°C • Relative humidity: 25% to 85% • Atmospheric pressure: 700 hPa to 1060 hPa

System Charger Specifications	
Use medical Class II safety approved power supply provided/approved by Bioness Inc with the following ratings:	
Input	
Voltage	100–240 V AC
Current	400 mA
Frequency	50–60 Hz
Output	
Voltage	5 V ± 5%
Current	2400 mA

Note: Do not use the L300 Plus Control Unit, Thigh RF Stim Unit, or L300 RF Stim Unit while charging.

Wireless Link Specifications	
Frequency Band	2.4 GHz, ISM band
Transmission Power	Complies with FCC 15.247 (for US)/ETSI EN 300-440 regulations

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

Guidance and Manufacturer's Declaration—Electromagnetic Emissions		
The NESS L300 Plus System is intended for use in the electromagnetic environment specified below. The customer or the user of the NESS L300 Plus System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment — Guidance**
RF emissions CISPR 11	Group 1	The NESS L300 Plus 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 Plus 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	

Guidance and Manufacturer's Declaration— Electromagnetic Immunity for All Equipment and Systems			
The NESS L300 Plus System is intended for use in the electromagnetic environment specified below. The customer or the user of the NESS L300 Plus System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment—Guidance**
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.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the NESS L300 Plus 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.			

Guidance and Manufacturer's Declaration—Electromagnetic Immunity			
The NESS L300 Plus System is intended for use in the electromagnetic environment specified below. The customer or the user of the NESS L300 Plus System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment—Guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the NESS L300 Plus 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	**Recommended separation distance:** d = 1.2√P
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	$[E_1]$ = 10 V/m in 26 MHz to 1 GHz $[E_1]$ = 3 V/m in 1 GHz to 2.5 GHz	**Recommended separation distance:** d = 0.4√P, 80–800 MHz range d = 0.7√P, 800–1000 MHz range d = 2.3√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,[a] should be less than the compliance level in each frequency range.[b] NOTE 5: Interference may occur in the vicinity of equipment marked with the following symbol: 			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the NESS L300 Plus System is used exceeds the applicable RF compliance level above, the NESS L300 Plus 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 Plus System. [b] 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 Plus System				
The NESS L300 Plus 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 Plus System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NESS L300 Plus 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√P**	**80 MHz to 800 MHz** **d = 0.4√P**	**800 MHz to 1000 MHz** **d = 0.7√P**	**1000 MHz to 2.5 GHz** **d = 2.3√P**
0.01	0.12 m	0.04 m	0.07 m	0.23 m
0.1	0.38 m	0.13 m	0.22 m	0.73 m
1	1.2 m	0.4 m	0.7 m	2.3 m
10	3.8 m	1.3 m	2.2 m	7.3 m
100	12 m	4 m	7 m	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.